OXFORD

JAMA Network

PRINCIPLES OF SCIENTIFIC WRITING AND BIOMEDICAL PUBLICATION

A JAMA Editors' Guide for Authors

Phil B. Fontanarosa, MD, MBA
Annette Flanagin, RN, MA
Philip Greenland, MD

Downloaded from academic.oup.com/book/58841 by guest on 17 October 2026

Principles of Scientific Writing and Biomedical Publication

A JAMA Editors' Guide for Authors

Downloaded from academic.oup.com/book/58841 by guest on 17 October 2026

Downloaded from academic.oup.com/book/58841 by guest on 17 October 2026

Principles of Scientific Writing and Biomedical Publication

A JAMA Editors' Guide for Authors

Editors
Phil B. Fontanarosa, MD, MBA
Annette Flanagin, RN, MA, FAAN
Philip Greenland, MD

Downloaded from academic.oup.com/book/58841 by guest on 17 October 2026

OXFORD
UNIVERSITY PRESS

JAMA Network

OXFORD
UNIVERSITY PRESS

JAMA Network

Oxford University Press is a department of the University of Oxford. It furthers the University's objective of excellence in research, scholarship, and education by publishing worldwide. Oxford is a registered trade mark of Oxford University Press in the UK and certain other countries.

Published in the United States of America by Oxford University Press
198 Madison Avenue, New York, NY 10016, United States of America.

© American Medical Association 2024

All rights reserved, including those for text and data mining, AI training, and similar technologies.

This is an open access publication, available online and distributed under the terms of a Creative Commons Attribution - Non Commercial - No Derivatives 4.0 International licence (CC BY-NC-ND 4.0), a copy of which is available at http://creativecommons.org/licences/by-nc-nd/4.0/. Subject to this license, all rights are reserved.



Enquiries concerning reproduction outside the scope of this licence should be sent to the Rights Department, Oxford University Press, at the address above.

Library of Congress Cataloging-in-Publication Data
Names: Fontanarosa, Phil B., editor. | Flanagin, Annette, editor. | Greenland, Philip, editor. | American Medical Association, issuing body.
Title: Principles of scientific writing and biomedical publication : a JAMA editors' guide for authors / editors, Phil B. Fontanarosa, Annette Flanagin, Philip Greenland.
Other titles: JAMA.
Description: New York, NY : American Medical Association, 2024. | Includes bibliographical references and index.
Identifiers: LCCN 2024013053 (print) | LCCN 2024013054 (ebook) | ISBN 9780197783030 (hardback) | ISBN 9780197783054 (epub) | ISBN 9780197783061 (online)
Subjects: MESH: Medical Writing | Biomedical Research | Journalism, Medical | Scholarly Communication | Periodicals as Topic
Classification: LCC R119 (print) | LCC R119 (ebook) | NLM WZ 345 | DDC 808.06/661—dc23/eng/20240501
LC record available at https://lccn.loc.gov/2024013053
LC ebook record available at https://lccn.loc.gov/2024013054

This material is not intended to be, and should not be considered, a substitute for medical or other professional advice. Treatment for the conditions described in this material is highly dependent on the individual circumstances. And, while this material is designed to offer accurate information with respect to the subject matter covered and to be current as of the time it was written, research and knowledge about medical and health issues is constantly evolving and dose schedules for medications are being revised continually, with new side effects recognized and accounted for regularly. Readers must therefore always check the product information and clinical procedures with the most up-to-date published product information and data sheets provided by the manufacturers and the most recent codes of conduct and safety regulation. The publisher and the authors make no representations or warranties to readers, express or implied, as to the accuracy or completeness of this material. Without limiting the foregoing, the publisher and the authors make no representations or warranties as to the accuracy or efficacy of the drug dosages mentioned in the material. The authors and the publisher do not accept, and expressly disclaim, any responsibility for any liability, loss or risk that may be claimed or incurred as a consequence of the use and/or application of any of the contents of this material.

DOI: 10.1093/med/9780197783030.001.0001

Printed by Integrated Books International, United States of America

Downloaded from academic.oup.com/book/58841 by guest on 17 October 2026

To all readers and authors who may find this book useful and for trusting in these guidelines for writing and publishing their work; to all authors with whom I have worked over the years, for allowing me the honor to edit their manuscripts; and to all my editorial colleagues, especially those who contributed chapters to this book, for sharing the passion for biomedical editing and effective scientific communication. Most important, to my wife, Kris, for her constant support, understanding, and inspiration; to our children, Jen, Joel, Beth, and Julie, for their insights, thoughtfulness, and encouragement; to their spouses, Spencer, Jen, Dan, and Ryan, for their support and interest; and to our grandchildren, Lily, Mia, George, Dean, Bennett, Grant, Will, May, and Wes for their love of reading and books, and for the boundless joy and happiness they bring to life.

Phil B. Fontanarosa, MD, MBA

To all writers, authors, researchers, clinicians, and editors who inspire those of us who aim to improve the communication of science and health information. With recognition and gratefulness to our colleagues who contributed their experiences and insights to the chapters of this book. And with special gratitude to Drummond Rennie, MD, a mentor, friend, gifted and persuasive writer, and editor-virtuoso, whose exceptional command of language, prolific and influential publications, and commitment to promoting and upholding transparency and integrity in scientific publication serve as a beacon for us all.

Annette Flanagin, RN, MA

This book represents the culmination of discussions over many years with colleagues, and with many students and trainees who saw the need for a single source book on the subjects covered here. Biomedical publishing is critical for medicine to advance, and the communication of research is the responsibility of researchers, coauthors, mentors, colleagues, journal editors, and reviewers. Those of us who worked on this book hope it will be a way to improve biomedical writing, reviewing, editing, and publishing and that it will be an enduring source of advice to new as well as experienced writers. I am especially grateful to my *JAMA* and JAMA Network colleagues for helping prepare the material for this book; we could not have completed it without their help.

Philip Greenland, MD

Downloaded from academic.oup.com/book/58841 by guest on 17 October 2026

Downloaded from academic.oup.com/book/58841 by guest on 17 October 2026

CONTENTS

Foreword xi
Preface xiii
List of Editors and Contributors xv

Part 1 Biomedical Journals

1. **Principles of Scientific Writing and Biomedical Publication—Perspectives and Advice From Editors 3**
   PHIL B. FONTANAROSA, MD, MBA, ANNETTE FLANAGIN, RN, MA, AND PHILIP GREENLAND, MD
2. **Scientific Journals and the Dynamic Publication Landscape 8**
   PHIL B. FONTANAROSA, MD, MBA, HOWARD BAUCHNER, MD, AND ANNETTE FLANAGIN, RN, MA
3. **Selecting a Journal 21**
   JODY W. ZYLKE, MD
4. **Electronic Publishing 25**
   MICHAEL BERKWITS, MD, MSCE

Part 2 Scientific Writing

5. **Formulating an Organized Critical Argument in a Scientific Manuscript 37**
   PHILIP GREENLAND, MD
6. **Strategies for Efficient, Effective Scientific Writing 42**
   PHIL B. FONTANAROSA, MD, MBA
7. **Advice on Writing for Biomedical Journals 53**
   FREDERICK P. RIVARA, MD, MPH
8. **Avoiding Spin and Boasting in Scientific Writing 60**
   FREDERICK P. RIVARA, MD, MPH
9. **Tone, Terminology, and Technical Aspects of Scientific Writing 64**
   PHIL B. FONTANAROSA, MD, MBA, AND ANNETTE FLANAGIN, RN, MA

Downloaded from academic.oup.com/book/58841 by guest on 17 October 2026

Part 3 Manuscript Components

10. Creating an Informative and Effective Title 85
JODY W. ZYLKE, MD

11. Writing an Informative Abstract 90
PHIL B. FONTANAROSA, MD, MBA

12. Writing a Compelling Introduction 98
PHIL B. FONTANAROSA, MD, MBA, AND PHILIP GREENLAND, MD

13. Writing the Methods Section 102
ROBERT M. GOLUB, MD

14. Presenting the Results Section 111
JAY F. PICCIRILLO, MD

15. Writing a Convincing Discussion Section 120
JODY W. ZYLKE, MD

16. Referencing and Using Reference Managers 126
PAMELA L. SHAW, MSLIS, MS, KRISTI HOLMES, PHD, AND PHILIP GREENLAND, MD

17. Effective Use of Figures and Tables in Scientific Articles 134
DAVID L. SCHRIGER, MD, MPH, AND STEPHEN M. SCHENKEL, MD, MPP

18. Creating Effective and Efficient Tables 144
DAVID L. SCHRIGER, MD, MPH

19. Effective Use of Figures and Graphs in Scientific Publications 155
MARY (NORA) L. DISIS, MD, AND DENISE L. CECIL, PHD

Part 4 Specific Types of Articles

20. Clinical Trials 165
NEIL M. BRESSLER, MD

21. Meta-Analyses 175
CHRISTOPHER C. MUTH, MD

22. Review Articles 182
PHIL B. FONTANAROSA, MD, MBA

23. Brief Reports and Research Letters 194
JODY W. ZYLKE, MD

24. Letters to the Editor 199
ROBERT M. GOLUB, MD

Downloaded from academic.oup.com/book/58841 by guest on 17 October 2026

25. Editorials 203
PHIL B. FONTANAROSA, MD, MBA

26. Other Opinion Articles 208
JODY W. ZYLKE, MD

Part 5 Editorial Process and Peer Review

27. Manuscript Assessment and Editorial Decision-Making 215
ROBERT STEINBROOK, MD, AND RITA F. REDBERG, MD, MSC

28. Peer Review in Scholarly Publication 222
ANNETTE FLANAGIN, RN, MA

29. Reviewing Manuscripts for Peer-Reviewed Journals 231
FREDERICK P. RIVARA, MD, MPH

30. Communicating and Interacting With Journal Editors 240
MARY M. MCDERMOTT, MD

31. Responding to Journal Decision Letters and Reviewers' Comments 250
FREDERICK P. RIVARA, MD, MPH

32. Pet Peeves of Editors 259
JODY W. ZYLKE, MD

Part 6 Authorship and Ethical Issues

33. Authorship Criteria and Ethical Aspects 267
PHIL B. FONTANAROSA, MD, MBA, HOWARD BAUCHNER, MD, AND ANNETTE FLANAGIN, RN, MA

34. Group Authorship and Team Science 275
PHIL B. FONTANAROSA, MD, MBA, HOWARD BAUCHNER, MD, AND ANNETTE FLANAGIN, RN, MA

35. Ethical Issues in Biomedical Publication 283
PHIL B. FONTANAROSA, MD, MBA, HOWARD BAUCHNER, MD, AND ANNETTE FLANAGIN, RN, MA

36. Plagiarism 296
MELINA R. KIBBE, MD

37. Conflict of Interest and Biomedical Publication 304
PHIL B. FONTANAROSA, MD, MBA, HOWARD BAUCHNER, MD, AND ANNETTE FLANAGIN, RN, MA

38. Legal Issues in Biomedical Publication 316
JOSEPH P. THORNTON, JD

Downloaded from academic.oup.com/book/58841 by guest on 17 October 2026

Part 7 Current and Evolving Issues

39. Data Sharing 329
HOWARD BAUCHNER, MD, AND PHIL B. FONTANAROSA, MD, MBA

40. Preprints, Preprint Servers, and Biomedical Publication 340
GREGORY D. CURFMAN, MD

41. Interacting With the News Media 349
DEANNA BELLANDI, MPH, AND PHILIP GREENLAND, MD

Index 355

Downloaded from academic.oup.com/book/58841 by guest on 17 October 2026

FOREWORD

Before starting as the editor in chief of *JAMA* and the JAMA Network in 2022, I had spent nearly 2 decades as a full-time physician-scientist and faculty member at the University of California, San Francisco. My greatest joys in those positions were mentoring those just embarking on careers in biomedical research as well as collaborating with scholars from other disciplines seeking to translate their work for clinical relevance. Each passing year as a mentor and collaborator made clear to me that the skills needed to write clearly and concisely, to convey science accurately and in a manner that understands the needs of the reader, and to successfully navigate the often-opaque world of biomedical publishing are critical to the success of scholars and academics. Those who acquire these skills early and hone them well over time minimize the frustration and disappointment that often characterize various stages of an academic career. Those who do not achieve proficiency in these skills—even those with outstanding intellect and work ethic—struggle.

Beyond their importance to the success and well-being of scholars and academics, effective biomedical writing and publishing are even more important to the translation of scientific research findings into improvements in health. The scientific finding that is written in a way that is not easily understood, that is published in a manner that does not reach its intended audience, or, even worse, is not published at all, is a finding that does not fully enter the body of knowledge that informs the design of future studies and medical interventions. It is like the well-run race that does not quite get over the finish line, or the drive down the football field that ends in a fumble just before the end zone. Effective writing and publishing are critical to the very reason that we engage in biomedical enterprise: to advance the generation of knowledge to improve human health.

Against this backdrop of great need to advance the skills in writing and publishing enters this new textbook, *Principles of Scientific Writing and Biomedical Publication: A JAMA Editors' Guide for Authors*, edited by Fontanarosa, Flanagin, and Greenland. With chapters written by editors from *JAMA* and the journals of the JAMA Network who have over a century of combined years of editorial experience, this textbook should become the definitive resource on biomedical writing and publishing. The chapters provide detailed and actionable advice on each component of a biomedical research manuscript—from the title to the figures—and provide information across a variety of different article types, from original research reports to reviews and opinion articles.

Downloaded from academic.oup.com/book/58841 by guest on 17 October 2026

More important, the text addresses the intangible elements that separate technically good writing from excellent writing, with chapters such as "Formulating an Organized Critical Argument in a Scientific Manuscript" and "Avoiding Spin and Boasting in Scientific Writing." The authors marry the detailed advice on all elements of scientific writing with an insider's description of the often-daunting world of editorial and peer review processes. There is even a chapter in which the pet peeves of editors are revealed. Finally, the text includes important information on authorship and ethics and the new and evolving areas in biomedical publishing.

This is the primer that I wish I had more than 20 years ago when I embarked on my academic career. It is the resource I wish I had even 5 years ago to give to mentees seeking to become more effective writers and to navigate the world of biomedical publishing successfully. Fortunately, it is a guide that will now help all of us—authors, editors, writers, and readers—to build the skills needed to achieve our shared goal of communicating science better to improve human health.

Kirsten Bibbins-Domingo, PhD, MD, MAS
Editor in Chief
JAMA and the JAMA Network

Downloaded from academic.oup.com/book/58841 by guest on 17 October 2026

PREFACE

Publication of research reports and other articles in biomedical journals is essential for improvement and advancement of medical science and clinical practice and is a key element of academic achievement and career advancement in the biosciences. However, the core principles involved in the biomedical publication process as well as the specific skills of scientific writing and manuscript preparation are not commonly taught in a formal or comprehensive way in medicine, other health fields, or research curricula.

Principles of Scientific Writing and Biomedical Publication: A JAMA Editors' Guide for Authors was created as a practical, comprehensive, state-of-the-art guide designed to enhance understanding of the principles of scientific publication, promote improved writing and manuscript preparation skills, and help navigate the seemingly complex pathway from manuscript submission, through peer review and revision, to successful publication. A thorough knowledge of the principles of biomedical writing and publication includes understanding the issues that may arise during the scientific publishing process; being aware of the ethical and practical aspects related to manuscript preparation, reporting research, and writing reviews and opinion articles; and effectively and appropriately interacting with biomedical journal editors.

The unique feature of this book is that all contributors currently serve or have served as editors for major biomedical journals, including *JAMA* and the *JAMA* Network journals, or have extensive experience and knowledge related to biomedical publication and information dissemination. Collectively, the authors of the 41 chapters in this book have published thousands of articles, including research reports and opinion articles, and have hundreds of "editor-years" of experience serving as editors of major journals. The authors also have been extensively involved with numerous aspects of biomedical publishing, including developing and implementing editorial policies and procedures; organizing and participating in international and national conferences and committees on peer review, scientific publishing, reporting guidelines, and biomedical information dissemination; and teaching scientific writing and publishing at academic centers and major conferences. Accordingly, the information, recommendations, and advice in this book are intended to guide the preparation of high-quality manuscripts suitable for publication in biomedical journals and help demystify the scientific publication process.

We extend our appreciation to all authors who contributed chapters to this book for sharing their perspectives and knowledge about the principles of

Downloaded from academic.oup.com/book/58841 by guest on 17 October 2026

biomedical writing and publication. They are all listed in the Contributors section. We also thank and recognize the important contributions of Kate Pezalla, *JAMA* Assistant Editor, who was instrumental in managing this project and facilitating organization of the book manuscript. In addition, we thank and acknowledge Howard Bauchner, MD, former editor in chief of *JAMA* and the JAMA Network, who supported and participated in the planning and design of this book, as well as editing early versions of many chapters.

We hope the readers and users of *Principles of Scientific Writing and Biomedical Publication: A JAMA Editors' Guide for Authors* will find the content informative, practical, authoritative, and enjoyable, and will attain a thorough understanding of the principles involved in biomedical writing and publication. More important, we hope the information, recommendations, and guidance in this book, based on the collective wisdom and advice of experienced *JAMA* and JAMA Network editors, will serve to help authors prepare high-quality manuscripts that result in meaningful and important publications in biomedical journals.

Phil B. Fontanarosa, MD, MBA
Annette Flanagin, RN, MA
Philip Greenland, MD

Downloaded from academic.oup.com/book/58841 by guest on 17 October 2026

EDITORS AND CONTRIBUTORS

Editors

Phil B. Fontanarosa, MD, MBA
Former Executive Editor, *JAMA* and the JAMA Network
Adjunct Professor, Northwestern University Feinberg School of Medicine

Annette Flanagin, RN, MA
Executive Managing Editor and Vice President of Editorial Operations, *JAMA* and the JAMA Network

Philip Greenland, MD
Senior Editor, *JAMA* Harry W. Dingman Professor, Northwestern University Feinberg School of Medicine

Contributors

Howard Bauchner, MD
Former Editor in Chief, *JAMA* and the JAMA Network
Former Editor in Chief, *Archives of Disease in Childhood*
Professor, Boston University Chobanian & Avedisian School of Medicine

Deanna Bellandi, MPH
Former Director, Media Relations, Social Media, and News, *JAMA* and the JAMA Network
Director of Marketing and Communications, University of Illinois Cancer Center

Michael Berkwits, MD, MSCE
Former Electronic Editor, *JAMA* and the JAMA Network
Former Deputy Editor, *JAMA*

Neil M. Bressler, MD
Editor in Chief, *JAMA Ophthalmology*
James P. Gills Professor of Ophthalmology, Wilmer Eye Institute, Johns Hopkins University School of Medicine

Denise L. Cecil, PhD
Chief Scientist, University of Washington Cancer Vaccine Institute

Gregory D. Curfman, MD
Executive Editor, *JAMA*
Assistant Professor of Medicine, Harvard Medical School

Mary (Nora) L. Disis, MD
Deputy Editor, *JAMA*
Editor in Chief, *JAMA Oncology*
Director, Institute of Translational Health Science and UW Medicine Cancer Vaccine Institute
Associate Dean and Professor, University of Washington School of Medicine

Robert M. Golub, MD
Former Executive Deputy Editor, *JAMA*
Professor of Medicine and Preventive Medicine, Northwestern University Feinberg School of Medicine

Kristi Holmes, PhD
Director, Galter Health Sciences Library
Associate Dean and Professor, Northwestern University Feinberg School of Medicine

Melina R. Kibbe, MD
Editor in Chief, *JAMA Surgery*
Dean and Professor, University of Virginia School of Medicine

Downloaded from academic.oup.com/book/58841 by guest on 17 October 2026

Mary M. McDermott, MD
Deputy Editor, *JAMA*
Jeremiah Stamler Professor of Medicine, Northwestern University Feinberg School of Medicine

Christopher C. Muth, MD
Deputy Editor, *JAMA*
Assistant Professor, Department of Neurological Sciences, Rush Medical College

Jay F. Piccirillo, MD
Editor in Chief, *JAMA Otolaryngology-Head and Neck Surgery*
Professor, Washington University School of Medicine

Rita F. Redberg, MD, MSc
Former Editor in Chief, *JAMA Internal Medicine*
Professor, University of California San Francisco

Frederick P. Rivara, MD, MPH
Editor in Chief, *JAMA Network Open*
Professor, University of Washington

Stephen M. Schenkel, MD, MPP
Associate Editor, *JAMA*
Professor, University of Maryland School of Medicine

David L. Schriger, MD, MPH
Associate Editor, *JAMA*
Professor, UCLA David Geffen School of Medicine

Pamela L. Shaw, MSLIS, MS
Biosciences & Bioinformatics Librarian, Galter Health Sciences Library, Northwestern University Feinberg School of Medicine

Robert Steinbrook, MD
Former Editor at Large and Online Editor, *JAMA Internal Medicine*
Professor Adjunct of Internal Medicine, Yale School of Medicine
Health Research Group Director, Public Citizen

Joseph P. Thornton, JD
Editorial Counsel, *JAMA* and the JAMA Network

Jody W. Zylke, MD
Deputy Editor, *JAMA*

Downloaded from academic.oup.com/book/58841 by guest on 17 October 2026

PART 1

Biomedical Journals

Downloaded from academic.oup.com/book/58841 by guest on 17 October 2026

Downloaded from academic.oup.com/book/58841 by guest on 17 October 2026

CHAPTER 1

Principles of Scientific Writing and Biomedical Publication—Perspectives and Advice From Editors

Phil B. Fontanarosa, MD, MBA,
Annette Flanagin, RN, MA, and Philip Greenland, MD

KEY POINTS

- Having a thorough knowledge of the principles of biomedical writing and publication is essential for understanding the complex issues that may arise along the path of the scientific publishing process, for being aware of the ethical and practical aspects involved in manuscript preparation, and for successfully navigating interactions with biomedical journals.
- The practical, state-of-the-art, and up-to-date information in this book will enhance understanding of scientific publication, promote improved writing and manuscript preparation skills, and help authors navigate the complex and seemingly enigmatic manuscript submission, peer review, revision, and publication processes.
- The information, recommendations, and advice in this book are based on the collective perspectives and insights of experienced *JAMA* and JAMA Network editors and should help facilitate the preparation of high-quality manuscripts that may result in meaningful and important publications in biomedical journals.

Publication of biomedical research is essential for improvement and advancement of medical science and clinical practice. The history of scientific publication, including journals devoted to medical science, dates to the 1600s. The number of peer-reviewed scientific journals is estimated to be in the tens of thousands, and the number of journals, especially with the increasing creation of open access publications, continues to expand. Yet, despite the long history of and ubiquitous nature of scientific publications, the core principles involved in biomedical publication, as well as the specific skills of writing and

Downloaded from academic.oup.com/book/58841 by guest on 17 October 2026

manuscript preparation, are not commonly taught in a formal or comprehensive way in medicine, public health, or research curricula.

Having a thorough knowledge of the principles of biomedical writing and publication is essential for understanding the complex issues that may arise along the path of the scientific publishing process, for being aware of the ethical and practical aspects involved in manuscript preparation, and for successfully navigating interactions with biomedical journals. Moreover, recognition that the quality of manuscript preparation and the effectiveness of scientific writing may determine whether a submitted manuscript is received favorably by editors, peer reviewers, and by eventual readers of the published article is of utmost importance. A manuscript that is not clearly written or is not coherently organized, even if it reports valid and important new information, may be viewed unfavorably or misunderstood. Authors occasionally express the opinion that reviewers "did not understand my manuscript" without considering that the difficulty might not be related to reviewers' incorrect understanding but rather might be due to lack of clarity or ambiguity related to the authors' writing and communication skills.

Even for a high-quality research investigation, a disorganized or poorly written manuscript may fail to sufficiently convey the main study results and convincingly explain the importance of the findings. Consequently, editors and reviewers may perceive the report as low quality, possibly resulting in rejection of the manuscript from higher tier journals and necessitating resubmission of the manuscript to a series of multiple other journals, perhaps multiple revisions, and substantial amounts of elapsed time from completion of the study until the report is eventually publishable, perhaps in a journal with limited readership or reach and low relative measures of influence. Clarity of writing and organization of reports also may influence decisions regarding other documents in academic research, such as the outcome of grant applications for future work. It is therefore important that the same attention to detail that underlies the best scientific research should also be a fundamental component of scientific writing and manuscript preparation.

The purpose of this practical book on the principles of biomedical writing and publication is to provide state-of-the-art and up-to-date information that will promote authors' understanding of scientific publication, facilitate improved writing and manuscript preparation skills, and help authors navigate the complex and seemingly enigmatic manuscript submission, peer review, revision, and publication processes.

All contributors to this book are authors, and more important, nearly all also currently serve or have served as editors for *JAMA* and the JAMA Network journals. Collectively, the authors of the 41 chapters in this book have published thousands of articles, including research reports and opinion articles, and have hundreds of "editor years" of experience serving as editors of major journals. Over many years, these editors have been deeply involved with

Downloaded from academic.oup.com/book/58841 by guest on 17 October 2026

and have helped shape the current principles of biomedical publication by their involvement on influential committees in medical journals, by their research and writing on key topics in biomedical journalism, and by their development and upholding of policies related to various aspects of biomedical publication, such as ethical issues and best practices for scientific reporting. Herein, these editors share their substantial learning about and experience with effective scientific writing and reporting of biomedical science, present advice regarding tips and traps for authors to follow and avoid and provide succinct guidance on how to present study findings clearly, efficiently, effectively, and appropriately and, ultimately, achieve a successful publication.

Thus, all contributors to this book are well qualified to share their experience, insights, and practical knowledge about the principles of biomedical writing and publication with authors. For example, the editors of *JAMA* and the JAMA Network journals devote substantial time and effort to reviewing manuscripts and working with authors to revise manuscripts that are considered suitable for publication. In addition to providing comments from peer reviewers, the editors typically also provide the authors with detailed reviews and additional specific comments intended to improve the quality and clarity of the presentation of information.

Many journal editors are often surprised that even experienced authors may be unfamiliar with certain aspects of biomedical publication or may submit manuscripts that require considerable additional guidance and editorial assistance to achieve optimal clarity in communication. This experience has suggested that there is a great need for a book such as this one that can be considered an authoritative guide to effective scientific writing, manuscript preparation, and biomedical publication. In addition, several of the authors have taught full courses in medical writing and publishing as well as short courses on scientific publication to graduate students, postgraduate students, early-career faculty members, and other medical editors and manuscript editors. These courses have been valued by students and learners, as feedback for the course material has been given high reviews, and the deliverable assignments of some courses, such as writing a scientific manuscript or writing an opinion article, often result in subsequent publication in a biomedical journal. Yet, it has not been possible to recommend a specific current textbook on biomedical writing and publication for these courses due to the lack of comprehensiveness, depth, and state-of-the-science discussions about biomedical publication in available texts, and more important, to our knowledge, no text has provided the collective perspectives, insights, wisdom, and authoritativeness from a group of highly experienced editors of major biomedical journals.

Therefore, the goal of this book is to provide an authoritative and practical guide and assistance for authors of biomedical manuscripts, ranging from trainees and early-career authors to more experienced authors, and from students and learners to seasoned mentors, and to serve as a useful resource for

Downloaded from academic.oup.com/book/58841 by guest on 17 October 2026

all who read and explore the biomedical literature. Accordingly, the content of the book is designed as practical enough to be helpful for junior investigators and inexperienced authors yet sophisticated enough to be of interest for more experienced authors. Although many of the examples throughout this book used to illustrate some specific concepts of biomedical publication are based on information from *JAMA* and the JAMA Network journals, the principles, concepts, and issues addressed are directly applicable to most biomedical journals, as well as many other journals in the life sciences.

The book is organized into 7 sections, and each of the chapters in each section is practical and focused. Each chapter leads with a set of succinct key points that summarize educational objectives and provide actionable guidance. The section on Biomedical Journals includes 3 chapters that place medical journals and electronic publishing in context and provide insights into the daunting task of selecting a target journal. The section on Scientific Writing includes 5 chapters that present practical strategies for developing a cohesive manuscript, approaches for achieving effective and efficient writing, advice on writing for biomedical journals, and guidelines for appropriate use of language and technical aspects related to scientific writing. In the section on Manuscript Components, the 10 chapters provide detailed discussion of each section of the manuscript, including writing an effective title and abstract; thoughtfully preparing the Introduction, Methods, Results, and Discussion sections; and appropriately using tables and figures, as well as reference managers, to facilitate preparation of the report.

The 7 chapters in the section on Specific Types of Articles provide focused information for manuscript preparation based on study design (such as clinical trials and meta-analyses) or article type (such as Reviews and Brief Reports), and detailed guidelines for preparing persuasive and compelling opinion articles (such as Editorials, Viewpoints or Commentaries, and Letters to the Editor). The section on the Editorial Process and Peer Review includes 6 chapters that serve to demystify the biomedical publication process. These chapters provide a thorough "inside look" at the editorial decision-making and peer review processes, and provide practical guidance for critical tasks in the publication pathway, such as interactions and communication between editors and authors, specific recommendations for preparing an effective and successful response to the invitation to submit a revised manuscript, and information to help understand and avoid some of the "pet peeves" of editors with respect to submitted manuscripts. The section on Authorship and Ethical Issues includes 6 chapters that provide thorough discussion of the ethical aspects of biomedical publishing, including issues related to authorship, group authorship and team science, research irregularities and plagiarism, conflicts of interest, and the legal aspects of biomedical publication. The 3 chapters in the section on Current and Evolving Issues address topics that represent some rapidly

Downloaded from academic.oup.com/book/58841 by guest on 17 October 2026

changing aspects of biomedical publishing, including data sharing, preprint servers, and interactions with the news media.

We hope the readers and users of this book will find the content informative, practical, authoritative, and enjoyable, and will attain a thorough understanding of principles involved in biomedical writing and publication. But even more important, we hope the information, recommendations, and advice in this book, based on the collective perspectives and insights of these experienced *JAMA* and JAMA Network editors, will serve to help authors prepare high-quality manuscripts that result in meaningful and important publications in biomedical journals.

Downloaded from academic.oup.com/book/58841 by guest on 17 October 2026

CHAPTER 2

Scientific Journals and the Dynamic Publication Landscape

Phil B. Fontanarosa, MD, MBA, Howard Bauchner, MD, and Annette Flanagin, RN, MA

Downloaded from academic.oup.com/book/58841 by guest on 17 October 2026

KEY POINTS

- The number, focus, format, and types of scientific journals continue to increase and expand substantially, with approximately 48 000 scientific, technical, and medical peer-reviewed journals published worldwide, and more than 5200 scholarly life science journals indexed in MEDLINE.
- An evolution in the format and types of many publications has occurred, with an increasing number of journals published only in electronic format, expanded and prominent use of electronic dissemination of content by virtually all journals, and increasing numbers of open access journals.
- The characteristics of individual journals may serve to differentiate them from each other, including topic areas, scope, reach, dissemination, and prestige.
- Several metrics enable comparisons among journals and journal articles, including the Journal Impact Factor, article citations and other metrics, readership, online usage statistics, and social media presence; authors can compare these metrics as well as services journals offer to amplify attention and access to published articles when deciding about which journals to submit their work.
- Biomedical journals may follow a traditional publishing model, in which the author transfers copyright or a publication license to the journal, or an open access publishing model, in which authors pay article processing fees, retain copyright, and are granted a license that governs the use of the article content. Some journals are allowing authors to disseminate the accepted manuscript on the day of publication.

The number, focus, format, and types of scientific journals continue to increase and expand substantially. In 2021, approximately 48 000 scientific, technical, and medical peer-reviewed journals were published worldwide, of which approximately 35 000 are in the English language.[1] More than 5200 scholarly life science journals are indexed in the National Library of Medicine (NLM) MEDLINE biomedical journal citation database.[2] Another database, Scopus, described as the world's largest abstract and citation database of the peer-reviewed literature, enables tracking, analyzing, and visualizing of research and indexes content from more than 25 000 active publication titles from more than 7000 publishers worldwide.[3]

Along with the increasing number of journals, the number of available and new articles and citations continues to increase exponentially. The MEDLINE database includes more than 29 million references to journal articles in the life sciences, with a concentration in biomedicine, and is searchable as a subset of the PubMed database from the National Library of Medicine.[4] PubMed has been available since 1996 and includes more than 36 million citations, including citations in the MEDLINE database (the largest component) and articles in PubMed Central (the second largest component of PubMed).[4] PubMed Central is a free, full-text archive that includes articles from biomedical and life sciences journals selected by the NLM for archiving (current and historical) and individual articles collected for archiving in compliance with funder policies, and in 2023 it contained more than 8 million full-text records.[5]

In addition to the millions of citations already included in these databases, large volumes of new articles are published each year. For instance, more than 1.2 million citations were added to MEDLINE in 2021, and 1.3 million more citations were added in 2022.[6] Numerous additional articles are published in nonindexed journals.

Along with the continued increases in the number of journals and number of published articles, journals also continue to expand in terms of topic areas, corresponding to advances and new developments in scientific disciplines as well as perceived informational needs. For instance, new journals have recently emerged in fields such as genomics, climate change, and global health; in subdisciplines such as biotechnology and machine learning and artificial intelligence; and in specific clinical and research topic areas, such as COVID-19 and health equity.

A concomitant evolution in the format and types of many publications also has occurred, not only with an increasing number of journals published only in electronic format, but also with expanded and prominent use of electronic dissemination of content by virtually all journals. (See also Chapter 4, Electronic Publishing.) In addition, there has been a steady increase in the number of open access journals (including fully open access journals as well as hybrid journals, in which some research articles are published as open access), in which authors pay fees for publication to retain publishing licenses and

Downloaded from academic.oup.com/book/58841 by guest on 17 October 2026

content is freely available at the time of publication. (See also Chapter 38, Legal Issues in Biomedical Publication.) At the same time, interest in and demand for more rapid and more immediate dissemination of scientific information have continued to increase, and the expanded use of preprint servers has enabled posting of numerous clinical research manuscripts prior to peer review and formal editorial evaluation. (See also Chapter 40, Preprints, Preprint Servers, and Biomedical Publication.)

The dynamic nature of the scientific publication landscape creates opportunities and challenges for authors of biomedical research reports. Authors have more journals (and other publication outlets) than ever before in which to publish their manuscripts. A challenge for authors is navigating the changing and complex biomedical publication landscape to determine which journal may be best suited for publication of their work. (See also Chapter 3, Selecting a Journal.)

Journal Characteristics

Journals have certain characteristics that may serve to differentiate them from each other. Each biomedical journal has a topical focus, ranging from general journals that cover a wide range of topics in medicine (such as *JAMA*, *New England Journal of Medicine* [*NEJM*], and *The Lancet*), to specialty journals (such as *JAMA Cardiology* and *JAMA Oncology*), to subspecialty and ultra-specialized journals. Journals also vary in their publication frequency. For some journals, issues consisting of a collection of articles are published with a regular periodicity, such as weekly, monthly, or quarterly (in print, online, or both, although many journals are discontinuing print issues). For many journals, online posting of articles occurs as soon as the articles are ready to be published, which may occur any day of the week, at times accompanied by email alerts to subscribers and other readers. These online-first articles are considered published and are often republished or collected into specific issues of the journal.

Journals also differ in their circulation and reach, with some specialized journals reaching limited numbers of readers in a specific discipline, and with some major journals reaching potentially millions of readers each week via electronic distribution of content, social media uptake, and additional content dissemination through the news media. For example, *JAMA* reaches millions of readers each week via distribution of content in print, via electronic tables of content, and through social media amplification. In addition, many journals are distributed to subscribers or to members of organizations or societies that publish the journal, as a benefit of membership. Article downloads, especially content usage by academic libraries, is an important metric, not only for distribution of journal content, but also for business considerations, as sales and subscriptions of electronic site licenses at academic libraries represent an

Downloaded from academic.oup.com/book/58841 by guest on 17 October 2026

important source of revenue for some publishers. With these site licenses, for which the institution pays an annual subscription fee, all users at an institution (eg, faculty, fellows, residents, students, administrators, other staff and personnel) can access all information in the journals that are included in the subscription. Some journals and publishers may also offer institutions and other organizations (or entire nations) agreements to allow authors from those institutions or organizations to publish in those journals under open access licenses for worldwide readership in exchange for licensing fees. In the past, print advertising was a principal source of journal revenue for many journals, along with individual paid subscriptions, but that is no longer the case, and the revenue from site licenses, other licensing agreements, and other sources for electronic aggregation, dissemination, and access of content now surpasses the revenue from print advertising and individual subscriptions for many publications.

Other important differentiating factors for biomedical journals involve the journal's reputation and professional influence. Over time, journals become perceived as having certain attributes and characteristics. This may occur for a number of reasons, such as the types and importance of the articles the journal publishes, the rigor of the editorial review and peer review processes, and the quality of the articles; the demonstration of integrity in science and high-caliber biomedical journalism; the leadership, personality, and diversity exemplified by the journal's editorial team; the published positions the journal may take on certain important issues; the degree of efficiency, service, and fairness provided to authors who submit manuscripts; the ability to adapt and change within the dynamic scientific publishing environment; and the effective use of evolving technology to amplify published content and maximize content delivery in creative, innovative ways.

Journal Metrics

Several metrics are commonly used as measures of the perceived importance of a biomedical journal. One of the most commonly considered measures is the Journal Impact Factor (JIF). This metric was developed in the 1950s and has achieved widespread popularity.[7] Annual impact factor data are published by Clarivate Analytics as Journal Citation Reports[8] as a product in Web of Science. This organization tracks citations in articles in nearly 13 000 science journal titles in 114 countries and then relates the citations in these publications to articles published in individual journals.

The JIF for a specific year is calculated as the ratio of citations (numerator) to articles (denominator). For instance, for calculation of the 2023 JIF of journal A, the numerator in the ratio is the number of citations (from other journals and including citations from journal A) that occurred during calendar

Downloaded from academic.oup.com/book/58841 by guest on 17 October 2026

year 2023 to articles published in journal A in the previous 2 years (ie, 2021 and 2022).

The denominator is the number of citable or "countable" articles published in journal A in the previous 2 years (in this example, 2021 and 2022). The numerator includes citations to virtually all types of articles in the journal, including research articles, long and short clinical reviews, letters to the editor, research letters, and opinion articles (such as editorials, commentaries, Viewpoints, perspectives, etc), whereas the denominator of "countable" articles primarily includes research articles and long reviews.

Examples of the 2019 JIFs (released in 2020) for some selected well-known journals include the following: *NEJM*, 74.7; *The Lancet*, 60.4; *JAMA*, 45.4; *Nature*, 42.2; *Science*, 41.8; *Cell*, 38.6; *Nature Medicine*, 30.1; *BMJ*, 30.2; *Annals of Internal Medicine*, 21.3; *JAMA Internal Medicine*, 18.7; and *PLOS Medicine*, 10.5. The 2021 JIFs for these journals (released in 2022) were as follows: *The Lancet*, 202; *NEJM*, 176; *JAMA*, 157; *BMJ*, 93.9; *Nature Medicine*, 87.2; *Nature*, 69.5; *Cell*, 66.8; *Science*, 63.7; *Annals of Internal Medicine*, 51.5; *JAMA Internal Medicine*, 44.4; and *PLOS Medicine*, 11.6. The substantial increase in these numbers for many of these journals was directly related to the large volume of citations to research articles published on COVID-19 in 2020, especially during the early phases of the pandemic. (For example, a single Viewpoint published in *JAMA* in 2020 had 10 148 citations by mid 2023.[9]) The 2023 JIFs for these journals (released in 2024) were the following: *The Lancet*, 98.4; *NEJM*, 96.2; *BMJ*, 93.6; *JAMA*, 63.1; *Nature Medicine*, 58.7; *Nature*, 50.5; *Cell*, 45.5; *Science*, 44.7; *JAMA Internal Medicine*, 22.5; *Annals of Internal Medicine*, 19.6; and *PLOS Medicine*, 10.5. These numbers are expected to continue to normalize to prepandemic values for many journals.

In addition, the JIFs of specialty journals are usually lower than those of general journals, reflecting the number of publications in that field, and journals with highly specialized content typically generate lower numbers of citations, although there are some exceptions to this pattern. Also, in general, the JIFs in research disciplines with many journals and substantial research funding, such as oncology and cardiology, tend to be higher than those of journals in disciplines with fewer journals.

There also has been criticism of impact factors when used to assess researchers and the research they produce. For example, the Declaration on Research Assessment (DORA) was released in 2012 "to improve the ways in which researchers and the outputs of scholarly research are evaluated." DORA calls for elimination of the use of journal-based metrics, such as impact factors, in funding, appointment, and promotion considerations, and highlights "the need to assess research on its own merits rather than on the basis of the journal in which the research is published" and "the need to capitalize on the opportunities provided by online publication (such as relaxing unnecessary limits on

Downloaded from academic.oup.com/book/58841 by guest on 17 October 2026

the number of words, figures, and references in articles, and exploring new indicators of significance and impact)."[10]

The JIF is just one of many available measures for the perceived importance and influence of biomedical journals, but as noted somewhat controversially, it has been used to judge the quality of journals, the importance of research, and to a certain degree the accomplishments of academic faculty and authors. For some faculty in some countries and regions, the impact factor of the journal in which their articles are published is factored into decisions about academic promotions. In some other countries, authors are rewarded financially for their publications, with the amount of compensation they receive directly related to the impact factor of the journal in which their work is published.

In addition to the JIF, several other citation-based measures have been developed and may allow comparisons among scientific journals and publications, with most metrics relying on calculations involving citations in the scientific literature. Several selected examples include the following.

The Immediacy Index (from Web of Science) represents the average number of times an article is cited in the year it is published, and it is calculated by dividing the number of citations to articles published in a calendar year by the number of articles published in that year.[11] The 5-Year Journal Impact Factor (from Web of Science) is the average number of times articles published in the journal in the past 5 years have been cited in a specific year. It is calculated by dividing the number of citations that occur during 1 year by the total number of articles published in the 5 previous years.[11] The *h*-index (calculated from Web of Science, Google Scholar, or Scopus) measures the productivity and citation impact of the published body of work of an author. The *h*-index indicates the number of articles, *h*, that have been cited at least *h* number of times (eg, an *h*-index of 15 means that 15 articles have been cited at least 15 times).[12] The relative citation ratio (RCR), developed by the US National Institutes of Health (NIH), provides an article-level score derived from dividing the total number of citations a publication has received by the average annual number of citations for NIH-funded publications in that article's field, which is determined by the article's co-citation network.[13] The Scimago Journal Rank indicator (based on the Scopus database) is a measure of the prestige of a scientific journal based on both the number of citations to articles in the journal and the prestige of the journals that are the sources of the citations.[14]

However, the level of interest in and influence of articles published in scholarly journals can be assessed in other ways besides metrics related to citations, particularly with the ubiquitous nature of electronic communication of biomedical information. Social media allows for instantaneous dissemination of information from biomedical journals, as well as rapid responses to this information on social media platforms. Accordingly, many journals have created robust social media channels for distribution of information. In addition, many journals

Downloaded from academic.oup.com/book/58841 by guest on 17 October 2026

have developed approaches to help promote attention to published research in the news media. (See also Chapter 41, Interacting With the News Media.)

The measure of the attention and dissemination of articles published in biomedical journals can be assessed by the Altmetric score, which was developed in 2011 and quantifies the digital attention an article receives in numerous online sources.[15] This metric includes mentions about an article in news reports, blogs, and social media; page views and downloads; and mentions on Wikipedia, Reddit, YouTube, and other sources. In addition to the Altmetric score, the amount of attention an article receives from these various sources is depicted visually as the Altmetric badges ("donut").

Other metrics and scores also are used by journals and publishers.[16] Some journals display these metrics online with each article, along with the number of views the article has received on the journal's website and the number of citations the article has received in the literature. (See also Chapter 4, Electronic Publishing.)

Biomedical journals also continue to develop and enhance other approaches for dissemination of content, including providing embargoed journal content and news releases for credentialed reporters to access in advance of publication (see also Chapter 41, Interacting With the News Media); creating value-added materials, such as podcast summaries of articles and interviews with authors; developing creative methods for communicating scientific information, including animations, visual abstracts, and interactive graphics; personalized content delivery, to deliver the right information at the right time in the right format for the individual user; and translation of content into multiple languages. Biomedical journals should ensure efficient, effective dissemination of information and maintain quality of content to ensure the communication of clear scientific signals among increasing publishing noise.

Other measures of journal characteristics, reach, and influence may be helpful for authors to consider and may be made available on journal websites or in published information. For example, each year, *JAMA* and the JAMA Network journals publish reports on journal performance (such as manuscripts received, acceptance rates, and times to publication) and information dissemination.[17] For instance, for *JAMA* in 2024, there were 57.6 million article views and downloads, 132 000 recipients of the print journal, 1.6 million recipients of the electronic table-of-contents and online-first alerts, 1.5 million social media followers, and 7.7 million downloads of journal-related content in podcasts and videos.[17]

Journal Publishing Models

Along with expansion of the number and types of biomedical journals and the increasing number of articles published, there also has been an evolution of

Downloaded from academic.oup.com/book/58841 by guest on 17 October 2026

publishing models in the dynamic scientific journal environment. This evolution has been fueled by technological advancements, business considerations, and interest in promoting immediate and free public access or open access to information from biomedical research.

Biomedical journals may follow a traditional publishing model that includes free public access to some content, an open access publishing model that permits free access to all content, or a hybrid model that includes elements of both the traditional and open access models. *Public access* "is the free access to content and typically permits users to read, download, print, search, and link to content, but with some copyright restrictions or limitations on sharing and reuse."[18] *Open access* "is the free and unrestricted online availability of content" that permits "unrestricted access without typical copyright restrictions," allowing users to "freely read, download, copy, distribute, print, search, or link to full text of articles, as well as reuse and modify such content in part or whole for any lawful purpose provided that authors are properly acknowledged and cited."[18]

TRADITIONAL PUBLISHING MODEL

The traditional publishing model currently is followed by the majority of traditional biomedical journals. In this model, authors submit manuscripts to journals, and at publication, the authors transfer copyright of the article to the journal publisher. The authors generally are not required to pay any publication fees. The journals generate revenue by selling access to and providing the content, such as through subscriptions to individual subscribers, through site licenses and other licensing agreements with academic institutions or other organizations, or through licensing agreements with companies that aggregate and distribute content. For some journals, the research content is made freely available for public access on the journal websites after a certain time (for instance, research reports published in *JAMA* and *NEJM* are available at 6 months after publication). Some journals also deposit or permit authors to deposit copies of the published articles in public repositories following the same access terms.

This approach had been consistent with the public access policy of the NIH, which requires that "… all investigators funded by the NIH submit or have submitted for them to the National Library of Medicine's PubMed Central an electronic version of their final, peer-reviewed manuscripts upon acceptance for publication, to be made publicly available no later than 12 months after the official date of publication."[19] In August 2022, the White House Office of Science and Technology Policy directed all federal agencies to develop policies that ensure that all peer-reviewed publications resulting from federal funds are freely available on the day of publication. The timing of this mandate varies depending on the size of the federal agency, and how it will be implemented remains to be determined.[20]

Downloaded from academic.oup.com/book/58841 by guest on 17 October 2026

However, in response to increasing interest in immediate access to peer-reviewed research findings, and to funder mandates for immediate, open access to research, some journals, such as the JAMA Network journals, have adopted policies on public access to research that permit authors of original research investigations to deposit their accepted manuscript in a public repository of their choosing immediately on the day the article is published by the journal.[21] According to this policy, "the accepted manuscript is the fully peer-reviewed version of the manuscript that has been revised in response to review and is judged acceptable for publication; additional edits, refinements, and enhancements will still appear in the version of record that is published in the JAMA Network and to which the accepted manuscript that is deposited will link."[21]

OPEN ACCESS PUBLISHING MODEL

An increasing number of journals are following the open access publishing model. According to one estimate, in 2021 an estimated 45% of all scholarly articles were published as paid-for open access reports,[22] and it is likely that this proportion will continue to increase. In this model, authors submit research manuscripts to journals and are required to pay article processing charges (APCs) or fees for each published article and are granted a license that governs the use of the article.

These fees vary among journals and may vary by the type of license granted. For example, in 2023 the APC for *PLOS Medicine* (one of the publications in the group of PLOS journals, which were one of the prototypes for open access journals, launched in 2003) was $6300 per published research article; for *The Lancet*, the APC was $6830 per article; and for *JAMA Network Open*, the APC was $3000 per article. At publication, the article is immediately and freely available, with no charges to access the content and with the author retaining rights related to publication. However, most open access journals have a process in which APCs can be waived or discounted based on certain criteria.

In open access models, authors typically publish under a Creative Commons (CC) license and grant the journal a publication license. Six types of CC licenses are available, including the CC BY license and the CC BY-NC-ND license. The CC BY license, which is the most accommodating license, allows authors the maximum dissemination and use of the licensed materials. The license rights include immediate open access to the article on the journal website on the day of publication, retention of copyright by the authors, and a CC BY license that permits others to distribute, remix, tweak, and build on the work, even commercially, without permission, provided credit is given to the original authors and journal.[23]

The CC BY-NC-ND license is the most restrictive of the CC licenses. This license includes immediate open access on the journal website on the day of

Downloaded from academic.oup.com/book/58841 by guest on 17 October 2026

publication, retention of copyright by the authors, and permission for others to distribute the work without permission, provided credit is given to the original authors and journal and that the article is not altered or used commercially.[23]

There are several types of open access journals. One type (such as *PLOS Medicine* and *JAMA Network Open*) is a fully open access journal, in which every article is published with some type of CC BY license and is immediately freely available on the day of publication. Another type of open access journal is called a hybrid journal (such as *JAMA Oncology*), in which some articles are immediately available as open access by a CC BY license, and other articles are published under the traditional journal model and might not be immediately freely available, except to journal subscribers and to individuals at organizations with site licenses and other licensing agreements with the journal.

Some organizations and foundations that fund biomedical research (eg, the Wellcome Trust, the Bill & Melinda Gates Foundation) are requiring authors to publish work based on the funding provided in open access journals. In addition, some open access advocates and initiatives are calling for all scholarly publications of the results of funded research to be published in fully open access journals with immediate unrestricted access and without embargo.

PUBLISHING MODELS AND ETHICAL CONSIDERATIONS

All biomedical journals must ensure the highest ethical standards for their publications and journal editors must avoid potential conflicts of interest regarding editorial decisions. In all publishing models, editorial decisions must be based on the scientific quality, validity, rigor, and importance of the manuscripts the editors evaluate for publication, without any consideration for other factors, such as those related to journal revenue. For instance, traditional journals that derive revenue from advertising must ensure that appropriate firewalls are established so that editorial decisions are independent of business considerations, such as whether a study sponsor is also an advertiser in that journal or if a particular article is likely to generate sales of reprints. For open access journals, in which more revenue is generated when more articles are accepted for publication, editorial decision-making must be based in manuscript quality and importance, rather than achieving a certain quantity or quota of accepted articles.

PREDATORY OR DECEPTIVE JOURNALS

The increasing popularity of the open access publishing model has unintentionally contributed to the development of exploitative publishing enterprises that publish articles and charge publication fees but might not evaluate articles for quality and legitimacy.[24] These so-called predatory journals may mislead authors into paying APCs for publishing articles with them. These

Downloaded from academic.oup.com/book/58841 by guest on 17 October 2026

journals have been characterized as being driven by financial self-interest rather than scholarship; providing false and misleading information (eg, fabricated or unapproved names of editors and editorial board members and fabricated impact factors and other metrics); deviating from best editorial/publication practices (including no editorial assessment or peer review); lacking transparency; using aggressive and indiscriminate solicitation for submissions[24]; and often having titles that resemble the titles of well-known, established journals. Authors who receive solicitations to submit manuscripts to journals with which they are not familiar should be cautious about doing so and should investigate the veracity and legitimacy of the publication, such as by referring to resources that provide helpful information to detect predatory journals. A group of organizations has developed a website (https://thinkchecksubmit.org) to help authors identify trusted journals for submission of manuscripts.[25]

PREPRINT SERVERS

Posting of manuscripts on preprint servers has become increasingly common among biomedical researchers, especially following the COVID-19 pandemic. (See also Chapter 40, Preprints, Preprint Servers, and Biomedical Publication.) A preprint is the posting of an original version of a manuscript that has not been peer reviewed on a preprint server to disseminate content quickly and enable researchers to receive feedback on their work prior to submission to and publication in a journal. The aims are to improve the openness and accessibility of research findings and to enhance collaboration among researchers. The preprint also serves to document the provenance of ideas and to establish priority, authenticity, novelty, and ownership. A preprint server for medicine (medRxiv) was launched in 2019 and has been increasingly used by authors for posting of manuscripts before submission to a journal.

Preprints appear to have a role in the path to scientific publication, although some issues may continue to be addressed.[26] For instance, it is not clear whether posting of a non–peer-reviewed manuscript is always beneficial for patients and medical science or if the posting of preliminary high-profile content or controversial findings that have not been rigorously evaluated for validity and quality may be potentially harmful for patients and public health, especially if that information is widely disseminated or sensationalized in the media or on social media platforms. Authors should be aware that journals have policies regarding the evaluation and consideration of manuscripts that have been posted on preprint servers and require authors to inform the editors about whether the manuscript has been posted as a preprint.[26]

Downloaded from academic.oup.com/book/58841 by guest on 17 October 2026

Conclusion

The dynamic publication landscape for biomedical journals continues to evolve, with increasing numbers and types of scientific journals, more journals and articles published only in electronic format, and a substantial amount of scientific content published in open access journals. Characteristics of individual journals—including topic areas, scope, reach, dissemination, prestige, impact factor and other metrics, readership, online usage statistics, and social media presence—may help authors differentiate journals from each other and determine the best journal to which to submit their work.

References

1. STM. *STM Global Brief 2021—Economics & Market Size: An STM Report Supplement*. Accessed October 6, 2023. https://www.stm-assoc.org/2022_08_24_STM_White_Report_a4_v15.pdf
2. MEDLINE: overview. US National Library of Medicine. Updated February 5, 2024. Accessed March 15, 2024. https://www.nlm.nih.gov/medline/medline_overview.html
3. Scopus. Elsevier. Accessed July 8, 2023. https://www.elsevier.com/en-in/solutions/scopus
4. PubMed overview. US National Library of Medicine. Updated August 15, 2023. Accessed March 15, 2024. https://pubmed.ncbi.nlm.nih.gov/about
5. About PMC. US National Library of Medicine. Updated November 3, 2023. Accessed March 15, 2024. https://www.ncbi.nlm.nih.gov/pmc/about/intro/
6. Citations added to MEDLINE by fiscal year. US National Library of Medicine. Accessed July 8, 2023. https://www.nlm.nih.gov/bsd/stats/cit_added.html
7. Garfield E. The history and meaning of the journal impact factor. *JAMA*. 2006;295(1):90-93. doi:10.1001/jama.295.1.90
8. Journal Citation Reports. Clarivate. Accessed July 8, 2023. https://clarivate.com/products/scientific-and-academic-research/research-analytics-evaluation-and-management-solutions/journal-citation-reports/
9. Wu Z, McGoogan JM. Characteristics of and important lessons from the coronavirus disease 2019 (COVID-19) outbreak in China: summary of a report of 72 314 cases from the Chinese Center for Disease Control and Prevention. *JAMA*. 2020;323(13):1239-1242. doi:10.1001/jama.2020.2648
10. About DORA. DORA. Accessed July 8, 2023. https://sfdora.org/about-dora
11. Journal Citation Reports help. Clarivate. Accessed July 8, 2023. https://jcr.help.clarivate.com/Content/glossary.htm
12. Bornmann L, Daniel H-D. The state of *h* index research: is the *h* index the ideal way to measure research performance? *EMBO Rep*. 2009;10(1):2-6. doi:10.1038/embor.2008.233
13. Hutchins BI, Yuan X, Anderson JM, Santangelo GM. Relative citation ratio (RCR): a new metric that uses citation rates to measure influence at the article level. *PLOS Biol*. 2016;14(9):e1002541. doi:10.1371/journal.pbio.1002541
14. SJR. Accessed July 8, 2023. https://www.scimagojr.com/

Downloaded from academic.oup.com/book/58841 by guest on 17 October 2026

15. Warren HR, Raison N, Dasgupta P. The rise of Altmetrics. *JAMA*. 2017;317(2):131-132. doi:10.1001/jama.2016.18346
16. Research impact assessment (health sciences): alternative indicators. University of Michigan Library. Updated March 1, 2023. Accessed July 8, 2023. https://guides.lib.umich.edu/researchimpact/altmetrics
17. Bibbins-Domingo K, Flanagin A, Christiansen SL, Park H, Curfman G. 2023 year in review and what's ahead at *JAMA*. *JAMA*. Published online March 8, 2024. doi:10.1001/jama.2024.3643
18. Flanagin A. Intellectual property: ownership, access, rights, and management. In: Christiansen S, Iverson C, Flanagin A, et al, eds. *AMA Manual of Style: A Guide for Authors and Editors*. 11th ed. Oxford University Press; 2020. Accessed July 8, 2023. https://academic.oup.com/amamanualofstyle/book/27941/chapter/207564250#39577918
19. NIH Public Access Policy details. US National Institutes of Health. Accessed July 8, 2023. https://publicaccess.nih.gov/policy.htm
20. Nelson A. Memorandum for the heads of executive departments and agencies: ensuring free, immediate, and equitable access to federally funded research. Executive Office of the President, Office of Science and Technology Policy. August 25, 2022. Accessed July 8, 2023. https://www.whitehouse.gov/wp-content/uploads/2022/08/08-2022-OSTP-Public-Access-Memo.pdf
21. Bibbins-Domingo K, Shields B, Ayanian JZ, et al. Public access to scientific research findings and principles of biomedical research—a new policy for the JAMA Network. *JAMA*. 2023;329(1):23-24. doi:10.1001/jama.2022.23451
22. Open access market sizing update 2022: October 2022. Delta Think. Accessed July 8, 2023. https://deltathink.com/news-views-open-access-market-sizing-update-2022
23. About the licenses. Creative Commons. Accessed July 8, 2023. https://creativecommons.org/licenses
24. Grudniewicz A, Moher D, Cobey KD, et al. Predatory journals: no definition, no defence. *Nature*. 2019;576(7786):210-212. doi:10.1038/d41586-019-03759-y
25. Think. Check. Submit. Accessed July 8, 2023. https://thinkchecksubmit.org
26. Flanagin A, Fontanarosa PB, Bauchner H. Preprints involving medical research: do the benefits outweigh the challenges? *JAMA*. 2020;324(18):1840-1843. doi:10.1001/jama.2020.20674

Downloaded from academic.oup.com/book/58841 by guest on 17 October 2026

CHAPTER 3

Selecting a Journal

Jody W. Zylke, MD

Downloaded from academic.oup.com/book/58841 by guest on 17 October 2026

KEY POINTS

- Before selecting a journal for manuscript submission, investigators should evaluate the strengths and weaknesses of the study.
- Researchers can make a list of potential journals, based on audience, types of articles published, reach, and evaluation and publication times.
- Authors should consider their priorities for disseminating the work and speed of publication.
- When choosing a journal, authors should balance factors related to the study, journal, and their own priorities.
- Authors should also have alternative journals selected in case a second submission is necessary.

Flipping a coin may be a great way to choose between chocolate and vanilla or decide which team gets the ball first but may not be such a great way to choose a journal for manuscript submission. This decision requires a dispassionate assessment of the study, due diligence about possible journals, and matching of attributes to maximize the possibility of acceptance.

Success in publishing study findings is important. A study of a medication may be directly relevant to patients. An epidemiologic investigation may have implications for public health or policy. Sponsors provided funds and patients participated and contributed their data; thus, there is an ethical obligation to publish. But beyond the need to publish, the journal in which a study is published also matters. A journal with a large circulation may disseminate information to a wide audience, while a specialized journal may ensure the information reaches physicians and other readers who need it the most. Publishing and the journal selected are also important from the perspective of a researcher. Publications in more prestigious journals may influence promotion committees, and a track record of publications, especially in higher profile journals, may be convincing to research-funding organizations.

The journal submission process can be time consuming. Therefore, the goal of most investigators is to select a journal in which the work is likely to be accepted, thus avoiding sequential submissions to multiple journals, as a manuscript can only be submitted to one journal at a time. Researchers may have other priorities, such as publishing in the highest profile journal possible, publishing quickly, or publishing in the journal most read in their specialty. Therefore, authors have to weigh their own priorities along with factors relevant to the study and the journal.

When preparing to submit a manuscript for publication, the first step is to objectively appraise the study. How the work fits into the literature, both in terms of the topic and the design, should be evaluated. For example, a study could explore a novel or creative topic or it could address an issue that has been investigated previously. If many other studies have been conducted on the subject, it is important to consider whether the findings of the study are confirmatory or whether they are different, and if so, do the findings represent an incremental or important advance. A study that tips the balance of evidence in a particular direction may be valuable. In other words, how does this study contribute to the body of knowledge? Another consideration involves whether the topic is likely to be of interest to many physicians regardless of specialty or mainly to a particular subspecialty. In addition, the study design may be relevant, not only in terms of the strength of the study design, such as a randomized clinical trial vs a case report, but also the design of related published work. A prospective longitudinal study may be important when other studies have been retrospective cross-sectional ones. The limitations of the study may also be relevant, for example, if a study did not enroll as many participants as planned or a survey had a low response rate.

Once the assessment of how the study fits into the scientific literature and its strengths and weaknesses is complete, the search for the most appropriate journal for the work can begin. Before selecting a journal for submission, a researcher should make a list of potential journals. The investigator may be familiar with the journals in the field, either through reading specific journals or receiving advice from a mentor or from colleagues. A review of the manuscript citation list could also point to possible journals for publication. Even if a researcher is familiar with a journal, obtaining some additional information will be helpful before deciding whether to submit a manuscript there. It is always helpful to review recent issues of the journal, noting the topics and type of articles published, to assess likely priority for the intended submission. The home page of a journal's website often contains important metrics about the journal. For example, *JAMA*'s For Authors page has a tab entitled "Why Publish in *JAMA*." Search for editorials or other articles on publication data that may include information on number of manuscripts submitted, acceptance rates, and times from submission to rejection and acceptance to publication.[1]

Downloaded from academic.oup.com/book/58841 by guest on 17 October 2026

There are a number of factors to consider when selecting a journal. One consideration is the audience. General medical journals are read by clinicians from many specialties, whereas specialty or subspecialty journals have a more limited readership. Some journals are read not only by physicians but also by journalists or policy makers. Although several journals may have a similar audience, they may differ in the types of studies or topics that receive publication priority. One specialty journal may publish more epidemiologic studies; another may favor pathophysiologic studies. Some journals publish many randomized clinical trials. Others do not publish case reports or preclinical laboratory investigations.

Consider the reach of the journal. In this regard, several types of metrics may be of interest to an author. The Journal Impact Factor measures the number of citations to articles in that journal and reflects the journal's perceived importance to academic researchers. Downloads of articles (abstracts, PDFs, HTML versions) and the Altmetric score reflect the interest and attention that an article generates, including in the mainstream media and social media. In addition to these data for the journal overall often being available on a journal's home page, the numbers of citations and Altmetric scores for individual articles may be available on the title page of the article online.

The time from submission to initial decision or from acceptance to publication may also be a consideration, especially if a study has immediate clinical application or is going to be presented at a meeting. Journal statistics on the percentage of submissions sent for peer review or how long peer review takes may be relevant in this situation. If a study is particularly important, such as a large randomized trial with clinical outcomes that will affect practice, some journals will commit to rapid review and publication. If a study is going to be presented at a meeting, some journals can coordinate publication with the presentation.

Another relevant factor may be whether a journal is part of a network of journals. In this case, if a manuscript submitted to one journal is rejected, it may be referred to another journal in the network, along with any peer reviews received. This can streamline review and a decision at the second journal.

Publication costs can be influential in the choice of a journal. If the selected journal is an open access publication, a fee will be assessed to publish, which may involve thousands of dollars. To submit to such a journal, the author should be sure that this cost will be covered by the grant or university. The advantage is that the article will be free to all readers immediately and the author can retain a license with certain rights related to use of the article. Articles published in journals without publication fees may not be accessible to readers without a subscription for a limited number of months or may never be publicly accessible.

For some authors, submitting to an "author-friendly" journal may be important. For instance, authors who have published articles in a journal and have had positive experiences with the review process and favorable interactions with the editorial staff may be more likely to consider that journal for

Downloaded from academic.oup.com/book/58841 by guest on 17 October 2026

other manuscripts. An easy-to-use manuscript submission system, accessibility of editors, and helpful support staff can minimize frustration. If a manuscript is accepted, support from copyediting and graphics experts can be beneficial. In addition, some authors may want a journal that promotes the study with value-added features, such as editorials, podcasts, videos, press releases, or social media presence.

Some programs and websites are available to provide suggestions for finding a journal that may be suitable for a manuscript (including EndNote,[2] Journal/Author Name Estimator [JANE],[3] and Think. Check. Submit.,[4] among others) by using basic information from the manuscript (such as key words or the abstract). If such programs are used, the list of journals generated should be weighed against the authors' other priorities, such as perceived prestige or emotional preference.

Armed with an evaluation of the study and of their priorities, authors can now match the characteristics of the study to a journal. For example, a study that investigates a novel or controversial topic, that resolves an important question in a field, or that improves on previously reported work in terms of study design or analysis may belong in a top-tier general or specialty journal. A study that confirms previous observations, addresses a narrow topic of interest primarily to one group of physicians, has a weak study design, or leaves the question being investigated unresolved may be better for a specialty or subspecialty journal. An investigator may aim for a journal with greater reach or the resources to promote the work so that the study will be read by more clinicians or appeal to funding organizations or promotion committees. A disadvantage of aiming for a top-tier journal is that the bar will be higher for acceptance. Thus, it is important to determine the journal's acceptance rate. For example, many large general medical journals (such as *JAMA*) have acceptance rates of 10% or less overall, with even lower rates for research studies. In addition, journal editors may have priorities that an author cannot anticipate. Therefore, no matter the journal selected, authors must be prepared for rejection. Authors should always have a second or third option in mind when embarking on manuscript submission. When it comes to selecting a journal to which to submit a manuscript, it is best to leave as little to chance as possible.

References

1. Bibbins-Domingo K, Flanagin A, Christiansen S, Park H, Curfman G. 2023 year in review and what's ahead at *JAMA*. *JAMA*. 2024;331(14):1181-1184. doi:10.1001/jama.2024.3643
2. EndNote. Clarivate. Accessed March 21, 2023. https://endnote.com/product-details/manuscript-matcher
3. JANE: Journal/Author Name Estimator. The Biosemantics Group. Accessed March 21, 2023. https://jane.biosemantics.org
4. Think. Check. Submit. Accessed March 21, 2023. https://thinkchecksubmit.org

Downloaded from academic.oup.com/book/58841 by guest on 17 October 2026

CHAPTER 4

Electronic Publishing

Michael Berkwits, MD, MSCE

Downloaded from academic.oup.com/book/58841 by guest on 17 October 2026

KEY POINTS

- Authors should consider a social media plan for their publication and review the social media accounts of the journal to which they plan to submit their manuscript to understand how the journal promotes published articles. Authors could consider authoring and submitting text for journal social channels if appropriate.
- Authors also could consider developing audio, video, promotional images, visual abstracts, or other multimedia assets to help communicate their article's findings or other important aspects of the work. Authors should review these elements in the target journal and review its information for authors for details about the preparation of these materials. Journal editors could be contacted to see if they can publish or promote multimedia content.
- Although authors write for scientific and academic peer community readers, it is important not to forget the standards and practices of Google and other search engines. The right keywords in an article title can influence search rankings and discoverability.
- A journal's online reach and "alternative metrics" that indicate online attention to its articles should be considered as measures of a journal's non-citation influence.
- Authors should be aware of a journal's free public access and open access practices and policies, recognize the difference between free public and open access, and choose destination journals based on funder requirements or author objectives.

In the early years of the internet, it was widely assumed that medical journals could shed the cumbersome logistics of print and publish issues online effortlessly at little or no cost, freeing up time and resources for other priorities. The truth quickly became apparent: electronic publishing is anything but simple. Authors and journals must consider online enhancements and a complex electronic online ecosystem if their work is to be discovered and have influence in

public and professional spheres, and journals must make sustained investments to meet ever-evolving standards. The topic of electronic publishing is vast; this chapter emphasizes several broad categories representing important aspects and proposes that authors and journals account for each as they develop their scientific work and websites. None of these aspects will be unfamiliar to even casual users of the internet, and none are exclusive of the other, as best practices in any one category will contribute to success in the others.

Social Media

A presence of journals and journal content on social networks like Facebook, X (formerly known as Twitter), Instagram, Reddit, and countless others is important for several reasons. With reported registrations on social networks surpassing billions of users, many readers of a journal are likely to have social media accounts and likely are spending more time on social media apps than on any journal website, so the potential to reach readers, and grow followers and audience, is vast. The ubiquity of social media and the presence of so many publisher and organizational accounts on the platforms allow users to bypass traditional journal outreach mechanisms like subscriptions, mailings, and email alerts and use their social media accounts as an aggregated front page, homepage, or table of contents for personalized news and information. The platforms make user commenting and conversations easy, so authors and publishers can receive real-time reactions to their content and can interact with their audience if they choose to, engagement that may make a post more visible to users.

Some journals have a share function provided by their website's hosting service, whereby readers can autogenerate a post populated by preset text (usually a title and link) for posting on the reader's personal account on more common social media platforms, but the feature is becoming less important as most browsers now have a similar function that facilitates sharing to numerous clients and platforms. Journals are increasingly managing their own social media accounts, perhaps overseen by early- or mid-career editors or public relations or marketing colleagues. Social media–savvy authors can inquire at the time of the acceptance of their manuscript whether the journal has a mechanism to accept a written post to be published through the journal's account.

Many authors use their own social media accounts (eg, X, LinkedIn, Reddit, Substack) to share their work and have professional (and personal) conversations with academic colleagues. The potential benefits and risks of using social media as a means of communication in academic medicine include community building, crowdsourcing idea and project development, public outreach, and countering scientific misinformation (benefits); and superficial or inaccurate information, echo chamber conversation, and distraction and loss

Downloaded from academic.oup.com/book/58841 by guest on 17 October 2026

of productivity (risks).[1] While authors are characteristically and deservedly proud of their published work, that enthusiasm should not lead to overinterpreting or overgeneralizing study findings in social media beyond what appears in the final edited manuscript, and authors should not break journal embargo policies with social media posts before publication.

Evidence that social media activity is associated with citations is mixed,[2-6] but it is generally understood that social media activity helps search engine discoverability.[7,8]

Multimedia

Multiple trends make multimedia important to electronic publishing, not least the omnipresence of mobile devices that normalize consumption of multimedia formats over long-form reading, and the inherent appeal of sound and images over text when competing for user attention on screens.

Most medical journals now routinely publish audio and video to accompany scientific articles, and a few journals publish video exclusively (eg, *Journal of Visualized Experiments*,[9] *Video Journal of Sports Medicine*[10]). Authors should think creatively while preparing their work for publication about whether audio and video can help them better communicate their study's details or findings and could consult with journal editors to understand opportunities to develop and publish multimedia, noting that journal staff often cannot yet edit audio and video files as easily as they can text documents. Videos of physical findings and of clinical or scientific procedures or interventions are especially useful and popular. Authors and publishers should consider the value of third-party platform publication of multimedia (eg, Apple Music or Spotify for audio, YouTube or Vimeo for audio and video) given the vast usage of these services by the public; YouTube, as a component of Google, can theoretically help a journal's search rankings (see below). Social media platforms may favor short-form video published on their platforms (including videofied audio clips) for visibility in user feeds.

Multimedia need not only be audio and video; still images or animated images (eg, gifs) may be as effective for communicating the topic or message of an article. No journal or website home page is text only, and a featured or promotional image related to the article title or topic, or a brief summary (ie, 1 or 2 sentences or phrases) indicating the key message of the article, helps draw attention to the content. Few journal publishers are equipped to use images that are not already included in an article as a figure, but authors can identify and use clinical or other images for their own social media activity, provided they have the rights to use such content. Authors could ask journal editors if they may use submitted images to promote the article, for example on journal homepages or in email promotions.

Downloaded from academic.oup.com/book/58841 by guest on 17 October 2026

Visual abstracts, first introduced to medical journals in 2015[11] and now a regular additional element of randomized clinical trials published in *JAMA* and JAMA Network journals,[12] are essentially article infographics, visual representations of the study question, methods, and findings of the clinical trial. Evidence suggests visual abstracts are associated with increased site traffic and engagement when published on social media,[13,14] and some publishers have taken to internally producing visual abstracts and formally publishing them online with articles. Media relations departments at academic institutions and authors now also produce these, and authors can offer them to journals for their use. Guidance for how to create visual abstracts is available online.[11,12]

Contemporary publishing standards and user expectations point to still other multimedia formats, such as interactive experiences (data visualizations or clinical decision challenges, for example), which are often commissioned by a journal or internally produced rather than spontaneously submitted by authors. Journals may need to expand their policies and procedures of editorial peer review for this internally produced or coproduced material.

For any multimedia, patient privacy is as important as it is for scientific research. Patients should not be identifiable by others or by themselves unless they have explicitly given permission for their voices or images (or other personal information) to be featured.[15] (See also the section on confidentiality in Chapter 35, Ethical Issues in Biomedical Publication.) In addition, journals should ask that authors own the copyright or a license for multimedia and any images that may be used to summarize or promote published articles, and that they are able to transfer that copyright or license, so that the journals are protected against claims of rights infringement. (See also Chapter 38, Legal Issues in Biomedical Publication.)

Search

While some users may bookmark favorite websites for direct access, search is the way most people access information online, and it is the primary source of traffic to most journal websites and specific articles. Google dominates the search market, so meeting basic Google search standards is good practice and should help an article's search ranking. The company's search algorithms are closely held secrets and are updated frequently without warning or explanation, but the company provides basic guidance about best standards that journals and authors would do well to be aware of.[16,17] While authors' first obligation is to meet the standards and format of scientific reporting required by their scientific field and its journals, a clear, accurate article title with keywords that match likely search terms or trends (which authors can explore[18]) meets the communication needs of authors, readers, and editors/publishers and helps search visibility. Authors might also consider as a secondary factor how

Downloaded from academic.oup.com/book/58841 by guest on 17 October 2026

journals appear or rank in searches important to their professional work when considering journals to which they might want to submit their work.

Many journals add metadata to articles to ensure web-based search engine discoverability. Publishers also deposit content and metadata to bibliographic databases such as PubMed/MEDLINE and others to aid in discoverability of published articles.

The search industry is experiencing substantial change with the public launch of large language-model based platforms and other generative artificial intelligence (AI) solutions to information queries. As search engines evolve to provide users with AI-generated answers to search queries on their own sites, rather than linking them to external webpages, journals may experience a decline in search ranking visibility and site visitors. Like the broader public, editors, publishers, and authors are advised to stay abreast of these changes to position their work for visibility and dissemination through the transition from "search engine" to "AI engine" optimization. (See also Use of Artificial Intelligence Tools for Scientific Writing in Chapter 6, Strategies for Efficient, Effective Scientific Writing.)

Alternative Metrics

In the print era, academic citations were a principal means of characterizing the importance of an article to scientific work and conversations. Then and now, the citation-based Journal Impact Factor of the journal in which the article is published is a metric used by many authors and academic promotion committees as an indication of the quality of a journal and as a reflection of the importance or competitiveness of an author's work. The Journal Impact Factor is calculated as the ratio of article citations (impact factor numerator) to published articles (impact factor denominator) in the previous 2 years. Specifically, a Journal Impact Factor in a year (eg, 2024) is (A) the number of citations that occur in that year (2024) from other (or the same) journals to articles published in the journal in the previous 2 years, ie, 2023 and 2022 (impact factor numerator), divided by (B) the total number of countable articles published by the journal in those previous 2 years, ie, 2023 and 2022 (impact factor denominator) (ie, A/B = Journal Impact Factor).[19,20] (See also Chapter 2, Scientific Journals and the Dynamic Publication Landscape, for further information on Journal Impact Factors.)

In the internet era, the notion of citation has expanded to include data that can be collected about an article's online performance, reach, and influence, including views, online mentions, and links on news sites, Wikipedia pages, blogs, social media platforms, and more. Collectively these online mentions have come to be known as alternative metrics, or Altmetrics for short.[21] Altmetric scores measure some aspect of the popular appeal of an article, but as a

Downloaded from academic.oup.com/book/58841 by guest on 17 October 2026

relatively new measure of article attention and possible influence, its meaning is debated in scientific communities. An article that generates vigorous online conversation, regardless of whether it is a research report or an opinion piece, may be merely provocative and clinically or scientifically unimportant, while clinically or scientifically important articles might not capture public conversation. But public Altmetric scores give authors some measure of the extent to which a broad online community is paying attention to a journal's output. To date, most promotion committees have not incorporated Altmetrics as a measure of the quality or importance of an investigator's body of work, but that could conceivably begin to shift as the importance of the digital reach of published articles is increasingly recognized and appreciated, and as younger digital-native faculty advance to more senior advisory positions. Authors can contribute to their article's Altmetric score through their own activity on social media, blogs, and Wikipedia.

Open Access

Open access is the free availability of scientific articles online generally without restrictions on reuse or redistribution, often paid for by article processing charges (which may be covered by funders). A complete discussion of open access is beyond the scope of this chapter and appears elsewhere in this book (see Chapter 2, Scientific Journals and the Dynamic Publication Landscape, and Chapter 38, Legal Issues in Biomedical Publication), but a few points are worth mentioning. (For additional information on open access, see also Section 5.6.2, Public Access and Open Access in Scientific Publication, in the *AMA Manual of Style*.[22])

There are several misunderstandings about open access. First, open access is often confused with free or public access. Public access includes free access to content but with copyright restrictions or limitations on sharing and reuse without permission.[22] Second, electronic publishing platforms are a precondition for free and open access; no one expects publishers of print journals to print and mail paper journals for free, even though print and online content for most journals is still largely identical. Third, the expectation that published science should be free online is a contemporary expression of early-era misunderstandings about the ease of online publishing and does not acknowledge the substantial and material investments that some journals and publishers make in infrastructure and editorial evaluation for submitted manuscripts, including many that are not accepted for publication, and final manuscript preparation, editing, production, and dissemination for those that are published.

These investments theoretically keep more questionable science out of wide circulation and transform author manuscripts into scientific documents of record, often with the development of accompanying unfunded content such

Downloaded from academic.oup.com/book/58841 by guest on 17 October 2026

as editorials, podcasts, videos, and other electronic enhancements. All require resources, and fully open access journals often must publish high volumes of articles to meet their essential operating costs. Predatory or deceptive journals and some "mega journals" exploit this structure, soliciting manuscripts or publishing high article volumes as much or more for profit than for scientific communication motives.[23,24]

Journals can nevertheless provide free public access content in any number of implementations short of becoming free entirely, including temporary or selective free access and toll-free links, which allow journals to make articles free in targeted distributions to specific audiences to meet reader demands; delayed onset of free public access (eg, 6 or 12 months after publication); allowing authors of original research investigations to deposit their accepted manuscript in a public repository for access immediately on the day the article is published by the journal[25]; or by participation in initiatives such as the Research4Life Hinari program, which grants institutions in low-income countries free access to biomedical journals.[26] Some extent of free access is desirable for all parties in the interest of science and because free content tends to be more widely shared and made more visible by online platforms. (See Chapter 38, Legal Issues in Biomedical Publication, for a more complete discussion of content licensing options that meet the full definitions of open access.)

Conclusions

Electronic distribution of science is a community and cultural standard. The pace of change in electronic platform evolution is fast and ever-accelerating; authors, journal editors, and publishers would do well to keep up as best they can with advances in those many requirements and opportunities and should collaborate to advance the possibilities of scientific communication on journal electronic platforms, and thereby enhance the dissemination of content efficiently and effectively.

References

1. Choo EK, Ranney ML, Chan TM, et al. Twitter as a tool for communication and knowledge exchange in academic medicine: a guide for skeptics and novices. *Med Teach*. 2015;37(5):411-416. doi:10.3109/0142159X.2014.993371
2. Sousa JA, Alves IA, Donato H, Sargento-Freitas J. The Twitter factor: how does Twitter impact #Stroke journals and citation rates? *Int J Stroke*. 2023;18(5)586-589. doi:10.1177/17474930221136704
3. Deshpande N, Crossley JR, Malekzadeh S. Association between Twitter mentions and academic citations in otolaryngology literature. *Otolaryngol Head Neck Surg*. 2022;167(1):73-78. doi:10.1177/01945998211044680

Downloaded from academic.oup.com/book/58841 by guest on 17 October 2026

4. Ladeiras-Lopes R, Vidal-Perez R, Santos-Ferreira D, et al. Twitter promotion is associated with higher citation rates of cardiovascular articles: the ESC Journals Randomized Study. *Eur Heart J*. 2022;43(19):1794-1798. doi:10.1093/eurheartj/ehac150
5. Betz K, Giordano M, Hillmann HAK, Duncker D, Dobrev D, Linz D. The impact of Twitter/X promotion on visibility of research articles: Results of the #TweetTheJournal study. *Int J Cardiol Heart Vasc*. 2023;50:101328. doi:10.1016/j.ijcha.2023.101328
6. Branch TA, Côté IM, David SR, et al. Controlled experiment finds no detectable citation bump from Twitter promotion. *PLoS One*. 2024;19(3):e0292201. doi:10.1371/journal.pone.0292201
7. Ramdani Z, Taylor E. Does social media impact SEO? we ran an experiment to find out. Hootsuite. May 10, 2018. Accessed April 18, 2024. https://blog.hootsuite.com/social-media-seo-experiment/
8. Jones K. How social media helps SEO [final answer]. *Search Engine Journal*. June 29, 2021. Accessed April 18, 2024. https://www.searchenginejournal.com/social-media-seo/196185/#close
9. JoVE. Accessed April 18, 2024. https://www.jove.com/journal
10. *Video Journal of Sports Medicine*. Accessed April 18, 2024. https://journals.sagepub.com/home/vjs
11. Ibrahim AM. A surgeon's journey through research and design. Surgery Redesign. Accessed April 18, 2024. https://www.surgeryredesign.com
12. Visual abstracts. JAMA Network. Accessed April 18, 2024. https://jamanetwork.com/pages/visual-abstracts
13. Ibrahim AM, Lillemoe KD, Klingensmith ME, Dimick JB. Visual abstracts to disseminate research on social media: a prospective, case-control crossover study. *Ann Surg*. 2017;266(6):e46-e48. doi:10.1097/SLA.0000000000002277
14. Trueger NS, Aly E, Haneuse S, Huang E, Berkwits M. Randomized clinical trial visual abstract display and social media–driven website traffic. *JAMA*. 2023;330(16):1583-1585. doi:10.1001/jama.2023.16839
15. Flanagin A, Bauchner H, Fontanarosa PB. Patient and study participant rights to privacy in journal publication. *JAMA*. 2020;323(21):2147-2150. doi:10.1001/jama.2020.3590
16. Google search engine optimization (SEO) starter guide. Google. Accessed April 18, 2024. https://support.google.com/webmasters/answer/7451184?hl=en
17. Google image SEO best practices. Google. Accessed April 18, 2024. https://developers.google.com/search/docs/appearance/google-images
18. Explore what [country] is searching for now. Google. Accessed April 18, 2024. https://trends.google.com
19. Journal Impact Factor (JIF). Clarivate. Accessed April 18, 2024. https://incites.help.clarivate.com/Content/Indicators-Handbook/ih-journal-impact-factor.htm
20. McVeigh ME, Mann SJ. The Journal Impact Factor denominator: defining citable (counted) items. *JAMA*. 2009;302(10):1107-1109. doi:10.1001/jama.2009.1301
21. Warren HR, Raison N, Dasgupta P. The rise of Altmetrics. *JAMA*. 2017;317(2):131-132. doi:10.1001/jama.2016.18346
22. Flanagin A. Public access and open access in scientific publication. In: Christiansen S, Iverson C, Flanagin A, et al, eds. *AMA Manual of Style: A Guide for Authors and*

Downloaded from academic.oup.com/book/58841 by guest on 17 October 2026

Editors. 11th ed. Oxford University Press; 2020. Accessed April 18, 2024. https://academic.oup.com/amamanualofstyle/book/27941/chapter/207564250#39577926
23. Grudniewicz A, Moher D, Cobey KD, et al. Predatory journals: no definition, no defence. *Nature*. 2019;576(7786):210-212. doi:10.1038/d41586-019-03759-y
24. Ioannidis JPA, Pezzullo AM, Boccia S. The rapid growth of mega-journals: threats and opportunities. *JAMA*. 2023;329(15):1253-1254. doi:10.1001/jama.2023.3212
25. Bibbins-Domingo K, Shields B, Ayanian JZ, et al. Public access to scientific research findings and principles of biomedical research—a new policy for the JAMA Network. *JAMA*. 2023;329(1):23-24. doi:10.1001/jama.2022.23451
26. Research4Life: Hinari. World Health Organization. Accessed April 18, 2024. https://www.research4life.org/about/programs/hinari

Downloaded from academic.oup.com/book/58841 by guest on 17 October 2026

Downloaded from academic.oup.com/book/58841 by guest on 17 October 2026

PART 2

Scientific Writing

Downloaded from academic.oup.com/book/58841 by guest on 17 October 2026

Downloaded from academic.oup.com/book/58841 by guest on 17 October 2026

CHAPTER 5

Formulating an Organized Critical Argument in a Scientific Manuscript

Philip Greenland, MD

Downloaded from academic.oup.com/book/58841 by guest on 17 October 2026

KEY POINTS

- A scientific research report is not just a set of facts; it is a critical argument that poses a question and reaches an answer with a clear conclusion.
- The article should focus on a single major question; this will help the authors, reviewers, editors, and readers.
- The reader is usually most interested in what the question is and whether there is a clear answer. Authors should stay focused on these key points: what is the question, and what is the answer?
- The overall organization of the manuscript, the logical progression of ideas, and consistency with the interrelatedness of key concepts are essential elements for formulating an effective critical argument.
- An outline of 1 to 2 pages, with sufficient detail to show the logical flow of ideas, can be a helpful way to get started and to receive feedback from coauthors and other colleagues about the completeness and logic of the manuscript.

Scientific medical journals hold a special status within the world of medical communication due to the rigor associated with peer review, editorial oversight, and wide distribution of content, as occurs at leading medical journals such as *JAMA* and the JAMA Network journals. High-quality journals are cited by authors and continue to be recognized within academia, clinical practice, funding agencies, and the media as reliable and accurate sources of new medical information, as journals provide the most complete, concise, readily accessible source of information about most research studies. The purpose of this chapter is to describe the approach to formulating an organized critical argument in a scientific manuscript for submission to a peer-reviewed journal.

What is the reader looking for in a peer-reviewed medical article? The full article is valuable in helping readers reach their own conclusions about the

accuracy, reliability, and validity of a particular study. As such, the report is more than just a set of facts, and it must certainly be more than a simple summary (such as an abstract) or a conclusion. The critical reader is looking for answers to questions, often answers to clinically important questions for which a new finding could change how medicine is practiced. The reader is seeking to know if this information is not only new but also true. An experienced medical editor, Edward Huth, termed this the critical argument and likened it to a courtroom proceeding leading to a verdict.[1] The full report must state the question, why it was important and new, and convince the reader that there was a definitive answer one way or the other. The overall organization of the manuscript, the logical progression of ideas, and the clear indication of internal relatedness of key concepts are essential elements of formulating an effective critical argument.

The sequence that allows the reader to reach a convincing conclusion follows a well-established pattern that is expected by readers, peer reviewers, and editors of medical journals. The usual order in a scientific manuscript is as follows:

a. State the question, problem, or gap (the Introduction).
b. Describe the way in which evidence was gathered and analyzed (the Methods).
c. Present the evidence and the findings without comment—"just the facts"—including tables and figures (the Results).
d. Explain the implications of the evidence: did it answer the question? How do the findings fit in with other research? Are there alternative ways to consider the results? What are the strengths and weaknesses of the research? (the Discussion).
   Note: A useful acronym for the above is IMRAD, for Introduction, Methods, Results, and Discussion.
e. Present a clear take-home summary, based on the evidence (the Conclusion).
f. Provide supporting information (the References).

Why does a specific order matter? Simply put, it is the way the reader expects to find the manuscript organized and written. For example, if the research question, or gap in evidence, is not clearly stated in the Introduction, even a careful reader may reach the conclusion that the findings have no particular importance, possibly leading to a "so what?" reaction. If details of the Methods are missing or misplaced (such as reporting validity of data collection methods in the Results section), the reader might not appreciate the rigor of the research. If a result is not mentioned in the Results section, but only reported for the first time in the Discussion, a casual reader might overlook it.

Thus, the traditional order of a research manuscript actually matters, and this internal logic is especially important for editors and peer reviewers, the

Downloaded from academic.oup.com/book/58841 by guest on 17 October 2026

first readers after the authors. Many authors may not realize that only a limited number of reviewers will evaluate a submitted manuscript and a very small number of editors will make the decision about the acceptance or rejection of a manuscript. Authors must strive to have their manuscripts make the best first impression by presenting the critical argument in the most logical and cohesive manner possible.

Several other elements within the manuscript contribute to presenting a logical and cohesive critical argument. For instance, the objective in the abstract must be consistent with the objective in the Introduction and clearly indicate the research question. The answer to that question is provided in the conclusion of the abstract, is highlighted in the first paragraph of the Discussion section, and is also stated in the final conclusion of the manuscript. Another approach for helping to ensure the internal logic of the manuscript involves how the Methods section should be organized to address the research question, with a logical and consistent arrangement of key elements such as study population, exposures or interventions, and outcomes. For example, outcomes should be organized as primary, secondary, exploratory, and post hoc; the statistical analysis section follows the same order by describing the analysis for these outcomes; the Results section presents the findings in the same logical order; and the Discussion section should explain the results using the same organizational approach. These consistent approaches to organization of the manuscript may be helpful for readers to follow the authors' critical argument, especially in reports with complex methods or multiple outcomes.

To get started writing a manuscript and to make certain all key elements are included in a logical fashion, one very effective approach is to create an outline before starting to write. The outline can be very basic, listing each section and making bullet points for each major feature of each paragraph. The outline enables the author to get started, to share the flow of ideas with colleagues easily and quickly, and to stay focused. For most manuscripts, a detailed outline is no longer than 1 to 2 pages and can help the author organize the manuscript according to the approach outlined above. The outline is also exceedingly helpful for formulating the critical argument. Since the critical argument depends on a logical and convincing flow of ideas from question to answer, the outline should be able to convey this logic without all the additional verbiage that would go into the full manuscript. A succinct outline also can enable coauthors to provide feedback promptly (usually within a few hours), whereas receiving feedback on a full first draft of the manuscript will require more time (often days).

An example of an outline for an article that was published in *JAMA* in 2018[2] is shown in **Box 5-1**. This outline is 2 pages of standard printed text and illustrates the logical flow of information in the manuscript. It supports the critical argument, sets out a clear question, and provides an answer that is based on an understandable design that is described in the Methods and Results

Downloaded from academic.oup.com/book/58841 by guest on 17 October 2026

Box 5-1. Example of an Outline for a Research Manuscript

I. Title: Association of Blood Pressure Classification in Young Adults Using the 2017 American College of Cardiology/American Heart Association Blood Pressure Guideline With Cardiovascular Events Later in Life

II. Abstract
   a. Importance—little is known about association of blood pressure (BP) in young adulthood and cardiovascular disease (CVD) events in midlife.
   b. Objective—using guideline-defined BP levels in adults younger than 40 years old, what is CVD risk compared to those with normal BP?
   c. Design, setting, participants—using CARDIA cohort; describe these details.
   d. Exposures—normal BP < 120 mm Hg systolic and normal diastolic < 80 mm Hg; compared 3 higher strata of BP.
   e. Main outcomes—CVD events (list them).
   f. Results—include numbers in cohort, age of cohort, racial-ethnic composition. Provide duration of follow-up and main outcomes including quantitative data (numbers of events, rates, hazard ratios).
   g. Conclusions and relevance—findings showed higher risk for each BP stratum above normal BP in cohort younger than 40 years old. The 2017 guideline BP levels may help identify young adults at high risk for CVD.

III. Introduction—2 paragraphs
   a. A new BP guideline became available in 2017. Most of the evidence was based on middle-aged and older adults. Unclear if the new BP guideline levels (especially the category of stage 1 hypertension) are associated with higher risk of CVD in younger adults (this is the gap that this paper will try to address).
   b. To address this gap, we used data from the CARDIA study to examine associations of BP by 2017 guideline with CVD events in follow-up.

IV. Methods
   a. Informed consent and review and approval by an institutional review board or ethics committee.
   b. Reporting guideline—indicate the appropriate reporting guideline for the type of study.
   c. Describe the CARDIA cohort—ages, study center locations, number of examinations and years of study, and completeness of follow-up.
   d. Describe measurements of BP and standardization of technique.
   e. Describe other measurements—demographics, including race; other baseline variables including education, smoking, physical activity, laboratory measurements, etc.
   f. Details of BP classification—normal, elevated, stage 1, and stage 2.
   g. Outcomes—what were they and how were they obtained? Reference full details to study design papers but give sufficient detail so that reader knows which outcomes (CVD events) and how diagnosed.
   h. Statistical analyses—Kaplan-Meier for survival; Cox proportional hazards for hazard ratios and 95% confidence intervals; adjustment for covariates; post hoc analysis for individual CVD subtypes (coronary, stroke, heart failure).

V. Results
   a. Numbers in the analysis cohort—the analytical sample based on inclusion and exclusion criteria (flow diagram—include in main manuscript or the Supplement).

Downloaded from academic.oup.com/book/58841 by guest on 17 October 2026

b. Table 1—characteristics of the participants overall and in each of the 4 BP categories.
c. Primary analysis—numbers of events in each group along with hazard ratios, including the unadjusted and adjusted models. Plan to show a figure with Kaplan-Meier curves for the 4 categories of BP over 18 years of follow-up. Include numbers at risk under the curves. Plan to show a table with hazard ratios (HRs) and 95% confidence intervals (CIs).
d. Sensitivity analysis—using data from 2 or more BP levels in same BP category.
e. Post hoc analysis—events with HRs and 95% CIs for individual CVD events—details in supplemental tables since this is post hoc.

VI. Discussion
a. Main finding—significant associations of BP in each of the 3 categories above normal. Brief summary of additional main findings (first paragraph). Do not restate the question—state the answer.
b. How does this relate to or compare with prior studies? Absence of information in this age group. Importance of filling this gap.
c. Strengths—large cohort; ethnically diverse; long follow-up; detailed outcomes.
d. Limitations—lacking some information on diet and psychological factors as confounding variables; medication use not recorded in all participants; any others?

VII. Conclusion—same as conclusion in Abstract. Findings showed higher risk for each BP stratum above normal BP in cohort younger than 40 years old. The 2017 guideline BP levels may help identify young adults at high risk for CVD.

sections. The Discussion summarizes the answer to the question and offers important strengths, weaknesses, and an overall conclusion.

In summary, a research manuscript is more likely to be successful if it is well organized, presents a critical argument that poses a question and reaches an answer with a clear conclusion, and follows a logical structure with a consistent progression of facts and ideas.

References

1. Huth EJ. *Writing and Publishing in Medicine*. 3rd ed. Williams and Wilkins; 1999.
2. Yano Y, Reis JP, Colangelo LA, et al. Association of blood pressure classification in young adults using the 2017 American College of Cardiology/American Heart Association blood pressure guideline with cardiovascular events later in life. *JAMA*. 2018;320(17):1774-1782. doi:10.1001/jama.2018.13551

Downloaded from academic.oup.com/book/58841 by guest on 17 October 2026

CHAPTER 6

Strategies for Efficient, Effective Scientific Writing

Phil B. Fontanarosa, MD, MBA

Downloaded from academic.oup.com/book/58841 by guest on 17 October 2026

KEY POINTS

- To meet the challenge and overcome the demands of competing responsibilities requires that scientific writing is as efficient and effective as possible.
- Prewriting considerations, such as having a thorough understanding of the topic and the ability to crystallize the main message of the report and planning for manuscript creation by having a clear framework, including the most likely target audience and the specific format used by the target journal, are essential for efficient writing and manuscript preparation.
- Some approaches to overcome procrastination include strategies that are directed toward meeting deadlines and simplifying the task of manuscript preparation.
- Authors should strive to find their "writing zone" based on the environment, internal and external cues, and techniques that promote maximal writing efficiency and effectiveness.
- Strategies to help overcome writer's block may include shifting to other tasks, taking a break from writing, shifting to a new environment, or continuing to write but with the overarching goal of capturing ideas, phrases, and concepts related to the manuscript, without writing sentences or paragraphs.
- Practical approaches to promote efficient scientific writing include avoiding duplication of effort, adopting an intuitive and unambiguous nomenclature for electronic manuscript files, and developing an effective method for managing and tracking source materials.

Scientific writing is an essential skill for anyone who has or is contemplating a career in academic medicine, biomedical research, or other scientific disciplines. Scientific writing serves several important purposes, including communication

of scientific information, such as by disseminating findings from research studies; promoting new ideas and fostering debate and discussion, such as by publication of opinion articles; or preparing grant applications, such as to compete for research funding or career grants. Scholarly productivity, primarily measured by publications, is an important factor in academic promotion and career advancement and is based on effective scientific writing. In addition, scientific communication is an expectation of many academic institutions and funding bodies, and publication of scientific reports based on clinical research is a duty and responsibility to research participants so that their efforts and contributions to research studies can be recognized through dissemination of the results of the research investigations in which they participated to the scientific and clinical communities.

Every person with a career in academics, especially in biomedical research, has substantial and competing time demands related to their professional duties and responsibilities. For instance, some physicians in academic medical centers may have responsibilities for patient care, for teaching and supervision, for service on committees, and for conducting clinical research, yet are still expected to demonstrate evidence of scholarly accomplishment, primarily with scientific publications. Moreover, with career progression through residency and fellowship to junior faculty positions and to more senior faculty ranks, time demands generally continue to increase, not only based on professional responsibilities, but perhaps more important, also based on concomitant and increasing personal commitments, such as family responsibilities and community involvement. Accordingly, the challenge is to maintain or increase scholarly productivity as documented with scientific publications while having less time to do so because of competing demands from other professional and personal responsibilities. One solution to these challenges is to ensure that scientific writing is as efficient and effective as possible. This chapter describes strategies and suggestions that may help enhance efficiency with scientific writing, including approaches to prewriting and planning a manuscript; techniques for fostering efficient writing, such as overcoming procrastination; achieving peak writing efficiency by getting in the "writing zone"; and dealing with writer's block.

Prewriting and Planning

Prewriting considerations and planning can contribute to efficient writing and manuscript preparation. Fundamental qualities of successful manuscripts include original, good ideas; rigorous, solid studies or literature reviews; and relevant and timely information. Before beginning to write, authors must know the topic area thoroughly and should have a clear and realistic understanding of the potential importance the contribution might have, including the novelty,

Downloaded from academic.oup.com/book/58841 by guest on 17 October 2026

increment of new information, and differences compared with other published articles. It is also important for authors to determine the main message of the manuscript (which should be able to be captured in a single sentence) to create a clear, focused, cohesive, and compelling story in the manuscript. Without this level of understanding of the topic and ability to crystallize the main message of the report, it will be difficult to create an effective manuscript efficiently. Prior to beginning writing, authors should develop a working title that reflects the main message of the report and that will serve as the focal point for the manuscript.

Another factor that may help contribute to efficient writing is having a clear planning framework for creating the manuscript, including knowing the most likely target audience and the format used by the target journal. Because readerships and article formats vary widely from journal to journal, identifying the most likely target journal prior to beginning (or very early in) the manuscript preparation process can contribute to efficient writing. Although many factors are considered in journal selection (see Chapter 3, Selecting a Journal), identification of the target journal to which the manuscript likely will be first submitted can contribute to efficient writing.

For example, although a basic understanding of medical knowledge can be assumed for readers of most biomedical journals, readers of general medical journals (like *JAMA* and the *New England Journal of Medicine*) might not be familiar with concepts, terminology, and language that are standard in some specialty and subspecialty areas. For preparing manuscripts for general medical journals, authors would need to avoid extensive use of specialized terminology, and if technical jargon is included, authors would need to provide clear explanations to enhance understanding of content. In contrast, the readership of specialty and subspecialty journals can be assumed to have knowledge of the topic areas of those journals. Authors preparing manuscripts for these journals could use standard terminology, technical language, and when appropriate, specific jargon, without the need for detailed explanation. Deciding on the level of specialized content and terminology usage early in the manuscript preparation process will enable authors to use the appropriate language and terminology when writing the first draft of the manuscript and avoid extensive rewriting to revise and clarify terminology, thereby contributing to efficient manuscript preparation.

Another important factor for promoting efficient writing is to determine the article type and format in the target journal for reporting the content of the manuscript. These may include a full-length original research report; a brief research report, such as a case report, case series, or research letter; a review article, such as a systematic or narrative review; or an opinion piece, such as a commentary, perspective, or editorial. The strategy for writing a full-length research report will differ from that used for a more abbreviated research report, such as a research letter.

Downloaded from academic.oup.com/book/58841 by guest on 17 October 2026

Similarly, the strategy for writing a full-length research report will differ depending on the target journal selected, given the variation in article structure and length among journals. For instance, for original research reports, *JAMA* allows a maximum of 3000 words of text at submission and includes a section called Key Points; the *New England Journal of Medicine* allows a maximum of 2700 words of text; *The Lancet* allows up to 3500 words of text for research reports and up to 4500 words for clinical trials and includes a section called Research in Context; the *BMJ* does not set fixed word count limits and includes the sections What Is Already Known on This Topic and What This Study Adds; and *Nature Medicine* allows 2000 to 4000 words of text and uses an article structure consisting of Abstract, Introduction, Results, Discussion, and Brief Methods (with detailed methods online), which is different from the article structure of these other 4 journals, which consists of Abstract, Introduction, Methods, Results, and Discussion.

Consulting the instructions for authors for the target journal and determining article type, format, and length are essential to achieve efficient writing, and are helpful to ensure that the manuscript adheres to journal guidelines and to avoid multiple revisions based in formatting criteria. Once these details are identified, authors can develop an effective, detailed outline to guide preparation of the first draft of the manuscript and thereby ensure that the appropriate structure and length of the manuscript will be followed, based on the requirements of the target journal. (See Chapter 5, Formulating an Organized Critical Argument in a Scientific Manuscript.)

Overcoming Procrastination

One of the most difficult challenges in achieving efficient manuscript preparation involves overcoming procrastination. Several common factors contribute to procrastination, perhaps the most important of which are distractions, including from competing priorities, from time demands of other tasks, or from the opportunity to engage in other activities that are easier or more enjoyable than scientific writing. In addition, scientific writing is hard work and may be perceived as being a chore, and perhaps may seem stressful to perform. Other factors that may contribute to procrastination include the apparent complexity involved with manuscript preparation and concerns about the quality of the written product.

Some approaches to overcome procrastination include strategies that are directed toward meeting deadlines and toward simplifying the task. For instance, all authors involved with a study or review should make a joint commitment to write the manuscript in a reasonable time frame. Depending on the nature, complexity, and format of the manuscript, this time frame may be within days (such as for an opinion article) or weeks (such as for a research manuscript

Downloaded from academic.oup.com/book/58841 by guest on 17 October 2026

or literature review). A deadline agreed on by the authors should be realistic but reasonably short, so that the content of the manuscript (such as new findings from a research study) can be submitted for publication in a timely fashion. This agreement also helps to contribute to a common goal and a shared mission among all authors, and it creates peer pressure to encourage authors to fulfill their respective tasks within the chosen deadlines, such as writing the manuscript, drafting specific sections, or critically reviewing the draft of the manuscript and providing comments in a timely manner.

To overcome procrastination, it may be helpful to simplify the overall task of research manuscript preparation by deconstructing the writing of the manuscript into the main sections (ie, Introduction, Methods, Results, and Discussion) and consider writing each section as a separate, more discrete task. The author could focus on one task at a time, and perhaps begin by writing the section of the manuscript that the author considers the "easiest" to write. For instance, some authors may begin by writing the Introduction section first, as this section is usually brief and focused. Other authors may find it more efficient to begin with preparation of tables or figures rather than writing text because creation of these data displays is often straightforward, and these graphical displays provide the foundation for the message of the manuscript. In addition, authors also could establish a reasonable, achievable time frame for writing the initial section, followed by realistic deadlines for writing subsequent sections.

Another way to view deconstructing the manuscript is in terms of the number of paragraphs in each section. For instance, to prepare a manuscript with a 3000-word limit for the text, and assuming typical paragraph lengths of 150 to 200 words, the author would need to write between 15 and 20 paragraphs, of which 2 to 3 might be in the Introduction, 5 to 6 in the Methods, 4 to 5 in the Results, and 4 to 7 in the Discussion. Conceptualizing the manuscript with this type of approach may help simplify the perception that writing a scientific manuscript is a highly complex and overwhelming task.

Achieving Peak Writing Efficiency

Athletes, musicians, and performers often achieve a state of peak performance that may be sustained for various lengths of time, which has been referred to as being "in the zone." Similarly, some prolific writers achieve being "in the writing zone," during which ideas readily flow, attention is hyper-focused, and high volumes of high-quality writing are produced almost effortlessly. This writing zone is the time of peak productivity, peak creativity, and most efficient writing, and each author has certain techniques that facilitate achieving and maintaining this state.

For authors of scientific manuscripts, finding the "scientific writing zone" contributes to achieving the most efficient, most effective, and most productive

Downloaded from academic.oup.com/book/58841 by guest on 17 October 2026

scientific writing. Although finding this zone is highly individualized, several factors may enhance writing efficiency. Authors should find their most creative time, whether that is early morning, midday, or at night, and if possible, should write when their energy is high, not when they are tired. For instance, some authors may be most effective when writing during the early morning hours, during a period of relative calm and quiet, before the demands of the day begin. During prolonged writing periods, some authors may find that taking intermittent breaks may be helpful, such as taking brief walks or performing intermittent exercises, stretching, or yoga-like activities.

Another suggestion for finding the writing zone is for authors to find their most productive environment, including atmosphere, background, and setting, whether in a quiet office with the door closed or in a coffee shop while listening to music. Having an environment conducive to writing may be helpful, such as a quiet, comfortable space that has the elements and resources to concentrate and that will help guard against interruptions. Authors should find their most effective writing format, especially for the first draft of a manuscript, which may involve computer-based word processing, writing on paper, or dictation using voice-recognition software programs. Authors should strive to find the environment, internal and external cues, and techniques that promote maximal writing efficiency and effectiveness. Once factors that facilitate efficient and effective writing are established, authors may find it helpful to repeat these specific actions to build their writing zone (like a warm-up routine for athletes) and thereby make efficient writing a replicable phenomenon.

Another approach to facilitate efficient scientific writing is to plan writing sessions, as authors may find they are more efficient by maintaining a schedule and routine, and this ensures they have certain amounts of uninterrupted time to devote to writing. Authors should, if possible, try to schedule a specific time for writing by blocking out time each week (or ideally each day) devoted to scientific writing and manuscript preparation. Establishing a plan and goal for each session may be helpful in maximizing efficiency. For example, the goal for one scheduled session may be to write the Discussion section of the manuscript. During this session, it is not necessary for each sentence and each paragraph to be written perfectly, but rather it is more important for authors to capture all the ideas and concepts necessary to complete the goal of the session, such as having an organized, advanced draft of the Discussion section completed or nearly completed at the end of the session. It is then relatively easy to review and edit the text and finalize the section in another session.

Also, it is helpful to have readily available all materials necessary to write each manuscript section (eg, references for other reports that may be described in the Discussion) to avoid having to interrupt writing to perform searches for other information that may be needed (such as finding a new reference). If authors embark on these searches, it is easy to continue to search for other information and to succumb to other electronic diversions, such as checking email

Downloaded from academic.oup.com/book/58841 by guest on 17 October 2026

or social media. To maximize efficiency during these dedicated sessions, authors also should try to eliminate other potential distractions, such as by turning off cell phones and pagers (if possible). The purpose of the session is to focus on scientific writing, not to perform other tasks.

Dealing With Writer's Block

According to *Merriam-Webster's Dictionary*, writer's bock is defined as "a psychological inhibition preventing a writer from proceeding with a piece."[1] Writer's block has been discussed in a wide variety of disciplines, including psychology, literature, and journalism, with various causes described and a wide range of possible remedies suggested. Some commonly described factors that may contribute to writer's block include an uncertainty by authors, which may be related to the topic or to their research, knowledge, or competence, as well as a lack of confidence by authors, especially as related to their writing ability or writing quality. These factors may contribute to anxiety due to a perceived need for perfection both in the material communicated and in the manner by which it is communicated. These anxieties may be accompanied by internal self-criticism and fears of judgment and critique by others, especially colleagues or supervisors. Other factors that may contribute to writer's block include pressure from looming deadlines and unrealistic expectations and demands from coauthors, colleagues, or others.

Several strategies have been suggested to help address writer's block. For instance, if the writer's block is such that the author is unable to use the time available to write any meaningful sentences or portions of a manuscript, temporarily shifting from the task of writing to other tasks or activities may be helpful. For instance, instead of writing text of a manuscript, the author may shift to working on double-checking data, preparing tables or figures, or finalizing references. Completing these tasks successfully may lead to a sense of accomplishment that could be helpful when returning to writing the text. Another suggestion is to take a complete break from writing and shift to a new environment, such as by going for a walk, exercising, or pausing for a cup of coffee or tea. Interrupting the planned writing session with these activities may enable the author to resume productive writing after the break.

Perhaps ironically, one of the best antidotes for writer's block may be to try to continue writing. But rather than attempting to write polished sentences and organized paragraphs, authors may consider using brief episodes (eg, 15 to 20 minutes) of nonstop or free writing, during which the overarching goal is simply to capture ideas, phrases, and concepts related to the manuscript. During this exercise, the focus is on ideas, without any concern about structure, order, organization, grammar, spelling, or any errors. Devices such as outlines, tree

Downloaded from academic.oup.com/book/58841 by guest on 17 October 2026

diagrams, conceptual flowcharts, arrows connecting key words, or simple illustrations or pictures may be useful to help generate these ideas and concepts. For some authors, it may be easier to capture these ideas with a change in venue or format, such as visualizing the ideas by writing on a whiteboard in a classroom rather than typing on a computer keyboard. Another approach to help overcome writer's block is for the author to discuss with coauthors or other colleagues the concepts, ideas, and manuscript sections about which the author is having difficulty writing. Verbalization of the key ideas related to these concepts or discussion related to formulating the manuscript sections may be helpful when the author returns to writing the manuscript.

Practical Suggestions for Efficient Writing

Another important aspect of efficient writing is to avoid duplication of effort. For instance, for research that was supported by grants, required review and approval by an institutional review board or ethics committee, or involved creation of a study protocol and statistical analysis plan (such as with clinical trials and some meta-analyses), authors could use portions of these documents (such as grant applications or protocols) as a starting point for writing the manuscript. Similarly, authors who have submitted abstracts of their study for consideration for presentation at a scientific meeting could use that abstract as the basis for the abstract of the manuscript, with updating as needed (eg, after additional data analysis) and reformatting as needed for the target journal.

Another suggestion to avoid duplication of effort is to ensure that authors always use the correct and most recent manuscript file during the manuscript preparation, accounting for the various iterations of manuscript that occur. To help achieve this, authors should develop an intuitive and unambiguous nomenclature for electronic manuscript files and use that nomenclature consistently. Authors also should have a consistent system for numbering, dating, and identifying all drafts, all pages, and all electronic files and hard copies of manuscripts and manuscript elements (such as tables, figures, and supplemental information). This system should account for edited versions of manuscript files, including designations for documents with modifications showing (ie, in "track changes" mode) and for those same documents with modifications accepted (ie, as clean versions). An additional consideration in naming manuscript files should include accounting for comments and modifications made by coauthors, especially when multiple coauthors are involved and are making sequential changes to the manuscript file circulated for review and comment.

In addition, authors should develop an effective method for managing and tracking all source materials, such as references. All source materials used for a manuscript should be organized and readily available, whether as hard copies

Downloaded from academic.oup.com/book/58841 by guest on 17 October 2026

of printed articles or electronic files stored in reference manager programs. Notations and information taken from source materials should be carefully and meticulously referenced, with the citation to the original source, so that when this information is included in the manuscript, it will be accompanied by the needed citation. Reference management software can help manage citations to references, especially during revisions (see also Chapter 16, Referencing and Using Reference Managers).

Use of Artificial Intelligence Tools for Scientific Writing

Tools assisted by artificial intelligence (AI) for use in biomedical research are increasingly available, including natural language processing programs and generative chatbots that can create content or assist with writing and editing scientific manuscripts.[2] While these tools, like some other writing tools (eg, those for checking grammar and spelling and for verifying and formatting references), have the potential to increase efficiency with manuscript preparation and may help improve manuscript quality, there are important issues related to their use.

Among some of the potential advantages of AI-driven language tools for authors include the possibility of overcoming barriers to productivity, making interesting and overlooked analogies, identifying references that may have been missed, improving the manuscript title and abstract and matching those elements with the parameters of the target journal, providing guidance on writing structure, and facilitating writing and composition by authors for whom English is not their primary language.[3] Among some of the concerns related to AI-driven language tools include potential misuse and unreliability of these models, such as creation of formulaic, out-of-date, or false or fabricated text, with concocted evidence for some claims or statements[2]; that these tools "are incapable of understanding new information, generating new insights, or deep analysis"[3]; failure to provide both sides of controversial topics; and inability to generate text that is forward-looking.[3] Moreover, the output of AI-driven language tools cannot be taken at face value and all assertions must be verified, and the process involved in production of AI-driven text cannot replace creative or innovative thinking by humans.[3]

Some biomedical journals have developed policies regarding the use of AI and language models in scientific manuscripts, ranging from prohibiting the inclusion of AI-generated text in submitted manuscripts to requiring full transparency and statements of responsibility and accountability for how such tools are used and reported in scholarly publications,[4] as well as policies on authorship, including some that prohibit the inclusion of

Downloaded from academic.oup.com/book/58841 by guest on 17 October 2026

nonhuman language models as "authors" or to be listed or credited in the byline of a scientific article.[2]

JAMA and the JAMA Network journals have developed guidance for manuscripts that use AI-based technologies, as follows:

> "The submission and publication of content created by artificial intelligence, language models, machine learning, or similar technologies is discouraged, unless part of formal research design or methods, and is not permitted without clear description of the content that was created and the name of the model or tool, version and extension numbers, and manufacturer. Authors must take responsibility for the integrity of the content generated by these models and tools." In addition, "Nonhuman artificial intelligence, language models, machine learning, or similar technologies do not qualify for authorship."[2]

AI-assisted tools for use in biomedical research will continue to evolve in sophistication, capabilities, and availability. However, authors must carefully consider the potential advantages and important concerns and caveats before using these tools in the preparation of scientific manuscripts and any use must be applied with utmost responsibility, integrity, and transparency.

Conclusion

Efficient and effective scientific writing is essential to meet the challenge and overcome the demands of competing responsibilities, and to contribute to scholarly productivity in academic careers. Important considerations include having a thorough understanding of the topic and the ability to crystallize the main message of the report and planning for manuscript creation by having a clear framework, including the most likely target audience and the specific format used by the target journal. Authors should develop approaches to overcome procrastination, including strategies directed toward meeting deadlines and simplifying the task of manuscript preparation, and should strive to find their "writing zone" based on the environment, internal and external cues, and techniques that promote maximal writing efficiency and effectiveness.

References

1. Writer's block. *Merriam-Webster's Collegiate Dictionary*. 11th ed. Merriam-Webster Inc; 2003. Accessed November 8, 2023. https://www.merriam-webster.com/dictionary/writer's%20block
2. Flanagin A, Bibbins-Domingo K, Berkwits M, Christiansen SL. Nonhuman "authors" and implications for the integrity of scientific publication and medical knowledge. *JAMA*. 2023;329(8):637-639. doi:10.1001/jama.2023.1344

Downloaded from academic.oup.com/book/58841 by guest on 17 October 2026

3. Buriak JM, Akinwande D, Artzi, et al. Best practices for using AI when writing scientific manuscripts caution, care, and consideration: creative science depends on it. *ACS Nano*. 2023;17(5):4091-4093. doi:10.1021/acsnano.3c01544
4. Flanagin A, Pirracchio R, Khera R, Berkwits M, Hswen Y, Bibbins-Domingo K. Reporting use of AI in research and scholarly publication—JAMA Network guidance. *JAMA*. 2024;331(13):1096-1098. doi:10.1001/jama.2024.3471

Downloaded from academic.oup.com/book/58841 by guest on 17 October 2026

CHAPTER 7

Advice on Writing for Biomedical Journals

Frederick P. Rivara, MD, MPH

KEY POINTS

- The scope of a manuscript should be narrow and specific.
- Brevity in scientific writing is a virtue appreciated by both journals and readers.
- Authors can complete the first draft of a manuscript by attempting to "just get it down" and then repeatedly revise it, with input from critical readers.
- Authors should strive for clarity in their writing and avoid spin and boasting.

Writing is a learned skill. For many authors, first attempts at scientific writing may have been challenging or of poor quality, but usually writing improves over the years. Writing expertise comes from experience. It may never get easy for some, but for most authors, it will get better and easier with each manuscript.

General Approach to Scientific Writing

The first draft of a manuscript is the most difficult to write. Authors should not aim for perfection on the first draft, but rather to "just get it down" (on paper or in an electronic file) to begin to capture and organize ideas for the manuscript. Many authors find it helpful to begin to write the first draft of a research manuscript early in the course of the study, perhaps even before the results are known. When the major ideas are drafted in a tangible form, it is easier for authors and colleagues to see what further work is needed. First drafts can reflect grant applications or ethics committee approval forms, which are often the first written expression of the study.

For most manuscripts, the focus should be narrow. The best studies and articles are usually those that ask a single focused question and answer it well. They focus on 2 to 3 themes, and not more. This is not to suggest or advocate

Downloaded from academic.oup.com/book/58841 by guest on 17 October 2026

splitting the findings of a study into many publications; rather, a study and the resulting publication will be more readable and informative if the focus is on 1 question and the article tells a cohesive and clear story.

One way to make articles more readable is to use the active voice and the first person. Many authors were taught that scientific writing sounds more objective if the passive voice and the third person are used; however, articles are more interesting and more easily read if the writer says, "I conducted a randomized trial," or "We carried out a case-control study," rather than, "A study was done." Science is done or led by human investigators, not robots; authors should say what they did and take credit or blame for their work. However, when using first-person pronouns, it is essential for authors to be precise with usage. For instance, while use of *we* in the Methods section may clearly refer to the actions of investigators ("We enrolled 400 patients"), the use of this pronoun in the Discussion should be clear from the context. For example, a phrase such as "In this study, we found" would clearly refer to the authors, whereas a phrase such as "We should consider adopting these findings in clinical practice" would not clearly indicate whether the authors were referring to their own practices or the broader clinical community. In the latter case, rephrasing the sentence to avoid the use of the collective *we* would result in more precise meaning.

Editing

Authors should plan on putting the manuscript through many drafts. The first or second draft of a manuscript is almost never suitable for submission for publication, and sometimes the number of drafts may reach double digits. Multiple drafts are important to get a high-quality product. When creating drafts, double-space the text, single-space the tables, and date all versions.

When revising the manuscript, authors should seek feedback from critical reviewers. Only parents should think the work of their children is perfect. In addition to all coauthors, other potential critical reviewers for a manuscript include mentors and colleagues. Authors should invite reviewers who will improve the work, including the substantive issues and logical organization and flow of ideas, not merely correct typographical errors or grammatical mistakes. Authors who seek this advice should not take the comments they receive from these reviewers (or comments from journal editors or peer reviewers) personally. The comments are meant to make the manuscript better, and usually they will. Comments are like clinical advice from a consultant; the comments should be taken into consideration, evaluated carefully, and then the advice can be used to make a decision about what is best. Complete and uncritical acceptance of each comment from multiple coauthors may lead to a manuscript

Downloaded from academic.oup.com/book/58841 by guest on 17 October 2026

that does not make sense. The lead author (who often serves as a corresponding author) has the responsibility to ensure that the final product reads well.

Authors should also learn to be their own best editor. One helpful approach is to print a copy of the manuscript in double-spaced format and review it line-by-line with a critical focus on each word and sentence. Reading the text aloud will reveal errors of grammar and syntax and will help identify overly long and convoluted sentences. To review the manuscript with a fresh eye, authors may find it helpful to set the text aside for a few days, then read it again. Experienced authors generally learn to be a severe critic of their own writing.

Above all else, authors should strive for clarity. Avoid using jargon, numerous and unusual abbreviations, and highly technical terms unless these terms are absolutely necessary, and even then, these terms may require explanation or expansion at first mention. Simple, clear language is usually more effective at communicating ideas. For instance, a simpler, more familiar word (such as *deny* or *contradict*) will suffice and may be better than a less familiar word (such as *gainsay*). Readers will find a clear manuscript more persuasive and enjoyable than one that attempts to make its authors sound scholarly.

Brevity is a virtue. Authors should omit unnecessary phrases, sentences, and paragraphs and carefully examine the manuscript for empty phrases. For example, *a majority of* can be replaced with *most* (provided that there are numbers and percentages to support that expression). *It is of interest that* can just be deleted. *The fact is* is rarely needed. Search for useless sentences that lurk at the start and end of paragraphs. For instance, when writing the Introduction section for a study of obesity, there is no need to restate the well-known fact that obesity is a major problem in a specific country. Moreover, editors and readers generally prefer articles that are concise. In 272 words, Lincoln at Gettysburg changed the way of thinking about the founding principles of the United States.[1] Watson and Crick described the structure of DNA and won the Nobel Prize in a 900-word article.[2] The most complicated studies are now routinely published in fewer than 3500 words. Many readers do not have the time to read an article that is much longer.

General Advice About Manuscript Format

ABSTRACT

While the draft of an abstract may be available in the early stages of manuscript preparation (such as when the authors have presented an abstract at a scientific meeting), it is advisable to wait to write and finalize the abstract when nearing the last draft of the manuscript. The abstract should not contain information unless that information is also in the manuscript; a good strategy is to cut and paste phrases and quantities from the manuscript to the abstract.

Downloaded from academic.oup.com/book/58841 by guest on 17 October 2026

The main results should include data and absolute values (such as numbers of cases or incidence rates), not just qualitative findings or relative values (such as odds ratios). The numeric results in the abstract must be the same as those in the manuscript; when the results in the text and the abstract differ, reviewers are not favorably impressed. (See also Chapter 11, Writing an Informative Abstract.)

INTRODUCTION

The Introduction should be succinct, often no more than 200 words. A comprehensive review of the literature is not needed in the Introduction. The Introduction should indicate the importance of the problem (without being trite), point out the area in which important knowledge is lacking, and state the research question that the study will answer. (See also Chapter 12, Writing a Compelling Introduction.)

METHODS

The Methods section should include the study type and research design; readers should not have to guess. Use terms that readers will be familiar with to describe the design—randomized clinical trial, cost-effectiveness analysis, etc. Other important information should include definitions of the study population, the study setting, and the time interval for the research. Authors should explain how the data were collected, clearly state the main outcome measures that will be estimated, and describe the statistical analysis in clear language and with appropriate citations to new or unusual methods. (See also Chapter 13, Writing the Methods Section.)

RESULTS

All results should be reported in the Results section. Results should not appear in the Methods section and no new results should be introduced in the Discussion section. The Results section should begin with a description of the study population, with important demographic information, followed by the results that are directly related to the main study question. Tables and figures should be used to display the results, and text should succinctly address key findings in the tables, without repeating all the information in the tables. For example, a summary of a key message with referral to the table (in parentheses) can be presented as "Cases were younger compared with controls (Table 1)" rather than "A comparison of the cases with the controls is given in Table 1." Also, the results should be reported in past tense, because the study was conducted in in the past; for example, "boys were taller than girls."

Downloaded from academic.oup.com/book/58841 by guest on 17 October 2026

When reporting the results in text, reporting *P* values is usually of less interest[3,4] and less informative than point estimates and 95% confidence intervals. For example, in a study of outcomes of patients treated with drug A compared with drug B, report the proportion in each group that had the outcome of interest, then estimate the difference or ratio of these proportions and provide 95% confidence intervals for that estimate. Explanations about the results should not be included in this section; authors should just report the facts. (See also Chapter 14, Presenting the Results Section.)

DISCUSSION

The Discussion section is often too long in submitted manuscripts. This section should be concise and can be structured using the following framework: Begin with a 1-paragraph summary of the key findings, followed by a brief discussion of relevant past studies, and explain how the study results compare and contrast with those of others. It is helpful to give numerical comparisons when possible, and for results that disagree with prior work, it is helpful to discuss why this might have occurred. Next, include a brief and appropriately circumspect discussion about the potential implications of the study findings for clinical care, policy, or research. However, definitive recommendations about treatment or policy usually should be omitted; these recommendations are not generally justified by a single study and most research reports do not have space for a thoughtful, balanced review of policy options.[5,6] Describe the limitations of the study and how they may have influenced the results. No study is perfect. Authors should be well aware of the study limitations and should discuss these in an objective manner. Peer reviewers and knowledgeable readers will appreciate a forthright discussion of limitations.

Also, authors should be thoughtful about language used in the Discussion section. For instance, authors should not be boastful. If the study being reported was the first, simply note that it is not possible to compare the study with previous work. However, any claims of primacy should be qualified with language such as "This study is the first, to our knowledge …" because of the possibility that authors may not be aware of every study on a topic, such as those only reported as abstracts or published in other languages.

Authors also should avoid trite statements, such as "More research is needed." Instead, describe the specific type of research that is needed. For instance, if the authors are reporting preliminary findings from a small single-center study, it would be reasonable to suggest that additional research is needed to verify the results in larger, adequately powered multicenter studies. Above all, authors should avoid making statements that are not supported by the study data and should exhibit humility in describing their findings. (See also Chapter 8, Avoiding Spin and Boasting in Scientific Writing, and Chapter 15, Writing a Convincing Discussion Section.)

Downloaded from academic.oup.com/book/58841 by guest on 17 October 2026

TABLES AND FIGURES

The main message of a manuscript can often be presented in 1 or 2 well-formatted tables. A good plan is to examine the tables and figures in studies in the target journal that are similar to the manuscript being prepared and emulate those data displays, in terms of format and numbers of tables and figures usually included in articles published in that journal. (See also Chapter 17, Effective Use of Figures and Tables in Scientific Articles; Chapter 18, Creating Effective and Efficient Tables; and Chapter 19, Effective Use of Figures and Graphs in Scientific Publications.)

REFERENCES

A sufficient number of references should be used to support statements in the manuscript, but not so many that they become distracting or take up a great deal of space. Scientific articles published in journals are not doctoral dissertations aimed at a complete review of the literature. Some journals have limits on the number of references that can be included, depending on the specific type of article (original research, review, opinion, letter). Authors should ensure that the references are accurate and up-to-date. For example, vital statistics data that are 5 years old should not be used when more recent information is available. (See also Chapter 16, Referencing and Using Reference Managers.)

Common Problems

Several recurring errors make editors and reviewers less likely to look favorably on a submitted manuscript. Failure to read and follow the instructions to authors for the specific journal leaves the impression that the authors were either careless or lacked attention to detail. If some instructions seem a bit arbitrary, authors should keep in mind that journal editors review hundreds or thousands of manuscripts each year, and having a common format (eg, organizing the manuscript elements in a consistent fashion, such as Introduction, Methods, Results, and Discussion) may make the review task more effective and efficient by enabling editors to evaluate manuscripts with a common organizational format. Authors should be certain to check their manuscripts for typographical errors, as well as errors of grammar, syntax, and sentence construction. Computer spell-check programs are helpful, but do not replace the need to carefully proofread the manuscript. For instance, the software will not know if the author meant *from* instead of *form* or *there* instead of *their*.

Authors should avoid clichés and superlatives. Words such as *very*, *extremely*, or *enormous* are subjective and usually superfluous. In addition, it is important to be precise in use of language. For instance, do not use *rate* unless

Downloaded from academic.oup.com/book/58841 by guest on 17 October 2026

this means the number of events per person-time. The word *significance* should be reserved for discussion of statistical significance. Authors should not report that there was "no difference" based on a *P* value.[4] There is "no difference" only when the difference is zero. Authors also should be specific; for instance, rather than stating "We compared the groups with regard to demographic variables," it is more informative to indicate that groups were compared on age, sex, income, or whatever demographic variables were assessed.

Conclusions

Learning how to write scientific articles well is a key skill for any investigator and represents an important stage in the scientific process. Scientific writing with publication of study results is part of the contract with the participants in the research, the organization that funded it, and the scientific community. Writing effective scientific articles is part of the legacy authors create and on which science progresses.

ACKNOWLEDGMENT

This chapter is an updated version of the following previously published article: Rivara FP, Cummings P. Writing for publication in *Archives of Pediatrics & Adolescent Medicine*. *Arch Pediatr Adolesc Med*. 2001;155(10):1090-1092. doi:10.1001/archpedi.155.10.1090

References

1. Wills G. *Lincoln at Gettysburg: The Words That Remade America*. Simon and Schuster; 1992.
2. Watson JD, Crick FHC. Molecular structure of nucleic acids; a structure for deoxyribose nucleic acid. *Nature*. 1953;171(4356):737-738. doi:10.1038/171737a0
3. Gardner MJ, Altman DG. Confidence intervals rather than *P* values: estimation rather than hypothesis testing. *Br Med J (Clin Res Ed)*. 1986;292(6522):746-750. doi:10.1136/bmj.292.6522.746
4. Cummings P, Koepsell TD. *P* values vs estimates of association with confidence intervals. *Arch Pediatr Adolesc Med*. 2010;164(2):193-196. doi:10.1001/archpediatrics.2009.266
5. Weiss NS. Policy emanating from epidemiologic data: what is the proper forum? *Epidemiology*. 2001;12(4):373-374. doi:10.1097/00001648-200107000-00002
6. Cummings P. Policy recommendations in the discussion section of a research article. *Inj Prev*. 2007;13(1):4-5. doi:10.1136/ip.2007.015156

Downloaded from academic.oup.com/book/58841 by guest on 17 October 2026

CHAPTER 8

Avoiding Spin and Boasting in Scientific Writing

Frederick P. Rivara, MD, MPH

Downloaded from academic.oup.com/book/58841 by guest on 17 October 2026

KEY POINTS

- Authors should not exaggerate the importance of their topic and should avoid cliché statements about it.
- Authors should carefully critique prior studies and not disparage previous research.
- Authors should use objective language in discussing prior studies and their findings without editorializing on the results.
- Authors should be careful in claiming that a study is the first to explore a particular topic.
- Authors should not be boastful in describing the results and implications of their research.

Scientific writing should be objective, clear, and dispassionate. Unfortunately, some authors include spin and boasting in their manuscripts, such as by exaggerating the importance of their research and unfairly denigrating other studies.

Exaggerating the Importance of the Topic

Some authors exaggerate the importance of their work, especially in the Introduction or Discussion section. Examples include phrases such as "Disease X has reached an alarming proportion," "an awe-inspiring number," and "drastic increase." These sensationalized words lack scientific meaning. Instead, authors should report relevant quantities for a particular place and time: counts of events, incidence rates, or prevalence estimates. Another approach is to consider describing how these quantities have changed over time, then let the reader decide whether anything is alarming, awesome, or drastic. Writing that something is "a critical priority," even if true in some sense, is just an editorial opinion unlikely to persuade. Referring to "the obesity epidemic" or "the opioid epidemic" is a cliché. Hackneyed phrases do not make the writer appear

thoughtful, are not of interest for the reader, and take up space. Authors should consider whether the reader needs to once again hear that obesity is common, that the prevalence of diabetes is increasing, or that the cost of medical care is a problem. It seems unlikely that they do. Researchers should use a minimum of adjectives to describe their topic. Eliminating sentences about the magnitude of problems of which readers are already aware can save space and make the manuscript more concise.

Unfairly Disparaging Previous Research

To promote their work, some authors have declared a "crisis of credibility" and a "large research gap." Some dismiss past studies for the following specious reasons:

- **"Inconsistent" or "mixed" results.** These fuzzy words explain nothing. Studies are conducted in finite samples, usually with incremental advances, so some difference in results is almost inevitable. If a statistical test of homogeneity indicates that the difference is more than expected, a new study is unlikely to change that. Consider meta-analytic methods to describe the variation and seek explanations, such as dissimilar study populations or designs.
- **"Methodologic flaws."** These words are not helpful because essentially all studies have flaws. The new study will have its own flaws. If there is evidence that a prior study is biased, providing objective information to support that claim may be appropriate. However, a less than optimal design is not proof of bias.
- **Small sample size.** Some small studies provide useful evidence. The first report that diethylstilbestrol taken by pregnant women was related to vaginal cancer among their offspring had only 8 cases and 32 controls.[1] If all else is equal, a larger study will produce a narrower confidence interval around an estimate compared with a smaller study. But all else may not be equal; estimates from the larger study might be more biased. If several small studies have been done, pooling their estimates using meta-analysis may result in a confidence interval as narrow as that from a larger study.
- **"Retrospective."** Inaccurate recall is a potential source of bias, not evidence of bias. For example, the valuable studies that linked prone sleep position to sudden infant death syndrome were retrospective.

One recommended approach (among others) for authors to consider is to avoid critiques of other studies in the Introduction section and only report factual information. For example, "The association of exposure X with outcome Y has been estimated in 5 case-control studies [citations here] which used study

Downloaded from academic.oup.com/book/58841 by guest on 17 October 2026

participant recall to measure exposure after outcomes were known. The current study also used a case-control design, but obtained exposure data from records created before the outcome." In the Discussion section, a helpful approach is to summarize each study and compare the estimate to the findings from the current report, in an objective fashion, for example: "A study of 125 Norwegian children reported that those exposed to X, compared with those not exposed, had Y more often (adjusted risk ratio, 2.00; 95% CI, 1.05-4.16). This estimate, based on recall of exposure, was not much different from the adjusted risk ratio of 1.90 (95% CI, 1.31-2.75) in the current study based on past records of exposure." This wording suggests that recall is a potential source of bias, but that there is little evidence that it actually produced bias.

Using Words to Convince, Not Illuminate

Some authors claim clarity: "our results clearly show," "these analyses provide clear answers," "[X] was clearly affected," "we believe our study makes it clear." Others suggest strength: "our analysis provides strong evidence," "this study shows that [X] is very effective," "the robust association." Researchers should present the evidence in a clear, concise, and unambiguous manner so that readers can understand and make their own judgments. If findings are lucid and powerful, words to persuade are superfluous. If otherwise, these words just invite the reader to consider why the findings may not be true.

Boasting

Boasts of being first are common. Some are inadvertently amusing because they have so many qualifiers. If the study is truly the first, lack of comparison to previous work in the Discussion section will make this apparent. If the boasting about primacy is wrong (which is not rare), those who were truly first to make a discovery or demonstrate the relationship will often indicate that to authors (perhaps if they have been selected to peer review the manuscript or perhaps as postpublication letters to the editor) and thereby reveal the authors' lack of knowledge about prior work. For authors who truly have established that their findings are novel and wish to indicate so, it is advisable to qualify any claims of primacy with an appropriate caveat, such as, "This study is the first, to our knowledge … ."

Other boasts include "the findings open up a new frontier," "this study represents the first unequivocal demonstration," "largest sample size," "strong new evidence," "one of the most detailed studies," "this study provides new insights," and "this comprehensive assessment." Authors should resist such immodest chest-thumping. One of the most modest conclusions in the history of

Downloaded from academic.oup.com/book/58841 by guest on 17 October 2026

science is perhaps that of Watson and Crick in their 1953 paper describing the structure of DNA: "It has not escaped our notice that the specific pairing we have postulated immediately suggests a possible copying mechanism for the genetic material."[2]

An Example of Excellent Presentation

Authors can learn to avoid spin and boasting by reading good examples. For example, the results of a community-based cohort study that examined the association of the intensity of physical activity with healthy brain aging was published in *JAMA Network Open* in 2019.[3] The 2-paragraph Introduction explained what was known about the association between physical activity and brain health and laid out the rationale for the study without editorializing. This study included accelerometry measurement and brain magnetic resonance imaging on 2354 participants, an impressive accomplishment. The Discussion section compared the results to those of other studies and the authors modestly said, "To our knowledge, only 1 previous study . . . ." The authors were similarly modest in noting that this was an observational, cross-sectional study and did not claim the relationship was causal. This important article avoided both spin and boasting.

Writing for scientific journals should be as clear, concise, and dispassionate as possible. Authors should leave spin and boasting to others.

ACKNOWLEDGMENT

This chapter is an updated version of the following previously published article: Cummings P, Rivara FP. Spin and boasting in research articles. *Arch Pediatr Adolesc Med.* 2012;166(12):1099-1100. doi:10.1001/archpediatrics.2012.1461

References

1. Herbst AL, Ulfelder H, Poskanzer DC. Adenocarcinoma of the vagina: association of maternal stilbestrol therapy with tumor appearance in young women. *N Engl J Med.* 1971;284(15):878-881. doi:10.1056/NEJM197104222841604
2. Watson JD, Crick FHC. Molecular structure of nucleic acids; a structure for deoxyribose nucleic acid. *Nature.* 1953;171(4356):737-738. doi:10.1038/171737a0
3. Spartano NL, Davis-Plourde KL, Himali JJ, et al. Association of accelerometer-measured light-intensity physical activity with brain volume: the Framingham Heart Study. *JAMA Netw Open*. 2019;2(4):e192745. doi:10.1001/jamanetworkopen.2019.2745

Downloaded from academic.oup.com/book/58841 by guest on 17 October 2026

CHAPTER 9

Tone, Terminology, and Technical Aspects of Scientific Writing

Phil B. Fontanarosa, MD, MBA, and
Annette Flanagin, RN, MA

Downloaded from academic.oup.com/book/58841 by guest on 17 October 2026

KEY POINTS

- For manuscripts prepared for submission to scientific journals, the meaning of the content must be precise and unambiguous, language and terminology must be carefully chosen and specific, and information must be conveyed effectively, accurately, and in a manner that is easy to comprehend.
- Scientific writing has a scholarly and scientific tone. For most articles in biomedical journals, especially research reports, the tone is formal, factual, objective, explicit, precise, dispassionate, and circumspect.
- Effective and efficient scientific writing involves a direct style, characterized by brevity and clarity in the presentation of ideas.
- In addition to authors developing a scholarly tone and using language and terminology appropriately, having proficiency with technical aspects of writing is essential for preparing high-quality scientific manuscripts, including aspects related to sentence structure and paragraph composition.
- Authors should be aware that style and format for articles may vary among biomedical journals. Some journals may have conventions for scientific presentation that involve a specific style and terminology, with the goal of ensuring consistent tone and language among articles.

The goal of scientific writing in biomedical publications is clear communication of information. For manuscripts prepared for submission to scientific journals, the meaning of the content must be precise and unambiguous, language and terminology must be carefully chosen and specific, and information must be conveyed effectively, accurately, and in a manner that is easy to comprehend.

Given the limits on length for most articles in biomedical journals, each sentence in a manuscript is important and must be crafted to ensure that the main message is communicated efficiently and concisely, the tone is scholarly, and information is presented logically and cohesively.

While these overarching principles of writing are common in scientific communication, authors should be aware that style and format for articles may vary among biomedical journals. Some journals may have conventions for scientific presentation that involve a specific style and terminology, with the goal of ensuring consistent tone and language among articles. Recognizing the importance of adherence to these journal preferences and conventions, some authors have likened publishing an article in a journal to being an invited guest to the journal. Just as a person who is invited to another's home may be expected to follow certain expectations the host has established perhaps by tradition and convention, authors who submit a manuscript to a journal, are invited to submit a revised manuscript for consideration for publication in a journal, or are reviewing edited proofs of an accepted manuscript before publication also may be expected to follow certain conventions, policies, requirements, and preferences for scientific writing and publication, which may involve tone, style, language, and presentation of information.

This chapter presents selected examples of scientific writing frequently included in manuscripts in biomedical journals and focuses on (1) the importance of scholarly tone; (2) accurate, appropriate, and unambiguous terminology; and (3) some technical aspects of writing, including effective composition of sentences and paragraphs. This chapter and these examples are not meant to be a comprehensive or complete discussion of scientific writing, but rather reflect some selected common issues related to manuscripts submitted to biomedical journals. Also, some of these examples reflect the general style and conventions used by *JAMA* and the JAMA Network journals, although many of these aspects of scientific writing are relevant and applicable for other biomedical journals. More comprehensive and detailed information on scientific writing is available in textbooks on scientific style and format, such as the *AMA Manual of Style*.[1]

Scholarly Tone

Scientific writing has a scholarly and scientific tone. For most articles in biomedical journals, especially research reports, the tone is formal, factual, objective, explicit, precise, dispassionate, and circumspect. Some of the characteristics involved in creating a scholarly tone include language and first-person pronoun usage.

Downloaded from academic.oup.com/book/58841 by guest on 17 October 2026

LANGUAGE

Language in scientific articles, especially research reports and reviews, is formal. Phrases and language typically used in conversational speech detract from the scholarly tone and generally should not be included. This includes avoiding use of contractions (for example, "can't," "doesn't"), colloquial terms or clichés (such as "game changer," "silver bullet"), and informal language (eg, "the patient was on a statin"). In addition, in scientific reports, embellished and sensational language (eg, terms like "urgent," "urgently," "dramatic," "dramatically," "drastic," "alarming") usually should be replaced with less emotionally laden terms and more precise descriptions. Likewise, language that invokes war analogies or violent imagery (such as the "battle" against obesity, the need to "combat" poverty, an "explosion" of new cases) generally should be avoided, except in some reports directly related to war or violence.

In scientific research articles and reviews, language that represents the expression of personal views, beliefs, judgments, and biases also may be perceived to detract from the scholarly tone. In these reports, assertions are more convincing when based on facts and supported by evidence and references than when expressed as opinions. Accordingly, in scientific reports, authors generally should avoid positioning substantive assertions as personal opinions (eg, "we believe," "we feel"), which may be interpreted as anecdotal or parochial. However, in opinion articles (such as editorials and commentaries) in some journals, authors may be able to express their personal views or opinions and may be encouraged to do so, although even in these manuscripts the general tone should be scholarly. (See also Chapter 25, Editorials, and Chapter 26, Other Opinion Articles.)

Language in research articles and reviews should have a scientific tone and must precisely convey the intended meaning but should not be overly complex or excessively complicated. While technical language and terminology are inherent in many research reports, technical jargon should be minimized when possible, and when its use is necessary, terms should be explained or defined at first mention in the manuscript. Likewise, abbreviations and acronyms are common in many research reports, but their use should not be excessive, and they should be expanded and defined at first mention. (See also Chapter 13.0, Abbreviations, in the *AMA Manual of Style*.[1])

To some degree, the amount and type of technical language in a manuscript may depend on the journal to which the manuscript is being submitted. For instance, manuscripts submitted to general biomedical journals (such as *JAMA*, the *New England Journal of Medicine*, *The Lancet*) should be accessible to a general medical readership that includes generalist, specialist, and subspecialist physicians as well as other health care professionals. Authors generally can assume that most readers will have a basic understanding of concepts and topics in many medical disciplines but also should realize that some readers

Downloaded from academic.oup.com/book/58841 by guest on 17 October 2026

might not be familiar with the technical aspects and terminology inherent in a manuscript that involves knowledge or research from a specialty or subspecialty discipline. Therefore, when authors prepare manuscripts for submission to general journals, they should ensure that technical aspects are explained clearly, use of jargon is minimized, and the information and findings are communicated in an accessible manner.

In contrast, when authors prepare manuscripts for submission to specialty or subspecialty journals in which readers are most likely to be familiar with most of the technical language related to the specific topic, they may have more latitude with the inclusion of technical language and terminology, without requiring basic explanations of all these concepts or terms. Authors should review articles on topics like theirs published in the journal to which they plan to submit their manuscript to help determine the amount, nature, and type of technical terminology and information typically included in general or specialty journals, and the degree of explanation needed for this material.

FIRST-PERSON PRONOUN USAGE

The inclusion and amount of first-person pronoun usage (ie, first-person singular, "I" or "my"; first-person plural, "we" or "our") in scientific reports may vary according to journal style and preferences. Some journals may advise against first-person pronoun usage, others may encourage this usage, and others may have limits on usage. Excessive first-person pronoun usage in scientific reports may impart a more conversational and casual tone to the manuscript and generally should be avoided.

When first-person plural pronouns are used in a manuscript, authors must ensure it is clear to whom the pronouns refer. For instance, in research reports, the pronoun "we" may refer to the research team, as described in the Methods section (eg, "We enrolled patients in the study," in which "we" refers to the investigators). Some journals may limit first-person pronoun usage to the Methods section in research articles and may not include this usage in the Abstract, Introduction, Results, and Discussion sections. Journals that permit first-person pronoun usage in the Discussion section may have certain caveats to help ensure clarity of meaning. For instance, when describing study results, a phrase such as "In this study, we found …" would clearly suggest that the term "we" refers to the study investigators. However, when terms like "we" or "our" are used to describe previous work, such as "These findings are similar to the results of our previous study in which …" journals may advise that this type of first-person pronoun usage should reflect identical authorship between the previous report and the current manuscript.

Other use of first-person pronouns in the Discussion section of research reports or in scholarly opinion articles may involve placing the study results or assertions, respectively, in context; however, this usage must ensure that it is

Downloaded from academic.oup.com/book/58841 by guest on 17 October 2026

clear to whom the pronouns refer. For example, in a sentence such as "We lack a good solution for controlling health care costs," it may not be apparent or clear whether "we" refers to the authors or to some other collective group, such as the medical profession, government, society, or another entity. To avoid ambiguity, it would be helpful to replace the pronoun "we" with the specific group to whom "we" refers in this context.

In contrast, in narrative articles that describe personal experiences or reflections, use of first-person singular pronouns serves to convey the individual's perspectives, thoughts, and perhaps emotions. In these articles, it is usually clear that the first-person pronoun usage refers to the author, and this usage may contribute to creating a compelling, personal narrative. However, in narrative manuscripts related to clinical care or experiences, and in other reports, paternalistic terms such as "my patient" are best avoided in recognition of patient autonomy and the importance of shared decision-making.

OTHER FACTORS

Several other factors are helpful to ensure a scholarly tone in a manuscript. Among these are that scientific writing should be objective and dispassionate and authors should avoid exaggerating the importance of their topic, editorializing about their results, being self-congratulatory or boastful about the implications of their work, or disparaging previous research. In addition, authors should apply critical appraisal to their work and include a discussion of the limitations of their study methods, review, or approach. (See also Chapter 8, Avoiding Spin and Boasting in Scientific Writing.) In addition, the critical argument in the manuscript should be presented clearly and convincingly, and the overall organization of the manuscript should represent a logical progression of ideas and clear indication of the interrelatedness of key concepts. (See also Chapter 5, Formulating an Organized Critical Argument in a Scientific Manuscript.)

Terminology and Usage

Although specific terminology and language related to the subject matter and specific content of the manuscript may vary among biomedical journals, certain aspects of terminology and usage may be similar among journals. These include terms and usage that ensure clear and precise communication but also reflect evolving considerations for some terminology. Some selected examples of common issues related to terms and usage in scientific reports involve descriptions of people or populations; use of nonessential, overused, or imprecise words and phrases; and expression of numerical values.

Downloaded from academic.oup.com/book/58841 by guest on 17 October 2026

PEOPLE AND POPULATIONS

Research reports and other articles in biomedical journals commonly involve descriptions of the demographic characteristics of people, such as individuals who participate in clinical studies, patients, groups, subgroups, or others (eg, the population potentially affected by the clinical or policy implications of the article). In research reports, investigators should ensure that the study population includes diverse and representative participants appropriate for addressing the research question of interest.[2]

Demographic Characteristics. Reporting demographic information about individuals, groups, or populations in a study is helpful to convey the generalizability of the study findings to other individuals or populations and may include variables such as age, sex and gender, race and ethnicity, and other characteristics, such as socioeconomic factors. The demographic variables collected for a specific study should be reported in the Methods section of the manuscript, with an explanation of how these variables (such as sex and gender, race and ethnicity, education, socioeconomic status, or other variables) were assessed. This may include how these variables were determined (eg, self-reported, obtained from electronic health records, based on survey designations, or other methods).[2]

Age

The *age* of individuals or groups in a study population is reported in units of time (ie, days, months, or years). In research articles, age is expressed as the overall value of the age of the study population along with a measure of variation in the data set, such as mean and standard deviation for normally distributed age data (eg, mean age, 54.7 [SD, 4.6] years). In some reports, individuals or groups may be referred to with terms indicating age groups, such as newborns or neonates (aged birth to 1 month), infants (aged 1 month to 12 months), children (aged 1 year to 12 years), or adolescents (aged 13 years through 17 years). Other groups may be referred to with other age-related descriptions, such as young adults or older persons. With all these terms, the specific age range to which the terms refer should be stated; for example, "The study included 3 groups: children and adolescents (aged 1 through 17 years), young adults (aged 18 to 30 years), and older adults (aged 65 to 75 years)." In addition, for persons with older ages, ageist terms such as *the elderly* or *seniors* should be avoided, and other terms, such as "older adults," "older patients," or "persons 65 years and older," should be used.

Sex and Gender

Terms describing *sex or gender* are commonly used in scientific articles to describe the characteristics of a study population, and in research reports the

Downloaded from academic.oup.com/book/58841 by guest on 17 October 2026

main study outcomes are often reported by the sex (or gender, as appropriate) of the study participants. The term *sex* is used when reporting biological factors (defined via biological status and genotype or genetic factors)[2,3] and usually is categorized as female, male, or intersex. The term *gender* is used when reporting identity, psychosocial, or cultural factors[2,3] and may be categorized as women, men, or nonbinary, among other terms. In research reports, authors should indicate whether sex or gender (or both) are reported, and describe the methods used for designating these characteristics.

Race and Ethnicity

Reporting the *race and ethnicity* of a group of participants included in a research report, along with other sociodemographic variables, may provide information about the potential generalizability of the study results.[4] However, race and ethnicity are social constructs that are recognized as being indistinct and may lack biological or scientific meaning.[4] In scientific writing, the terminology and language used to describe race and ethnicity must be accurate, clear, and consistent.[4] In research reports, the methods and categories used for designating and defining race and ethnicity should be reported, although these approaches and categories may differ based on the databases or surveys used, the requirements of funders, and the geographic location of the study participants.[4]

Detailed guidance and preferred terminology for reporting race and ethnicity are available,[4,5] although terms and phrases to describe race and ethnicity continue to evolve. Two general concepts that may help ensure clear communication of information related to race and ethnicity in scientific reports include use of specific terms and categories and avoidance of collective terms, when possible.[4]

When reporting race and ethnicity in research articles, specific categories should be used. These categories may vary based on the data source used or methods used to collect the information. For example, some US data sources may collect data based on self-identification and may include information about race using several common categories, including American Indian or Alaska Native, Asian, Black or African American, Native Hawaiian or Other Pacific Islander, and White, and also may include information about Hispanic origin or ethnicity (ie, Hispanic, Latino, or Spanish origin). In research reports, it is helpful to include an explanation of the methods and terminology used by the data source to classify race and ethnicity.

Racial and ethnic categories should not be presented as nouns to describe people (eg, avoid use of "Asians, Blacks, Hispanics, or Whites"); these terms should be used as modifiers (eg, "Black patients," "individuals who are Hispanic").[4,5] If categories such as "other race," "multiracial," or "multiethnic" are used, these terms should be defined to be as specific as possible, and the term "mixed race" should be avoided because it may have negative connotations.[4,5]

Downloaded from academic.oup.com/book/58841 by guest on 17 October 2026

Collective terms for describing individuals or groups based on race or ethnicity generally should be avoided. For example, terms such as "people of color," "BIPOC (Black, Indigenous, and people of color)," "BAME (Black, Asian, and minority ethnic)," and "Black and brown people" may be perceived in several ways, such as being too broad, implying a hierarchy among included groups, excluding important populations, or lacking specificity about which groups are included.[4,5] To help ensure clarity, these terms usually should be replaced with clearly defined descriptions of the specific racial and ethnic categories to which they are intended to refer.

Patient-First and Person-First Language. In biomedical journal articles, individuals should not be defined or described with terminology that primarily reflects the disease or condition they have or primarily by other factors. Language that reflects "patient-first" descriptions is preferred and represents a respect for individuals, even if this takes a few more words. For instance, terms such as "cancer patient" or "dialysis patients" should be avoided, and individuals with these conditions should be described as "patient with cancer" or "patients receiving dialysis," respectively. Similarly, patients generally should not be labeled with their disease or disorder, such as "asthmatic" or "asthmatic patient," and these terms usually should be replaced with patient-first terms, such as "patient with asthma." There are some exceptions to this principle for people or groups that prefer identity-first language (eg, autistic child, Deaf community). It is important to use preferred terminology consistently within specific manuscripts.

In addition, individuals or groups should not be described primarily according to their insurance or socioeconomic status, and a term such as "Medicaid patients" should be replaced with "patients with Medicaid insurance." Another example of language that reflects respect for individuals involves terms describing individuals in research reports. Language such as "research subjects" may be perceived as subordinating these individuals and should be avoided and replaced with "research participants" or similar terms.

Imprecise Terms Used to Refer to Groups of People. Collective terms that describe groups of individuals or populations should be clear and unambiguous. Some selected examples of commonly used terms in reports in biomedical journals that may be ambiguous or imprecise include "provider" and "stakeholder."

The term "provider" is commonly used in reports about health care delivery and may refer to various types of clinicians, such as physicians, nurses, physician assistants, or other practitioners, or to various health care delivery entities that qualify for reimbursement for health services, such as hospitals,

Downloaded from academic.oup.com/book/58841 by guest on 17 October 2026

clinics, or other sites, or at times may refer to both. This term is ambiguous and potentially confusing, does not recognize the level of professionalism and training of physicians, and may be perceived as offensive to some,[6] especially in medical journals for which physicians and other clinicians are the primary audience, and therefore generally should be avoided.[6] However, if the term "provider" is used, the specific individuals, groups, or entities to which the term refers should be clearly defined and explained.

"Stakeholder" is another term commonly used in biomedical reports and may have uncertain or imprecise meaning. In most cases, the term could be avoided, unless clear context is provided to clarify the groups to whom the term refers. If the term is used, the individuals or specific groups who are considered stakeholders or have an interest in a topic should be explained in detail, and including the type of interest (ie, the "stake") these individuals may have (eg, personal, financial) may be helpful.

NONESSENTIAL, OVERUSED, AND IMPRECISE WORDS AND PHRASES

Effective and efficient scientific writing involves a direct style, characterized by brevity and clarity in the presentation of ideas. Certain words and phrases commonly used to introduce ideas in a sentence usually are not essential to the meaning. These phrases generally can be omitted and doing so usually improves the sentence.[1] Some examples of empty words and phrases that usually could be omitted include "it is apparent that," "it is believed that," "in order to," "it is interesting that," "interestingly," "it is clear that," "as a matter of fact," and "needless to say." Other selected examples of some commonly used words and phrases that could be condensed or replaced by other terms include "as a result of" or "due to the fact that," which could be replaced with "because"; "during the time that," which could be replaced with "while"; "despite the fact that," which could be replaced with "although"; and "at this point in time," which could be replaced with "now."[1]

Some other phrases and terms are overused, perhaps in part reflecting usage patterns in nonscientific communication or popular media. For example, hackneyed phrases (such as "paradigm shift" or "call to action") may appear to exaggerate the importance or implications of the scientific message, may detract from the scholarly tone of a manuscript, and generally could be replaced with more precise and specific terms. Likewise, phrases that represent variations on well-known phrases from classic literature, such as "To screen or not to screen, that is the question," are often used as seemingly clever attempts to convey a concept, but usually could be omitted and replaced with more specific language to express the key message.

Some selected examples of overused terms in scientific writing include the words "burden" and "impact." The word "burden" is often used to describe nearly any difficulty or challenge, but without specificity of meaning. Describing the type of difficulty represented by the term "burden" with other terms could improve meaning (eg, financial hardship, increased workload, or logistical challenge).

Downloaded from academic.oup.com/book/58841 by guest on 17 October 2026

The word "impact" has become ubiquitous in scientific writing, with use in various forms, such as a noun ("having an impact"), as a verb ("to impact," "impacted," "impacting"), and as a modifier ("being impactful"), sometimes with repetitive usage throughout a manuscript. Although appropriate use of the word "impact" is not incorrect, the term has been so extensively overused that the meaning has been somewhat diluted, and more precise terminology (eg, as a noun, "having an effect" or "having an influence"; as a verb, "to affect" or "to influence") could be considered.

Other commonly used terms in scientific writing may be imprecise or the meaning may be uncertain unless a specific explanation is provided. Some selected examples include the terms "real world" and "disparities" and language that suggests causal inference when not supported by evidence or research designs.

The term "real world" is commonly used to describe types or sources of data, evidence, or experience, although the precise meaning may not be apparent. For instance, the US Food and Drug Administration defines real-world data (RWD) as "data relating to patient health status and/or the delivery of health care routinely collected from a variety of sources. Examples of RWD include data derived from electronic health records, medical claims data, data from product or disease registries, and data gathered from other sources (such as digital health technologies) that can inform on health status."[7] When the term "real world" is used in scientific writing, including a precise definition is helpful and the specific source of the data may be preferred.

The term "disparities" is commonly used in scientific writing to refer to any difference, such as differences in health outcomes between or among any groups. However, according to the National Institute on Minority Health and Health Disparities, "A health disparity (HD) is a health difference that adversely affects disadvantaged populations, based on one or more of the following health outcomes: Higher incidence and/or prevalence and earlier onset of disease; Higher prevalence of risk factors, unhealthy behaviors, or clinical measures in the causal pathway of a disease outcome; Higher rates of condition-specific symptoms, reduced global daily functioning, or self-reported health-related quality of life using standardized measures; Premature and/or excessive mortality from diseases where population rates differ; Greater global burden of disease using a standardized metric."[8] Accordingly, in scientific manuscripts, providing a precise explanation for the type of disparities described and the context in which the term "disparities" is used is helpful.

In scientific writing, use of terminology that suggests causal inference must be precise and supported by appropriate evidence. For some journals, use of causal language (ie, including terms such as "effect" or "efficacy" or phrases such as "the exposure x resulted in [or caused] an increase in outcome y") is limited to reports or findings based on study designs that are likely to support cause-and-effect relationships, such as randomized clinical trials. For other

Downloaded from academic.oup.com/book/58841 by guest on 17 October 2026

study designs, the findings (such as those based on exposure/outcome relationships in observational studies) are described in terms of associations or correlations. However, with increasingly sophisticated statistical and methodological techniques,[9,10] other approaches for supporting causal inference will continue to evolve, and biomedical journals may expand use of causal language when inferences can be robustly supported. Authors should review the journal to which they plan to submit their manuscript for policies regarding use of causal language and examples of articles that include causal inferences or assertions.

NUMERICAL VALUES

Terminology related to expressing numerical values and describing economic terms is an essential aspect of research reports and is commonly included in other articles in biomedical journals. Journals may have specific guidelines for stylistic aspects of reporting numbers and numerical values. For example, some journals may use numerals (ie, digits) for all numerical values reported in manuscripts, whereas other journals may spell out numbers 1 through 9 as "one" through "nine" and use numerals for numbers 10 and greater and may have a similar stylistic approach for ordinal numbers (for instance, spell out first through ninth and use numerals for 10th or greater). (See also Chapter 18.0, Numbers and Percentages, in the *AMA Manual of Style*.[1])

Several selected common usage aspects related to numerical values include numbers at the beginning of sentences, terms describing changes in numerical values, and descriptions of relative changes, such as percent change in values. Numerical values reported as numbers (digits) should not be used to begin a sentence. For example, "75 patients completed the study" should be expressed as "Seventy-five patients completed the study." When describing changes in numerical values, terms such as "increase" or "decrease" (or "decline") are preferred, rather than describing changes as the values "grow" or "rise" or "drop" or "fall."

Changes in numerical values are commonly reported, including as "percent change" to describe how much a value has changed relative to a previous value or as "percentage point change" to describe or compare the absolute change between the percent values. For example, a sentence reporting percent change might state, "Daily use of e-cigarettes was reported by 20% of high school students in 2018 and by 30% of students in 2019, a 50% increase." In this case, the change in the rate in 2019 (30%) compared with the rate in 2018 (20%) was 10% (ie, 30% − 20%), and compared with the rate in 2018 (ie, 10% vs 20%) would represent a 50% relative increase. The absolute change in the percent values would be reported as a difference in percentage points: "Daily use of e-cigarettes was reported by 20% of high school students in 2018 and by 30% of students in 2019, a 10 percentage-point increase."

Numerical values related to certain aspects of health care economics may include terms such as "costs," "charges," "prices," "expenditures," or

Downloaded from academic.oup.com/book/58841 by guest on 17 October 2026

"reimbursement." These terms require clear explanation, perhaps including the perspective from which the values are considered, which may be that of, for example, a clinician or health care center, an individual, an insurer, or society. For example, from the perspective of a clinician or health care entity, the term *cost* is the expense incurred to deliver a health care service, whereas to a health care payer, *cost* is the amount they pay to a clinician or health care entity for the health care service provided.[11] The term *charge* is the amount requested by a clinician or health care entity for providing a health care service[11] and usually is higher than the actual cost incurred. *Expenditure* is the actual amount spent (eg, by individuals or insurers) to pay for health care services received or provided, and *reimbursement* is the payment made (such as from an insurer) to a third party (such as a clinician or health care entity) for providing health care services.

Technical Aspects

Effective scientific writing requires that information is conveyed accurately, is clearly presented, and is easy to understand. In addition to authors developing a scholarly tone and using language and terminology appropriately, having proficiency with technical aspects of writing is essential for preparing high-quality scientific manuscripts, including aspects related to sentence structure and paragraph composition.

SENTENCE STRUCTURE

Every sentence in a scientific manuscript is important and must be structured to present information clearly and in a straightforward manner. In most cases, information is communicated most clearly with a sentence structure that consists of the sequence of subject, verb, and object. Sentences generally follow 1 of the 4 types of sentence structures (simple, compound, complex, and compound-complex) based on the quantity and arrangement of clauses in the sentence.[12] A *clause* is a group of words that has a subject and a verb that usually form a sentence. The clause may be *independent*, when it forms and expresses a complete thought, or it may be *dependent*, when it depends on another part of the sentence to complete the thought it expresses.[12] A *phrase* is a group of words without a subject or predicate and usually is introduced by a conjunction or preposition.[1]

A *simple sentence* has only 1 independent clause.[12] For example, the following is a simple sentence that includes 1 subject and 1 verb: "Alzheimer disease is the most common type of dementia." A *compound sentence* has 2 independent clauses linked by a conjunction. "Alzheimer disease is the most common type of dementia, and the condition affects more than 5 million people in the United States."[13] Both clauses are complete thoughts, each has a subject and verb, and

Downloaded from academic.oup.com/book/58841 by guest on 17 October 2026

both could stand alone as independent ideas if the conjunction ("and") was removed.

A *complex sentence* includes 1 independent clause with at least 1 dependent clause. Sentences that use the "if/then" construction are a common example of this type of structure.[12] For example, "If the results of this preliminary study are verified in large-scale randomized trials, this new agent may represent a clinically useful therapeutic agent." A *compound-complex sentence* includes more than 1 independent clause and at least 1 dependent clause.[12] For example, "The patients were interested in enrolling in the study, but they did not meet inclusion criteria because they could not complete the baseline exercise regimen." That sentence has 2 independent clauses (patients were interested in enrolling in the study and they did not meet inclusion criteria) and 1 dependent clause (because they could not complete the baseline exercise regimen).

Scientific writing usually includes a combination of these sentence structures. This approach imparts variation in the cadence of the writing and helps avoid an overly repetitive structure in the text, as may occur with writing that only includes simple sentences. As a general approach, the sentences in a scientific manuscript should be short enough to express the intended meaning clearly while also including the complete relevant information, but they should not be so long that the sentence becomes excessively complicated or includes multiple embedded clauses that may convolute or obscure the intended meaning.

Another helpful approach, especially for longer sentences, is to keep the subject and verb close together. For example, the sentence "Every component of the operation, including discussion about informed consent, sequence of the procedures, duration of surgery, complications and risks, probable recovery time, and cost, was documented" could be revised with the subject ("component") and verb ("was documented") closer together, as follows: "Every component of the operation was documented, including discussion about informed consent, sequence of the procedures, duration of surgery, complications and risks, probable recovery time, and cost."

Some other selected technical aspects involved in sentence composition include active vs passive voice, verb tense, subject-verb agreement, pronoun usage, parallel construction, and use of modifiers. (For a detailed discussion of these and related topics, see Chapter 7.0, Grammar, in the *AMA Manual of Style*.[1])

ACTIVE VS PASSIVE VOICE

Most scientific journals encourage authors to write in the active voice, although articles published in many journals include some sentences that use active voice and some that use passive voice. With active voice for verbs, the subject of the

Downloaded from academic.oup.com/book/58841 by guest on 17 October 2026

sentence performs the action the verb describes. With passive voice, the subject is acted on or receives the action described by the verb. For example, the following sentences use active voice: "The research team collected the data" and "We collected the data." The following sentence uses passive voice: "Data were collected by the research team." Active or passive voice is acceptable in scientific writing, although in general, active voice is preferred.

VERB TENSE

Scientific writing may include present, past, and future verb tenses, depending on the context and intended temporal period. Present tense is usually used to express a general truth or statement of fact.[1] Past tense refers to a completed action, and in research reports it is used to describe the study methods and results.[1] Future tense may be used to describe implications or perspectives about the study findings.

SUBJECT-VERB AGREEMENT

The subject and verb in a sentence must agree in number, such that a singular subject will have a singular verb and a plural subject will have a plural verb.[1] However, several terms commonly used in biomedical writing have plural forms and generally are used with plural verbs. Some examples include "bacteria," "criteria," "phenomena," and "memoranda" (the singular forms of these terms are bacterium, criterion, phenomenon, and memorandum).[1] The term "data" generally is considered a plural noun and therefore should be used with a plural verb (eg, "The data were consistent between studies"). However, many sources use the term "data" as a singular noun with a singular verb when considering the data as a single unit rather than as the individual data items that are included.[1]

Other terms commonly used in biomedical writing may appear to be plural (ie, false plurals) but should be considered singular and are used with singular verbs.[1] Some examples include the terms "genetics," "statistics," "mathematics," "physics," "mumps," and "measles." In addition, organizations and groups of people that represent a single entity in the context of the sentence usually take singular verbs. For example, "The National Institutes of Health has issued new guidelines," or "The ethics committee has completed the investigation."

PRONOUN USAGE

Pronouns are used to replace nouns. The term the pronoun replaces or refers to (the antecedent) must be clear, and the pronoun must agree with the antecedent

Downloaded from academic.oup.com/book/58841 by guest on 17 October 2026

in number and generally in gender. A common potential source of ambiguity with pronoun usage involves the pronoun "it." For instance, in the sentence "Information about poison ivy is now available; to get it, contact our office," it is unclear whether "it" refers to "information" or "poison ivy."

In most cases, the personal pronouns "he" or "she" or combination forms "she or he" or "her or his" should not be used as generic third-person singular pronouns, unless the pronouns are known to match those preferred by the person or persons being described.[14] The term "they" has been accepted as a generic third-person singular pronoun to refer to a person whose gender is unknown or is not relevant to the context of the usage.[14] For example, "each patient had their blood pressure measured" is preferred rather than "each patient had her or his blood pressure measured."

PARALLEL CONSTRUCTION

Parallel sentence construction involves presenting 2 or more similar ideas in a sentence using the same pattern of clauses, phrases, and structure. This approach is useful to emphasize a common level of importance between the pieces of information presented and helps promote readability and comparisons. An example of parallel construction is the following: "Jones et al found a significant reduction in mortality, whereas Smith et al reported no significant reduction in mortality." The same ideas can be expressed without parallel construction, but the parallel concepts are not conveyed as effectively, as illustrated in the following: "Jones et al found a significant reduction in mortality, whereas no significant reduction in mortality was reported by Smith et al."

MISPLACED MODIFIERS

Modifiers are terms, phrases, or clauses that describe, clarify, amplify, or augment another term or group of words in the sentence. In general, the modifying word (which may be an adjective or adverb), phrase, or clause should be placed close to the word, phrase, or clause it modifies. Modifiers that are separated from the term or phrase they modify (ie, misplaced modifiers) may create ambiguity and confusion. For example, in the sentence "The patient's laboratory results were reassessed immediately after the operation was completed by the research assistant," the modifying phrase "by the research assistant" is misplaced. As written, the phrase implies that the research assistant completed the operation, whereas the intended meaning was that the research assistant reassessed the laboratory results. The revised sentence with the correctly placed modifier could read as follows: "The patient's laboratory results were reassessed by the research assistant immediately after the operation was completed." The sentence also could be revised with the modifier correctly placed and using active voice as follows: "The research assistant

Downloaded from academic.oup.com/book/58841 by guest on 17 October 2026

reassessed the patient's laboratory results immediately after the operation was completed."

Verbal phrase danglers are modifiers that usually involve a participle (ie, a verb form used as an adjective often ending with *-ing*). This type of misplaced modifier is a *dangling participle* when it implies an actor but fails to indicate who or what that actor is.[1] In many cases, the dangling modifier usually appears at the beginning of the sentence, and in some cases incorrectly describes or refers to a phrase or word that does not appear in the sentence.

For example, in the sentence "Working collaboratively, the kidney transplant procedure was completed promptly and without complication," the phrase "working collaboratively" is modifying the phrase "kidney transplant procedure," whereas the intended meaning was to refer to the collaboration among the surgical team, which is not mentioned in the sentence. A revision of this sentence to clarify the modifier could be as follows: "Working collaboratively, the surgical team completed the kidney transplant procedure promptly and without complication." The sentence also could be revised to eliminate the participle at the beginning of the sentence, as follows: "The surgical team worked collaboratively and completed the kidney transplant procedure promptly and without complication."

Paragraph Composition and Structure

Fundamental aspects of quality scientific writing include effective organization and logical flow of ideas. In addition to ensuring that each sentence clearly conveys the intended specific meaning, sentences must be organized into paragraphs that include a cohesive group of sentences and present a unified concept or several related thoughts or concepts.[1] Sentences within each paragraph should generally use a parallel structure and consistent tense.[1]

Each paragraph should have an initial topic sentence that highlights the key idea that will be presented in the paragraph. In addition, the topic sentences of each paragraph provide an overall roadmap for the article. Reviewing the topic sentences provides an indication of the logical progression of ideas throughout the manuscript.

The concept described in each topic sentence should be developed and supported throughout the paragraph, which could be structured in several ways and should be presented in a logical sequence. Some possible approaches for developing ideas and structuring paragraphs include the following: begin with a more general concept and progress to more specific concepts that further address and support the main ideas; present the most important idea or strongest evidence first, followed by other supporting evidence; present other evidence first, and progress to present the increasingly stronger evidence throughout the paragraph, with the most important and strongest evidence presented as the

Downloaded from academic.oup.com/book/58841 by guest on 17 October 2026

final sentence; present concepts in sentences in chronological order; or organize the sentences using enumerated ideas (first, second, third, etc).

The final (closing) sentence of each paragraph should relate to the topic sentence of the next paragraph. Transitional terms are used to bridge ideas and signal a connection between paragraphs (and between sentences) and are useful to facilitate the flow of ideas and text throughout the manuscript.[1] Some examples of transitional terms that could be used to signal different types of transitions between paragraphs include the following: terms to indicate additional or a continuation of ideas ("in addition," "furthermore," "moreover"); terms to indicate comparison of ideas ("similarly," "likewise"); terms to indicate contrasting ideas ("however," "in contrast," "conversely," "although," "on the contrary"); terms to indicate results ("thus," "as a result," "consequently," "hence," "therefore"); terms to indicate a sequence of ideas, which could include enumeration of paragraphs ("first," "second," "third," etc); and terms to indicate concluding ideas ("in conclusion," "in summary," "finally").[1]

Conclusion

For manuscripts prepared for submission to scientific journals, the meaning of the content must be precise and unambiguous, the language and terminology must be carefully chosen and specific, and the information must be conveyed effectively, accurately, and in a manner that is easy to comprehend. For most articles in biomedical journals, especially research reports, the writing and tone are scholarly, formal, factual, objective, explicit, precise, dispassionate, and circumspect. Effective and efficient scientific writing involves a direct style, characterized by brevity and clarity in the presentation of ideas, using language and terminology appropriately, and having proficiency with technical aspects of writing, including those related to sentence structure and paragraph composition. Authors should be aware that journals may have conventions for scientific presentation that involve specific style and terminology, with the goal of ensuring consistent tone and language among articles.

ACKNOWLEDGMENT

We thank Stacy L. Christiansen, MA, Managing Editor, *JAMA*, for her thoughtful review and insightful comments.

References

1. Christiansen S, Iverson C, Flanagin A, et al. *AMA Manual of Style: A Guide for Authors and Editors*. 11th ed. Oxford University Press; 2020. Accessed October 9, 2023. https://www.amamanualofstyle.com

Downloaded from academic.oup.com/book/58841 by guest on 17 October 2026

2. Reporting demographic information for study participants. Instructions for Authors. JAMA Network. Updated July 14, 2023. Accessed October 9, 2023. https://jamanetwork.com/journals/jama/pages/instructions-for-authors
3. Clayton JA, Tannenbaum C. Reporting sex, gender, or both in clinical research? *JAMA*. 2016;316(18):1863-1864. doi:10.1001/jama.2016.16405
4. Flanagin A, Frey T, Christiansen SL; AMA Manual of Style Committee. Updated guidance on the reporting of race and ethnicity in medical and science journals. *JAMA*. 2021;326(7):621-627. doi:10.1001/jama.2021.13304
5. Inclusive language for reporting demographic and clinical characteristics. JAMA Network. Accessed October 9, 2023. https://jamanetwork.com/pages/inclusive-language
6. Beasley JW, Roberts RG, Goroll AH. Promoting trust and morale by changing how the word *provider* is used: encouraging specificity and transparency. *JAMA*. 2021;325(23):2343-2344. doi:10.1001/jama.2021.6046
7. Real-world evidence. US Food and Drug Administration. Accessed October 9, 2023. https://www.fda.gov/science-research/science-and-research-special-topics/real-world-evidence
8. Definitions and parameters. National Institute on Minority Health and Health Disparities. US National Institutes of Health. Updated October 4, 2023. Accessed October 9, 2023. https://www.nimhd.nih.gov/about/strategic-plan/nih-strategic-plan-definitions-and-parameters.html
9. Zaslavsky AM. Exploring potential causal inference through natural experiments. *JAMA Health Forum*. 2021;2(6):e210289. doi:10.1001/jamahealthforum.2021.0289
10. Hernán MA, Wang W, Leaf DE. Target trial emulation: a framework for causal inference from observational data. *JAMA*. 2022;328(24):2446-2447. doi:10.1001/jama.2022.21383
11. Arora V, Moriates C, Shah N. The challenge of understanding health care costs and charges. *AMA J Ethics*. 2015;17(11):1046-1052. doi:10.1001/journalofethics.2015.17.11.stas1-1511
12. 4 types of sentence structures & how to use them. Thesaurus.com. January 17, 2017. Accessed October 9, 2023. https://www.thesaurus.com/e/grammar/what-are-the-types-of-sentence-structures/
13. Rosenthal MB. Novel Alzheimer disease treatments and reconsideration of US pharmaceutical reimbursement policy. *JAMA*. 2023;330(6):505-506. doi:10.1001/jama.2023.11702
14. Singular "they." APA Style. American Psychological Association. Updated July 2022. Accessed October 9, 2023. https://apastyle.apa.org/style-grammar-guidelines/grammar/singular-they

Downloaded from academic.oup.com/book/58841 by guest on 17 October 2026

Downloaded from academic.oup.com/book/58841 by guest on 17 October 2026

PART 3

Manuscript Components

Downloaded from academic.oup.com/book/58841 by guest on 17 October 2026

Downloaded from academic.oup.com/book/58841 by guest on 17 October 2026

CHAPTER 10

Creating an Informative and Effective Title

Jody W. Zylke, MD

Downloaded from academic.oup.com/book/58841 by guest on 17 October 2026

KEY POINTS

- Titles of research articles should concisely and accurately describe the content of the study and include key concepts to allow the article to be discovered in web-based searches.
- Titles of research articles commonly present the independent variable, followed by the dependent variable and the study population.
- Authors can use subtitles to indicate the study design, such as a randomized clinical trial or systematic review and meta-analysis.
- Whether a title includes the results of the study depends on the journal to which the author is submitting the article.
- The titles of opinion articles can be more flexible and include questions and subtitles.

First impressions matter. An individual interviewing for a job would be wise to dress appropriately and have questions prepared. An effective movie trailer captures viewers' interest visually or emotionally. A positive first impression may translate into a job offer or profits for a production company. The first impression of an article in a medical journal occurs with the title, and a positive first impression could mean the difference between a study being read or ignored.

Titles of articles in medical journals have always been important to attract readers' attention, but their importance has increased as journals have moved from print to electronic formats. A physician perusing a print journal can easily skim the abstract or entire article, but most readers no longer skim print journals. They may receive an electronic table of contents or find an article by searching for a topic. In these cases, the title of the article may be the only available information, and an additional click or 2 may be required to access the abstract or article. If a title is not sufficiently interesting or is unclear, readers may not bother to access the full article, especially if other articles on the same topic with more appealing titles appear in their search results.

A distinction must be made between titles of research articles and opinion pieces. This chapter first will consider titles of research articles, including randomized clinical trials, observational studies, and systematic reviews and meta-analyses. If an abstract is a summary of the article, the title can be viewed as the summary of the abstract, the ultimate distillation of the essence of a study. Titles of research articles are used for indexing in PubMed, allow electronic retrieval in search engines, and represent the study in reference lists if cited by other researchers. For these reasons, authors should endeavor to write an informative, concise, and accurate title. Titles of scientific articles should not be catchy, clever, or witty. Authors should never write a title that could possibly be perceived as trivializing a disease process; rather, the title should reflect the seriousness of the scientific effort and, in biomedical journals, respect for patients in the study with the disease or condition.

Titles of research articles should include the main topic, such as the disease entity studied or the intervention assessed, the comparison groups, and key elements of the study design in as specific a way as possible. Aspects of the background or implications of a study should not be included. A common format presents the independent variable (X, the variable that is altered or controlled) first, followed by the dependent variable (Y, the variable that is being assessed) and the study population (Z)—ie, X for Y in Z. Describing the study population indicates to whom the results might apply. If a study was conducted in older patients, for instance, the study might not be generalizable to younger adults, and readers might want to know that before reading the study. An example of a title in this format is "Adenotonsillectomy for snoring and mild sleep apnea in children: a randomized clinical trial."[1] For investigations of trends, the years of the study might be included to indicate the currency of the study or whether the time period encompasses changes in treatment or policy. One example is "Life expectancy and mortality rates in the United States, 1959-2017."[2] A title should not be overly general; leaving out key information could produce an unclear or misleading title.

Some journals include the study design in the title or subtitle. The first entry in the checklist from the CONSORT (Consolidated Standards of Reporting Trials) 2010 guideline for reporting of parallel group randomized trials is "Identification as a randomised trial in the title."[3] The first entry in the checklist from the Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) statement guidelines is "Indicate the study's design with a commonly used term in the title or the abstract."[4] However, journals may have their own style and standards for titles. For example, the style at *JAMA* is to include the study design for randomized clinical trials and systematic reviews and meta-analyses in a subtitle. These types of studies are specifically identified with a subtitle because they represent the highest level of evidence, which may be important for readers and other researchers. *JAMA* does not incorporate the design of observational studies

Downloaded from academic.oup.com/book/58841 by guest on 17 October 2026

(ie, case-control, cohort, cross-sectional) in the title, but rather indicates the study design in the abstract. *JAMA* usually includes the name (or acronym) of a randomized clinical trial in the subtitle if it is the first report from the study; for example, "Continued treatment with tirzepatide for maintenance of weight reduction in adults with obesity: the SURMOUNT-4 randomized clinical trial."[5]

Some journals may include other information in subtitles. If an author includes a subtitle, the main information about the content of the study should be contained in the title, and the subtitle should only contain secondary information that complements the title. The title should be able to stand alone, without the subtitle.

Including all the key information about a study in a title may lead to difficulty constraining the length. However, researchers should strive for a concise title. The *JAMA* Instructions for Authors recommend 100 characters for titles and 60 characters for subtitles. Phrases such as "role of" or "use of" can be omitted. Although it may be tempting to use abbreviations to shorten a title, in general they are not used except for well-known abbreviations (eg, DNA, HIV, COVID-19).

A brief title is easier to read; a very long title may discourage some readers. In addition, a very long title is not visually appealing for articles. A few studies have examined the length of titles and article citations. One study from 2008 of 22 journals and 9031 articles found that longer titles were associated with higher citation rates, with the association more pronounced in higher impact journals.[6] In contrast, another study of 423 articles published in open-access journals in 2008 found shorter titles were associated with higher citations.[7] These results could be confounded by the quality or type of study, so it is unclear whether the length of a title is related to citations.

More specific information about technical aspects of titles can be found in the section Titles and Subtitles in the *AMA Manual of Style*.[8] For example, questions should not be used for titles of research reports. In addition, quotations and jargon should be avoided.

Journals differ widely on whether the result of the study should be part of the title: "The association between sugar-sweetened beverages and childhood obesity" vs "Sugar-sweetened beverages are associated with an increased risk of childhood obesity." Many journals, including *JAMA* and the JAMA Network journals, do not state the results of the study in the title. The conclusion of a study is rarely straightforward—in a clinical trial, secondary outcomes may be important to consider, limitations of the study may introduce reservations about the conclusion, or additional factors may contribute to the interpretation. The nuances of the data cannot be conveyed in a title. If the title states the result of a study, readers may be tempted not to look at the abstract or text of an article and as a result may not reach a full understanding of the clinical implications of a study.

Downloaded from academic.oup.com/book/58841 by guest on 17 October 2026

Opinion articles such as Viewpoints and Editorials can take greater liberties with titles, although the need to include the main topic so that the article can be identified on web-based searches remains. Opinion articles often use subtitles or questions, may be declarative, and may include a play on words. An example of a title of a Viewpoint with a subtitle and a question is "New federal requirements to inform patients about breast density: will they help patients?"[9] Since many journals have readers from around the world, the use of clichés, jargon, or colloquial language usually should be avoided in titles because some readers may not understand them. Titles of Viewpoints and Editorials should be concise; for example, *JAMA* recommends that titles for opinion articles not exceed 60 characters.

As is true for any part of a manuscript, it is essential that authors consult the instructions for authors for the journal to which they wish to submit and look at examples of titles in that journal.

Conclusion

First impressions in personal encounters are said to occur within 30 seconds. In a similar brief time (perhaps even less), the title of an article in a medical journal must convince a reader that investing more time in reading the article is worthwhile.

References

1. Redline S, Cook K, Chervin RD, et al. Adenotonsillectomy for snoring and mild sleep apnea in children: a randomized clinical trial. *JAMA*. 2023;330(21):2084-2095. doi:10.1001/jama.2023.22114
2. Woolf SH, Schoomaker H. Life expectancy and mortality rates in the United States, 1959-2017. *JAMA*. 2019;322(20):1996-2016. doi:10.1001/jama.2019.16932
3. CONSORT 2010 Statement: updated guidelines for reporting parallel group randomised trials. EQUATOR Network. Accessed March 21, 2023. https://www.equator-network.org/reporting-guidelines/consort
4. The Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) Statement: guidelines for reporting observational studies. EQUATOR Network. Accessed March 21, 2023. https://www.equator-network.org/reporting-guidelines/strobe
5. Aronne LJ, Sattar N, Horn DB, et al. Continued treatment with tirzepatide for maintenance of weight reduction in adults with obesity: the SURMOUNT-4 randomized clinical trial. *JAMA*. 2024;331(1):38-48. doi:10.1001/jama.2023.24945
6. Habibzadeh F, Yadollahie M. Are shorter article titles more attractive for citations? Cross-sectional study of 22 scientific journals. *Croat Med J*. 2010;51(2):165-170. doi:10.3325/cmj.2010.51.165

Downloaded from academic.oup.com/book/58841 by guest on 17 October 2026

7. Paiva CE, Lima JP, Paiva BS. Articles with short titles describing the results are cited more often. *Clinics (Sao Paulo)*. 2012;67(5):509-513. doi:10.6061/clinics/2012(05)17
8. Iverson C. Titles and subtitles. In: Christiansen S, Iverson C, Flanagin A, et al, eds. *AMA Manual of Style: A Guide for Authors and Editors*. 11th ed. Oxford University Press; 2020. Accessed September 11, 2023. https://www.amamanualofstyle.com/view/10.1093/jama/9780190246556.001.0001/med-9780190246556-chapter-2
9. Keating NL, Pace LE. New federal requirements to inform patients about breast density: will they help patients? *JAMA*. 2019;321(23):2275-2276. doi:10.1001/jama.2019.5919

Downloaded from academic.oup.com/book/58841 by guest on 17 October 2026

CHAPTER 11

Writing an Informative Abstract

Phil B. Fontanarosa, MD, MBA

Downloaded from academic.oup.com/book/58841 by guest on 17 October 2026

KEY POINTS

- A well-prepared abstract in a published article provides the main results and the take-home message of the study in a clear, concise, and efficient manner.
- The abstract of a scientific report may be an important factor for readers in determining whether to read the entire article and is an important entry point in the editorial evaluation of the manuscript.
- Authors should review the journal instructions and articles published in the journal to which they are considering submitting their manuscript to determine the structure of the abstract, including format, presentation standards, and stylistic elements.
- All information in the abstract, including the objective, results, and conclusion, must be reported in the main sections of the manuscript, and the information in the abstract and manuscript must be consistent.
- Although the abstract must be concise, informative, and sufficiently detailed to make sense when read alone, the abstract cannot provide enough detail to enable critical appraisal of the study for validity, and for studies that have any complexity the abstract should not be used as the basis for nuanced interpretation, even if caveats are included.

For articles in biomedical journals, the abstract occupies a prominent position. After the title, the abstract is the section of the article most likely to be accessed and read and serves several important purposes.[1] The abstract of a research article represents an overview and provides a summary of the study design and main results, thereby making the key findings of the article readily available, such as in literature searches or in translations of the article. A well-prepared abstract in a published article also provides the main results and the take-home message of the study in a clear, concise, and efficient manner and may be an important factor for readers in determining whether to read the entire article.

For manuscripts submitted to biomedical journals, the abstract also is an important entry point in the editorial evaluation of the manuscript. For instance, a high-quality, well-written, detailed abstract not only will give the editors and reviewers a clear understanding of the main message of the manuscript, but also may signal that the same quality will follow throughout the full report. In contrast, a low-quality, poorly written, incomplete abstract (for example, one in which data points or other information do not precisely match those in the Results section of the manuscript) may create negative initial perceptions about the manuscript. In addition, abstracts of published articles are publicly available in many bibliometric databases, such as PubMed. Therefore, authors should ensure that the abstract is accurate, complete, and carefully prepared.

Abstract Format

Authors should review the journal instructions and articles published in the journal to which they are considering submitting their manuscript to determine the structure of the abstract, including format, presentation standards, and stylistic elements. The basic elements of full research reports are generally consistent among many biomedical journals and consist of Introduction, Methods, Results, and Discussion sections (ie, the IMRAD format). However, the abstract format and length often vary among journals, and a journal may require a structured format (with specific sections) or an unstructured narrative format. For example, the abstract format for the JAMA Network journals has the sections Importance; Objective; Design, Setting, and Participants; Main Outcomes and Measures; Results; and Conclusions and Relevance, with a recommended length of no more than 350 words. The *New England Journal of Medicine* uses a 4-part abstract format with the sections Background, Methods, Results, and Conclusions, and limits the length to 250 words. *The Lancet* abstract includes the sections Background, Methods, Findings, Interpretation, and Funding, with a length of 300 words. The abstract format for *Annals of Internal Medicine* has the sections Background, Objective, Design, Setting, Patients, Measurements, Results, Limitations, Conclusions, and Primary Funding Source, with a length of 275 words. In contrast, the *Proceedings of the National Academy of Sciences* has an unstructured, narrative abstract format, limited to 250 words of text. *Science* also uses an unstructured abstract, with a length of 125 words or fewer, and includes sentences that describe the background, objectives/methods, results, and conclusions.

Journal editors adopt specific abstract formats for various reasons, such as to emphasize certain aspects of the report, to make it easier to identify key elements of the study, to highlight certain details (eg, relevance, study limitations, or funding), or to impart a sense of uniqueness to the journal's article format.

Downloaded from academic.oup.com/book/58841 by guest on 17 October 2026

Accordingly, authors should be familiar with the abstract format used by the journal to which they are submitting their manuscript and should follow that format exactly as specified in the journal's information for authors. Failure to use the correct abstract format may suggest to the editor that the author is not familiar with the journal or that the author lacks an appropriate level of attention to detail. Moreover, manuscripts submitted to a journal that have an incorrect abstract format, such as those that use the specific abstract format used by another "competing" journal, may raise the possibility that the manuscript has been previously submitted to another journal and rejected, and may prompt editors to ask authors whether this has occurred, and if so, request that authors consider providing copies of prior reviews and indicate whether and how the manuscript has been revised in response to those reviews.

General Principles

Even though abstract formats vary between journals, several principles apply to most abstracts in biomedical journals. (Additional guidance on formatting of abstracts for research and review articles is available in Section 2.5, Abstract, of the *AMA Manual of Style*.[2])

Perhaps most important, all information included in the abstract also must be reported in the main manuscript and must be consistent with information included in the main manuscript. This includes background information, the statement of the study objective, the description of the study design, the main results and specific data points, and the conclusions. With this consistency, the abstract also serves as the beginning of "signposting" of content in the article. For instance, the language used for the objective or research question in the abstract is usually the same as or similar to the language used for the statement of the objective or research question included at the end of the Introduction section of the main manuscript. The primary outcome, as described in the abstract section for study methods and reported in the abstract section for results, should be positioned and described consistently in the Methods section of the full manuscript and reported consistently in the Results section. Likewise, the conclusion in the abstract must reflect the data in the abstract and be consistent with the main conclusion of the article, which typically is summarized in the first paragraph of the Discussion section and usually also appears at the end of the article.

The abstract must be concise (given length limitations), but also must be informative and sufficiently detailed to make sense when read alone. However, the abstract cannot provide enough detail to enable critical appraisal of the study for validity, and for studies that have any complexity the abstract should not be used as the basis for nuanced interpretation, even if caveats are included.[3]

Downloaded from academic.oup.com/book/58841 by guest on 17 October 2026

In addition, the terminology and language for reporting information in the abstract of research reports should be precise and accurate, and authors should be aware of the journal policies with respect to this issue. For instance, language that reflects causal inferences is commonly used in reports of findings from randomized clinical trials (eg, "effect of the intervention," "the intervention caused"). For observational studies, many journals do not permit use of causal language for reports in which only associations can be estimated. However, some journals may allow use of causal language in reports of observational studies when inferences can be robustly supported by rigorous methods. Authors should review the journal to which they plan to submit their manuscript for policies regarding use of causal language and inferences.

Specific Components and Abstract Sections

The specific components and amount of information to include in the abstract vary from journal to journal. The following information, based on the *JAMA* Instructions for Authors[4] and the recommendations of Cummings et al,[1] provides details that authors may consider in preparing sections of a structured abstract. Some journal abstract formats may include all or most of these sections. For other journals, the information in some of these sections may be combined; for instance, in a journal that uses a 4-part abstract format (ie, background, methods, results, conclusion), information from the design, setting, intervention, and main outcome sections may be combined in the methods section of the abstract.

IMPORTANCE (OR BACKGROUND)

This section presents a brief (1 or 2 sentences) explanation of the clinical, research, policy, or other importance of the study question. For example, "Physical activity, such as brisk walking, is recommended as part of a healthy lifestyle, although information on the amount of walking, in steps per day, associated with a reduction in cardiovascular mortality is limited."

OBJECTIVE

This section clearly states the precise objective or study question addressed in the report, often using phrases such as "to determine whether," "to estimate the prevalence of," or "to determine the effect of." If more than 1 objective is addressed, the main objective should be indicated, and only key secondary objectives stated. If an a priori hypothesis was tested, it should be stated.

Downloaded from academic.oup.com/book/58841 by guest on 17 October 2026

DESIGN

This section describes the basic design of the study and includes the specific study type and methods (eg, randomized clinical trial, retrospective cohort, cross-sectional, case-control, case series, survey, meta-analysis, bibliometric analysis). It is important to use methodologic descriptors that signal what will follow in the Results section. The years of the study (such as when a clinical trial was conducted, or when data were collected for an observational study) and the duration of follow-up should be stated. If the data are older (eg, collected more than 3 years before), the date the analysis was conducted also should be reported. If applicable, the name of the study could be included (eg, the Women's Health Initiative, the National Health and Nutrition Examination Survey). If relevant, whether observers were masked to patient groupings, particularly for subjective measurements, could be indicated.

SETTING

This section includes a description of the study setting in which participants were selected. This information is useful for readers to determine the applicability and generalizability of the report to other settings and circumstances. The setting description may include, for example, whether the study was conducted at research centers or primary care or referral centers; if there were multiple, few, or single sites; if there were regional, national, or international sites; and whether there were population-based or local population settings.

PARTICIPANTS

This section describes who was studied and how many participants were included in the study. This should include a specific description of the clinical disorders and important eligibility criteria for patients or other study participants. The number of eligible participants and how they were selected should be provided, including the number approached but who refused or were excluded. For selection procedures, these terms could be used, if appropriate: random sample (whereby *random* refers to a formal, randomized selection in which all eligible individuals have a fixed and usually equal chance of selection), population-based sample, referred sample, consecutive sample, volunteer sample, and convenience sample. If matching was used for comparison groups, characteristics that are matched should be specified. In follow-up studies, the proportion of participants who completed the study should be indicated.

Downloaded from academic.oup.com/book/58841 by guest on 17 October 2026

INTERVENTIONS OR EXPOSURES

This section includes essential features of any interventions that were implemented or controlled by the researchers, or exposures that the researchers measured but did not implement, manipulate, or control. For clinical trials, the intervention should be described in detail, including the methods of administration and the duration. The control intervention (eg, standard therapy, placebo, usual care) also should be described. For observational studies, the exposure and assessment of the exposed group should be described, along with a detailed description of nonexposure in the comparator group.

MAIN OUTCOME AND MEASURES

This section includes the primary study outcome (and perhaps other outcomes) and measurements as planned and prespecified before data collection began. The primary outcome always should take precedence, and all outcomes should be described in detail and should be as specific as possible. For instance, if the primary outcome is mortality, this should be described in terms of timing (eg, in-hospital, 30-day, 1-year mortality) and classification (eg, all-cause mortality, cancer-related mortality). If the primary outcome is a composite end point, the elements of that end point should be described (eg, a composite of cardiovascular disease outcomes, including myocardial infarction, stroke, and cardiovascular death).

If secondary outcomes are included, they must be placed in the context of all secondary outcomes examined, rather than selectively reported. For instance, if 10 secondary outcomes are examined in the study, listing only 1 or 2 as an outcome measure can be misleading. For outcomes based on measurement instruments, the name of the instrument and the scale should be provided, including the range of values and the interpretation of higher (or lower) scores. For example, a quality-of-life scale may range from 0 to 100 points, and higher scores may represent better quality of life; a pain scale may range from 0 to 10 points, and a lower score may represent less pain.

RESULTS

Some journals include a brief summary of the number of participants included in the study and brief demographic information (eg, sex and age) in the first sentence of the results section of the abstract. The focus of the results section should be the primary outcome of the study. These results should be reported and quantified, with numerical results (eg, absolute numbers, rates, or both) along with appropriate indicators of precision, such as confidence intervals. For comparative studies, reporting the rates of the primary outcome in

Downloaded from academic.oup.com/book/58841 by guest on 17 October 2026

the intervention group and control group (or in the exposed and unexposed groups), followed by the between-group difference and confidence interval around the difference, is informative. Measures of relative risk also may be reported (eg, relative risk, hazard ratios) and should include confidence intervals. However, results should include absolute values or rates whenever possible, and usually should not be reported solely with relative measures (eg, hazard ratios or odds ratios) or only with qualitative statements followed by *P* values. In addition, some journals also advise to avoid redundant reporting of relative data (eg, % increase or decrease).[4]

Reporting the results of secondary outcomes in the abstract is determined on a study-by-study basis.[3] For example, reporting findings from a clinical trial that has a limited number of prespecified secondary outcomes (ie, 2 or 3) is usually more straightforward than reporting findings from a trial that has multiple secondary outcomes (ie, 10 or 20). In the former, these results may be considered for inclusion in the abstract. However, in the latter, reporting of only selective results without the context required to interpret these within the totality of the numerous secondary outcomes examined creates challenges and may represent an unbalanced presentation of the study findings. The results of other outcomes, such as exploratory and post hoc analyses, ordinarily are not included in the abstract of many reports but are reported in the full article. However, in most studies, including all clinical trials, the abstract should include a statement of adverse effects or adverse outcomes, when these data have been collected. Studies of screening and diagnostic tests should report sensitivity, specificity, and predictive values. If predictive value or accuracy is reported, prevalence or pretest likelihood should be given as well. All surveys should include response/participation rates.

In addition, for selected studies, reporting the results in a table embedded in the results section of the abstract (ie, as a "tabstract") may facilitate clear, concise, efficient reporting of the main study findings.[5] However, some bibliometric databases may not be able to display these tables in abstracts.

CONCLUSIONS AND RELEVANCE

The conclusions in the abstract must be objective, circumspect, and directly supported by the results reported in the abstract. The primary interpretation should represent an objective statement of the results of the primary outcome and usually can be reported in the PICO format (patient/population, intervention, comparator, outcome). The interpretation should be based directly on prespecified criteria (such as threshold for declaring statistical significance or for meeting other criteria). For instance, for an observational study, the format for the conclusion may be, "Among patients with Z, exposure to A, compared with exposure to B, was associated with improved X [outcome]." The study design and time course also could be added to the

Downloaded from academic.oup.com/book/58841 by guest on 17 October 2026

conclusion, with a D-PICO-T format (design, patients/participants, intervention, comparator, outcome, time duration). For example, the format for the conclusion of a clinical trial may be, "In this multicenter clinical trial among patients with Z, treatment with A, compared with treatment with B, resulted in X [outcome] at 2 years."

An additional statement may be included in the conclusion section of the abstract of some journals to highlight the relevance of the findings, to help ensure that important limitations and other issues are highlighted, or to provide caveats about the interpretation. The statement also may indicate the potential implications for clinical practice or health policy, while avoiding speculation and overgeneralization and without overstating the importance of the study. The relevance statement may also indicate whether additional study is required before the information should be used in clinical settings. The content for this additional sentence is based on information included in the abstract (usually related to the primary outcome) and as such is necessarily conservative; nuanced interpretation or speculation requires far more information than the abstract can provide and is the role of the Discussion section of the article.[3] In addition, the abstract conclusion should avoid including clichés or platitudes, such as "more research is needed."[1]

Conclusions

The abstract is a prominent element of scientific manuscripts and provides a concise and objective summary of the study findings. Although the format and content of the abstract may vary among journals, inclusion of an accurate, complete, and well-prepared abstract that adheres to journal criteria is an important and essential component of high-quality biomedical manuscripts.

References

1. Cummings P, Rivara FP, Koepsell TD. Writing informative abstracts for journal articles. *Arch Pediatr Adolesc Med*. 2004;158(11):1086-1088. doi:10.1001/archpedi.158.11.1086
2. Iverson C. Abstract. In: Christiansen S, Iverson C, Flanagin A, et al, eds. *AMA Manual of Style: A Guide for Authors and Editors*. 11th ed. Oxford University Press; 2020. Accessed March 21, 2023. https://academic.oup.com/amamanualofstyle/book/27941/chapter-abstract/207562779
3. Bauchner H, Golub RM, Fontanarosa PB. Reporting and interpretation of randomized clinical trials. *JAMA*. 2019;322(8):732-735. doi:10.1001/jama.2019.12056
4. Abstracts. Instructions for Authors. JAMA Network. Updated April 3, 2024. Accessed April 7, 2024. https://jamanetwork.com/journals/jama/pages/instructions-for-authors#SecAbstracts
5. Bauchner H, Henry R, Golub RM. The restructuring of structured abstracts: adding a table in the results section. *JAMA*. 2013;309(5):491-492. doi:10.1001/jama.2013.76

Downloaded from academic.oup.com/book/58841 by guest on 17 October 2026

CHAPTER 12

Writing a Compelling Introduction

Phil B. Fontanarosa, MD, MBA, and
Philip Greenland, MD

Downloaded from academic.oup.com/book/58841 by guest on 17 October 2026

KEY POINTS

- The Introduction of a scientific article should provide the background, importance, and objective (ie, the "BIO") of the article.
- The background should include specific information about the specific problem the study will address, and it should avoid including well-known general information about the topic.
- The importance section of the Introduction should establish the need for the study, identify research gaps, and include selected key current references.
- The Introduction should conclude with a clear statement of the study objective. This should represent the key focused question that the study is designed to answer, should be unambiguously stated, and generally should not include the "answer" to the research question.

Like an appetizer before dinner, like a test drive before purchasing a car, or like a warm-up act before the main event, introductions are important. Yet, everyone is familiar with introductions that are not that effective, such as long-winded, convoluted, and disjointed introductions, as sometimes may occur with the introduction of keynote or commencement speakers. However, other introductions are highly effective and perhaps memorable, such as occurred in 1964 when Ed Sullivan announced the appearance of a British quartet making its live US television debut with a now famous 5-word introduction: "Ladies and gentlemen—the Beatles!" Similarly, in scientific articles, an effective, concise Introduction section serves an important purpose in providing a prelude to what will follow and setting the tone for the article.

Structure

The Introduction of a scientific article could be thought of as providing the "BIO" for the article, presenting the background, importance, and objective, in that order, and represents the distillation of why the study was conducted, why the manuscript is being written, and perhaps most important, the reason that the information is needed or new. In formulating the Introduction, it is helpful to consider an approach modeled like an inverted pyramid or a funnel, beginning with more general information in the background, becoming more focused with discussing the importance, and ending with the specific research objective, purpose, and hypothesis of the article.

BACKGROUND

The background section of the Introduction is intended to generate interest from the beginning of the article, and an approach to do so is to avoid telling readers something they already know. For example, in a manuscript on cardiovascular disease, it is not necessary to state "Cardiovascular disease is the leading cause of death in the world." Most readers of such an article are likely to know this common fact, and authors do not need to reiterate information that is common knowledge or easily found in any textbook in the field. Inclusion of this basic and common information may lull readers into thinking that the article is going to provide information about topics they already know; in which case, the reader may perceive that the content of the manuscript is not novel, even if the findings are valid.

A more effective approach is to start the Introduction with information about the specific problem the study will address. For example, a manuscript reporting on a new risk factor for cardiovascular disease might begin with the statement, "Numerous risk factors for cardiovascular disease have been described, and a small number are commonly used in clinical practice for risk assessment." The background information could then discuss the need for additional risk markers and the potential to improve risk prediction with a new marker.

IMPORTANCE

The authors could then establish the importance of the topic, such as by discussing key previous research on the topic, identifying critical gaps in the literature, and highlighting information from authoritative guidelines on the importance of refining and improving risk predictors for cardiovascular disease outcomes. These statements establishing importance should be supported by selective use of key, timely, authoritative references. Referencing reports from professional societies or authoritative groups like the National Academy of Medicine or

Downloaded from academic.oup.com/book/58841 by guest on 17 October 2026

the World Health Organization usually is more effective in establishing importance than referring to articles reporting the work of individuals. However, it usually is not necessary to delve deeply into any previously published study or to give excessive details (such as effect sizes or *P* values) from prior research. In addition, excessive criticism of previous research is not effective, and it may be perceived as being condescending, offensive, or inappropriate by readers or reviewers. The goal is to inform the reader about the importance of the topic and to establish the need for research without including extraneous information, such as about the entire field of cardiovascular disease or disease prediction.

OBJECTIVE

The Introduction should conclude with a clear statement of the study objective, perhaps expressed as the study aim or purpose. The statement represents the key focused question that the study is designed to answer, and it should be clear and unambiguously stated. For instance, "The objective of this study was to evaluate the accuracy of a new biomarker for predicting incident myocardial infarction and stroke among individuals with no history of cardiovascular disease." This statement could be followed by a statement of the study hypothesis, such as "The study hypothesis was that the new biomarker would be associated with improved risk prediction compared with standard cardiovascular disease risk factors." The study objective should not include details about the study sample size or study methodology, although brief mention of the study design may be helpful, such as in a clinical trial: "The objective of this randomized clinical trial was to compare the effect of warfarin vs direct-acting anticoagulants on risk of stroke in patients with atrial fibrillation."

Content and Format

The Introduction section in most major journals does not include the "answer" to the research question, which is based on the study results. The reasoning is that the answer is only knowable and interpretable after describing how the question will be addressed (in the Methods section), presenting the evidence that answers the question (in the Results section), and explaining the findings that answer the question (in the Discussion). However, some journals may allow inclusion of the key finding of the study in the Introduction, so authors should examine previous articles from their target journal to assess the style and convention of the Introduction sections in that journal.

The length and format of the Introduction section vary from journal to journal, but in most major biomedical journals the Introduction section is brief and focused. For instance, in the JAMA Network journals, the Introduction section for a Review manuscript is 150-250 words (generally 2 to 3 paragraphs),[1]

Downloaded from academic.oup.com/book/58841 by guest on 17 October 2026

and usually with no more than 10 to 15 references. These guidelines are important because they require authors to carefully consider what information and how much detail to include in the Introduction. Many Introductions are considered by editors to be too long, so authors should avoid including unnecessary detail or hackneyed background information.

Conclusion

A focused, brief, and thoughtfully prepared Introduction will provide a clear understanding of the background, importance, and objective of the study, and a clear description of the rationale for addressing the critical question. A well-structured, concise, and carefully prepared Introduction will generate interest in the topic and provide an efficient and effective prelude to what will follow in the article.

Reference

1. *JAMA* Instructions for Authors. Reviews. Updated April 4, 2024. Accessed April 7, 2024. https://jamanetwork.com/journals/jama/pages/instructions-for-authors#SecReviews

Downloaded from academic.oup.com/book/58841 by guest on 17 October 2026

CHAPTER 13

Writing the Methods Section

Robert M. Golub, MD

Downloaded from academic.oup.com/book/58841 by guest on 17 October 2026

KEY POINTS

- The Methods section is one of the most important sections that editors and reviewers use in deciding whether to consider a manuscript for publication.
- The Methods section should have a logical and coherent organization. A chronological approach with subsections that follow the order in which the study was conducted may often be the clearest approach.
- The Methods section should be complete. It is better to have too much information and too much detail than not to have enough.
- The Methods section should be written with sufficient detail that other researchers could replicate the study.
- Authors can use technical language or jargon if necessary, but they should define all terms at first use if the terms are likely to be unfamiliar to readers of that journal.
- Authors should consider having a colleague provide feedback on clarity and completeness of the Methods section before submitting the manuscript.

A metaphor that can help in writing a scientific report is to think of it as a story. The Introduction is the "Once upon a time . . . ." The Methods section introduces the characters and sets up the dramatic tension. The Results are the resolution. The Discussion is the denouement.

With this approach, the Methods and Results can be seen as the core of the article, the most important sections. These are the sections that will be the basis for critical appraisal of the study. The presentation of the Methods and Results may therefore be the key factor in the success of the article. This chapter first considers general principles that apply globally to the Methods section, followed by overall advice, and then a suggested organization for the Methods that may help with effective communication.

But the overriding principle can be summed up briefly: there should not be a madness to the Methods. The section must be coherent, clear, and precise.

General Principles

To invoke another metaphor, in writing the Methods section the authors should think of themselves as an informed and friendly guide to their research and think of the reader as a first-time tourist. Authors should always keep in mind that there are 2 audiences for their manuscript, and ultimately for the published article. The proximate audience is those who will decide whether the article is published in a particular journal—the editors, with assistance from the peer reviewers. The distal audience is the readers of the published article. Because each audience may have a different focus in reading the article, there are different implications in preparation.

First, consider the editors and reviewers. Journal editors need to make an initial judgment about study validity and appropriateness of the study for their journal. The Methods section is where judgment about the study design (in contrast to study execution) is made. To the extent that the Methods section is incomplete, inaccurate, or difficult to follow, the editors cannot make this judgment, and the same is true for external peer reviewers.

In addition, the quality of the manuscript as submitted is likely to be perceived as a reflection of the quality of the research. Disorganization, typographical errors, lack of clarity, incompleteness, and inconsistencies, among other factors, may send an unconscious message that the research was also conducted poorly. At this early stage of evaluation, a poor first impression may preclude the opportunity for a second impression.

It is important to recognize that editors are generally busy and must make initial decisions about rejection vs external review on a large number of manuscripts. Authors should therefore consider it a top priority to make the editors' assessment as easy as possible when reading the submission, and to create a positive—or at least neutral—first impression. While this is true for the entire article, a poorly written Methods section will call into question the validity of the results.

Although external reviewers are consultants rather than decision makers with respect to whether the manuscript gets published, the quality of the Methods section may be a rate-limiting step in the ability of peer reviewers to provide a thoughtful and complete review. Indirectly, this may also jeopardize the chances of the manuscript being viewed positively by the journal editors.

With respect to readers, the same issues need to be considered, because an informed reader—whether researcher or clinician—will be critically appraising the study based largely on the Methods and Results. It is therefore just as

Downloaded from academic.oup.com/book/58841 by guest on 17 October 2026

important that they are reading a Methods section that adheres to the principles important for editors and reviewers.

In addition, authors should generally assume that readers do not have technical expertise in the research area. Jargon should only be used if necessary to achieve precision, and if this is done the terminology should be explained at first use. Abbreviations that are not common should be avoided; it is confusing and frustrating to have to repeatedly refer to the beginning of the article for definitions of abbreviations. Methods that are not common should be explained, whether related to patient selection, intervention or exposure measurement, end points, or statistical techniques. If an editor believes that the writing is too verbose or simplistic, they can later modify the text as needed. But it is unlikely that later editing by the journal will add this type of explanatory information.

Overall Advice

- The article should be written with an assumption that a reader would be able to reproduce the study based on the methods that are reported. Keeping this in mind will help prevent leaving out important information.
- It is critical that the Methods section be complete in the submitted manuscript. Details can be later omitted or condensed if the journal requests, but if these details are not present at the outset (resulting in a gap in the information needed for critical evaluation) it could adversely affect the evaluation of the submission, and even lead to a rejection that could have been avoided if the editors had had all the relevant information. It is better to have more information than not enough, within the constraints of the journal's word limits.
- Given the prevalence of online supplements, some Methods material can be placed there rather than in the full article if the word count for the main manuscript becomes an issue. However, this still presents a barrier to easy understanding of the study design, and any barriers should be avoided. It is best to consult the journal's instructions for authors for guidance about what is appropriate for an online supplement vs the full article, but in general authors should try to include all but the most technical information in the full article.
- The study design may be unusual, or it may include methods or assumptions that are not standard for this area of research or for the journal of submission. In that case, it is critically important to justify these choices or assumptions. These might include the use of a noninferiority design, basing the primary analysis of a randomized clinical trial (RCT) on a per-protocol rather than intention-to-treat

Downloaded from academic.oup.com/book/58841 by guest on 17 October 2026

approach, choosing a proxy end point or an otherwise nonstandard end point, using an ad hoc or otherwise unvalidated instrument, or using 1-sided hypothesis testing for superiority analyses. If editors, reviewers, and readers cannot immediately understand the rationale for these design elements, it is more difficult for them to accept the validity of these choices.

- If the study had a prespecified protocol and statistical analysis plan, there is an expectation that the Methods adhered to those documents. While these documents are most common for RCTs, they are increasingly being prespecified for other study designs such as meta-analyses and observational studies. If there were any deviations from these documents in study execution, such deviations need to be detailed and justified in the Methods section.
- When authors have been working on a research project for a long time and writing multiple drafts of a manuscript, they may become unconscious of errors in the writing. Moreover, it is easy to be unaware of reliance on jargon or on cumbersome writing that will be unclear to anyone who is not closely involved in this area of research or clinical care, or conversely to have left out information that an author has internalized. Before submitting a manuscript, it is advisable to have a colleague in a different research area or specialty read a draft of the Methods and give feedback.

Organization of Subsections

To provide coherence to the Methods section, it is helpful to follow a clear and logical order in a set of subsections. The most effective way to "tell the story" is to make it chronological—to describe the study more or less as it unfolded. The following is a suggested order, if the journal of submission does not have a recommended template.

The subsections described here are mostly relevant to RCTs and observational studies, since other designs (such as meta-analyses, survey studies, decision analyses, and economic analyses) will have additional relevant subsections. In addition, different observational designs (eg, cohort study, case-control study, cross-sectional study) will have their own particular elements that need to be included. Reporting guidelines have been developed for most study designs and can provide a roadmap for organization and to make sure that all relevant information is included in a submitted manuscript. These guidelines have been compiled by the EQUATOR Network and are available at https://www.equator-network.org[1]; they are an excellent resource, especially if the study design is less common. However, the following subsections are frequently used in the Methods section of many research reports.

Downloaded from academic.oup.com/book/58841 by guest on 17 October 2026

PREAMBLE

The Methods section should begin with a brief statement of the overall study design and structure. Use terms that most readers will be familiar with; for example, *randomized clinical trial*, *meta-analysis*, *cohort study*, *case-control study*, *decision analysis*. The description of the design should be complete and explicit. It can also include a statement of study purpose or hypothesis if that was not included in the Introduction section.

In addition, it is appropriate to include links to the study protocol/statistical analysis plan or other background documents here, either as citations to a published article or as callouts to the online supplement if they are included there. Statements about institutional review board or ethics committee approval or exemption, and participant informed consent or waiver of informed consent, also should be included here.

Include the key study dates, such as beginning of first participant enrollment, end of last participant enrollment, and end of last participant follow-up. If the study is based on older or historical data, report the dates of the analysis.

PARTICIPANTS

Readers need to have good sense of how the participants were identified and included in the study to be able to judge the potential for selection bias, and to assess whether the study findings (if valid) can be extrapolated to patients in other settings. While the Results section will generally describe the study population and provide a table of characteristics, that information will not necessarily indicate bias in study design.

This subsection needs to describe in detail the inclusion and exclusion criteria, the source and setting for identifying participants, and the method used for selection. If the basis for any of these criteria is not obvious, it should be justified. If some of the criteria were defined because of pragmatic concerns, rather than the problem being studied, this may have led to a bias in the spectrum of patients studied; this should be addressed subsequently in the Discussion section.

There should also be presentation of the various filters that potential study participants needed to go through to be included in the final study population because this can also introduce bias or lead to limitations in generalizability. However, the numbers of participants at each stage of filtering should be presented in the Results section, rather than the Methods, since these numbers were not determined by the design; they represent study findings.

All relevant variables (other than outcomes) that were measured on the participants and were used in the data analyses or in the participant description should be described here, including how they were ascertained.

Downloaded from academic.oup.com/book/58841 by guest on 17 October 2026

RANDOMIZATION (IN AN RCT)

The technique used to create random groups should be described, and the description should include whether (and how) the study investigators were masked to the allocation process. If there was a blocking scheme, that should be noted, along with the range of block sizes.

INTERVENTIONS (IN AN RCT)

The interventions should be described in detail. As noted above, readers should be able to replicate the intervention based on these descriptions.

All allocation groups need to be described, including controls. If the control is "usual care" or "standard care," that is generally not a sufficient description. Details about what comprised usual care should be provided. Without understanding what the comparison group received, it is not possible to judge the meaning of an effect size for a new intervention.

There should be a description or at least indication of masking (ie, blinding) to allocation status in administering the intervention. If masking was not done, this needs to be indicated and justified, and the implications addressed in the Discussion.

The technique and planned duration of participant follow-up should also be described in this subsection. However, the follow-up data should be reported in the Results section.

EXPOSURES (IN AN OBSERVATIONAL STUDY)

The criteria used to define an exposure and nonexposure should be described in detail. This includes the metric for exposure and any instruments used to measure the exposure. Whether the exposure was based on a database designed for research (such as the National Health and Nutrition Examination Survey), a claims database, or laboratory values measured by the researchers, readers need to understand the accuracy of the measure of exposure. If the study was not based on a well-known research database, authors should provide measures of completeness and accuracy of the exposure data (eg, sensitivity and specificity), with supporting references. If such performance measures have not been made, this is likely to be considered an important threat to validity, and authors should plan to address this in the Discussion section.

If the outcome is already known at the time exposure status is assessed, as in a case-control design, there should be a description or at least indication of blinding to outcome status in measuring the exposure. As with interventions, if masking of outcomes was not done when measuring exposure, this needs to be explained, and the implications addressed in the Discussion.

Downloaded from academic.oup.com/book/58841 by guest on 17 October 2026

The technique for and planned duration of participant follow-up should also be described in this subsection. However, the follow-up data should be reported in the Results section.

OUTCOMES

There should be a clear and unambiguous distinction between the prespecified primary end point, prespecified secondary end points, prespecified but exploratory end points, and post hoc end points. If there was a protocol/statistical analysis plan, these definitions need to be consistent with those documents; any deviations need to be noted and justified. In general, there should have been only a single primary end point, but if there were 2 or more coprimary end points, there should be a statement about the a priori plan to handle divergent results (eg, all coprimary end points need to be significant to label the study as "positive," or only a single coprimary end point needs to be significant to label the study as "positive"). Clarity of end points is critical. For example, only indicating that quality of life will be measured at 3 months and 6 months is different than stating that quality of life above a certain threshold is the primary outcome at 3 months and 6 months.

As with exposure variables, there needs to be a clear definition of each end point and description of how it was measured. Information should be provided on the accuracy of the end point measurement, and supporting references provided for any end points that are not common. The minimal clinically important difference should be noted, if it has been established. For any end points measured as scales, there should be information about the potential range and anchors (definitions of best and worst outcomes).

All prespecified secondary end points should be noted, even if some are not analyzed or reported in the current manuscript.

As with intervention or exposure, there should be a description or at least indication of whether the assessment and measurement of end points were conducted without knowledge of (masked to) or with knowledge of (nonmasked to) allocation or exposure status. If this type of masking was not done, it also needs to be acknowledged and justified, and addressed in the Discussion.

POWER AND SAMPLE SIZE

In general, all RCTs except pilot studies will have a prespecified sample size calculation and estimated study power. This is also true of many observational studies. If a sample size estimate was performed, it should be reported here and should include all the elements of the power analysis (which generally include the assumed control event rate, minimal detectable difference, assumed standard deviation, alpha level, and desired power). For studies that begin with a fixed sample size, the analysis may calculate an estimated power given the other

Downloaded from academic.oup.com/book/58841 by guest on 17 October 2026

assumptions. A justification for the minimal detectable difference should be provided, with a supporting reference. It should not solely be based on what the investigators thought important or on effect sizes found in previous studies.

If no sample size calculation or power analysis was done, this should be noted and explained.

STATISTICAL METHODS

The principles for describing the statistical methods are the same as with the rest of the Methods section: provide complete information so that the editor and peer reviewers can judge the appropriateness of the methods and so other investigators could replicate the study. (For more information on this topic, see also Section 19, Study Design and Statistics, in the *AMA Manual of Style*.[2])

Important statistical aspects of the study that generally need to be reported here include:

- Details of all statistical methods used for analyses of the primary and secondary outcomes
- Description of the analysis sets used for each analysis; the term *intention-to-treat*, or *modified intention-to-treat*, is often ambiguous and should be accompanied by or replaced with a precise definition of which participants were included in each analysis
- Details of how confounding was addressed, including multivariable modeling, such as logistic regression or Cox proportional hazards modeling; this should address how the model was constructed as well as relevant assumptions and whether they were met
- Subgroup analyses and interaction testing
- Details of sensitivity analyses
- Distinction between preplanned and post hoc analyses
- Planned interim analyses and the basis for potential early stopping of the study
- Description of how missing data and loss to follow-up were handled in the analyses, such as multiple imputation; missing data and loss to follow-up should be quantified in the Results section
- Significance threshold, and whether testing was 1-sided or 2-sided; if there were multiple comparisons, particularly among secondary outcomes, describe how the potential for type 1 error was addressed
- Name and version of statistical software

Conclusion

If all of these elements are included in the Methods section, and are presented in a coherent and precise way, the section will have accomplished its goal.

Downloaded from academic.oup.com/book/58841 by guest on 17 October 2026

The reader of this story will now know the characters, will be engaged in the plot, and will be eagerly awaiting the next chapter: the Results.

References

1. EQUATOR Network. Accessed September 11, 2023. https://www.equator-network.org
2. Livingston EH. Study design and statistics. In: Christiansen S, Iverson C, Flanagin A, et al, eds. *AMA Manual of Style: A Guide for Authors and Editors*. 11th ed. Oxford University Press; 2020. Accessed October 30, 2023. https://academic.oup.com/amamanualofstyle/book/27941/chapter/207572072#414759758

Downloaded from academic.oup.com/book/58841 by guest on 17 October 2026

CHAPTER 14

Presenting the Results Section

Jay F. Piccirillo, MD

Downloaded from academic.oup.com/book/58841 by guest on 17 October 2026

KEY POINTS

- Authors should report results as described in the prespecified study protocol and with the research questions in mind.
- Authors need to understand the advantages and disadvantages of reporting results with *P* values and effect size metrics.
- Confidence intervals around the effect size estimates should be included in the Results section.
- Authors should determine whether results are compatible with clinically meaningful effects.

The purpose of the Results section is to report the data and information obtained through the conduct of the study in a clear and unambiguous manner. The presentation should be efficient and logical, guided by the research questions as posed in the Introduction and defined in the Methods section. The Results section is written in the past tense to reflect that the author is reporting on work that is already completed.

In the Results section, the main or most important findings relevant to the research questions should be presented first, followed by the secondary outcomes. No results should be presented without a description of the planned analyses in the Methods section. The Results section should be written in an objective, "just the facts" fashion. The text of the Results section should highlight the data, including data contained in the tables and figures, that address the study hypothesis or research questions, which ideally had been specified before the study was begun ("prespecified"), and it also should report data that reveal unexpected findings. All data or information obtained from the conduct of the study and pertinent to the research question should be reported in the Results section, regardless of whether those data show an effect. No new results or repeat of results already presented should be included in the Discussion section. The Discussion section is reserved for the interpretation of the results in the context of previously published work.

Organization of the Results Section

The organization of the Results section should be logical and ideally follow the same framework and order of the Methods section. The pretrial or prespecified research protocol will help guide the organization and writing of the Results section. The EQUATOR (Enhancing the Quality and Transparency of Health Research) Network[1] provides reporting guidelines and checklists for clinical trials (Consolidated Standards of Reporting Trials [CONSORT]),[2] observational studies (Strengthening the Reporting of Observational Studies in Epidemiology [STROBE]),[3] and a variety of other study designs[4] that can be useful when organizing and writing the Results section. Authors should refer to these sources for guidance on the recommended way to report results for different research study designs.

Deciding what data and information to include in the Results section can be challenging. For some individuals, creating the tables and figures first and ensuring that all authors agree on what data are important are helpful. For each item mentioned in the Methods, an appropriate item should follow in the Results. In a similar way, each item presented in the Results should be introduced into the Methods first. In this way, there is an internal consistency to the manuscript.

The logical sequence of the Results section, regardless of the study type, begins with a description of the study participants followed by enrollment and participation, primary analysis, secondary analyses, and any additional or unplanned analyses. The description of the study population includes key demographic, clinical, comorbid, and treatment information and is usually represented in a table ("Table 1"). Means and standard deviations for normally distributed data and medians and interquartile ranges or ranges for data that are non-normally distributed should be used to describe the data.

For clinical trials and other interventional studies, data on participant flow should be presented as a figure ("Figure 1") and should include the following: the numbers of participants in each intervention or exposure group, including those who received the intended treatment or had the exposure and those who completed the study protocol; information and data showing deviations from the study protocol, such as crossovers; the amount of missing data, such as the number of participants who were lost to follow-up or excluded because the study was stopped early; and the number available to be analyzed for the primary outcome.

The reporting of the primary or main outcome of the study is usually presented immediately after the description of the study population. The primary and secondary outcome measures and analytical plan should be prespecified in the research study protocol, described in the Methods section, and be directly related to the primary study question. Emphasis should be given to reporting the primary outcome(s), regardless of statistical significance. Presentation

Downloaded from academic.oup.com/book/58841 by guest on 17 October 2026

of adverse effects, other outcomes, and subgroup, exploratory, and sensitivity analyses follow the description of the prespecified primary and secondary outcomes. All exploratory and post hoc analyses should be clearly identified as such.

At times, however, and depending on the study design, it may be helpful to consider reporting the findings of a process measure that is related to the intervention and that directly affects the primary outcome prior to reporting the data for the primary outcome. For example, in a randomized trial that compares the effect of 2 antihypertensive medications titrated to achieving a specific blood pressure target level on the primary outcome of cardiovascular disease events, it may be helpful to report the proportion of patients in the 2 interventions groups that achieved the desired blood pressure target prior to reporting the primary outcome of cardiovascular events. In some studies, it also may be appropriate to report adherence with treatment prior to reporting of the primary outcome. The extent to which research participants completed their assigned intervention may influence the outcome of interest. In all these cases, reporting of process measures and degree of adherence helps readers to correctly interpret the results of the study.

Presentation of Outcome Data

The outcome data can be presented in a variety of ways depending on the research question, but some general recommendations are provided here. The key findings are summarized as quantitative values in the text of the Results section and readers are referred to the tables for detailed presentations of individual values and group values, as well as detailed comparisons between groups. Figures are used to visually communicate findings, such as trends over time and patterns of relationships. (For more detailed descriptions on the use of tables and figures, see also Chapter 17, Effective Use of Figures and Tables in Scientific Articles; Chapter 18, Creating Effective and Efficient Tables; and Chapter 19; Effective Use of Figures and Graphs in Scientific Publications.)

The most common method of quantitatively comparing the results of a clinical research study is to contrast 2 numbers (A and B), such as means or rates, between 2 groups (eg, experimental and control). In this situation, the 2 numbers (A and B) can be compared as an absolute difference (A − B), ratio (A / B), or relative change ([A − B] / B). The meaning of the measurements and familiarity with the rating scales are also required to adequately interpret results. To avoid abstruse comparisons, authors must provide information regarding the type of quantitative contrast (eg, absolute, relative) and the qualitative or clinical meaning of the rating scales.[5]

Reporting the change in a variable between initial ("baseline") and final ("outcome") is another common way to report results. The advantage of this

Downloaded from academic.oup.com/book/58841 by guest on 17 October 2026

approach when comparing groups is that it removes any differences between the groups with respect to the baseline value. In this way, each change in the value from baseline for each participant is calculated and then the difference between the mean change value in each group is compared. For this type of reporting, it is important to present the baseline and outcome data for each group, the within-group change with confidence intervals, and the between-group difference with confidence intervals.[6] An important caveat when reporting change is to avoid using a correlation metric to describe the relationship between the baseline value (A) and the change (A − B) in that same variable at some other time. It should not be surprising that there will be a high correlation between the value (A − B) and A, because the baseline value (A) is present in each function.

An important challenge when reporting quantitative results is to convey the clinical meaning to the patient and health care professional or the public health importance to policy decision makers.[7] Presentation of results as a difference in the mean values for participants in 2 different groups can be difficult to understand and misleading. Difficulty in understanding arises when the investigator selects measures for which the readers have no understanding of the value and importance of the change for an individual patient or population and thus are unable to interpret the results. The results, presented as a mean value for the whole group, may be misleading depending on the variability in individual responses.

For example, in a parallel study of 2 groups receiving treatments, A and B, the mean value for the primary outcome measure may be similar between the 2 groups and yet the distribution of values for individual participants within each group may be substantially different. It is possible that a number of participants in one study group may experience a large and clinically meaningful difference whereas few participants in the other study group may experience a similar effect. Yet, the mean values for the 2 groups could be identical and the change between the 2 groups would be zero.

As a potential solution to this problem of making inferences concerning individuals and inferences concerning groups,[7] before conducting the study investigators should determine how much of a difference in outcomes between the compared groups is clinically meaningful and practically important.[8,9] The determination of how large a difference is clinically meaningful can be accomplished with quantitative or qualitative methods and is distinctly different from the determination of statistical significance. Clinically meaningful differences for each of the outcome measures should be described to help the reader interpret the observed findings in the context of the clinical question under study. References should be provided if available. If the authors determine what represents a clinically meaningful difference, they should explain the approach for making the determination (ie, consensus) and provide the rationale and justification for the assumption. Ideally, this determination of clinical significance

Downloaded from academic.oup.com/book/58841 by guest on 17 October 2026

is made during the research planning phase before data collection and analysis has begun and should inform sample size determinations.[9,10]

Once a clinically meaningful difference is established, each participant's change score is transformed from a continuous value to a dichotomous value based on whether the magnitude of the change exceeds the threshold value established for the clinically meaningful difference. The investigator then reports the proportion of participants in each study group that achieved a change in the outcome measure that exceeds the clinically meaningful difference threshold. In addition, the investigator could compare the percentages of participants who experience a change that exceeds the threshold difference between the groups of the study.

In some cases, especially in observational studies, other approaches may be needed to make meaningful comparisons between the compared groups. For example, consider the measurement of body mass index (BMI) in studies evaluating the association between an exposure and the outcome of childhood obesity. The investigator may not be able to simply calculate mean BMI values for the different groups because interpretation of BMI varies by age and gender. Instead, age-standardized and gender-standardized measurements can be used to transform each child's BMI measurement to a *z* score, which reflects the distance each child's measurement is from average. The *z* score is a standardized measurement, which in the case of BMI "corrects" for differences based on age and gender, and it reflects the number of standard deviations a value is from the mean value of the group. Once the *z* score for each participant is determined, an average *z* score for each group can be used for comparison between the groups. Authors who elect to present results as *z* scores should take the next step in results reporting by translating *z* score values back to some clinically meaningful finding. In other words, the authors must "close the loop" and clearly indicate how to interpret the findings based on the *z* score data. This is often done in the Discussion section of the article.

Issues Related to Reporting Statistical Testing and *P* Values vs Effect Size and Confidence Intervals

A current issue in biomedical research involves reporting results in terms of "statistical significance" and *P* values, with primary and secondary analyses presented based on an approach using null hypothesis statistical testing. The principles of this approach require the establishment of a level of significance, establishment of a null and alternative hypothesis, acceptance and rejection of the null hypothesis, and consideration of α (type I) and β (type II) errors. The use of the *P* value represents the probability of obtaining the observed results by chance alone assuming the null hypothesis of no difference is true. The conventional *P* value of .05, or 1 in 20, was selected in 1925 by Fisher to

Downloaded from academic.oup.com/book/58841 by guest on 17 October 2026

be the threshold for judging whether a value was so extreme from an expected distribution of values that the deviation can be considered "significant."[11] This boundary between results that are "significant" or "not significant" became entrenched in biomedical research, including drug approval at the US Food and Drug Administration.

There are several advantages and disadvantages to the reliance on null hypothesis statistical testing and *P* values for the interpretation and reporting of scientific research.[12] One main advantage of the use of *P* values is the ability to obtain an exact probability for the observed result, assuming the null hypothesis is true.[13] In this way, the comparison of the observed *P* value to the α threshold value of 5% assists in the interpretation of the results. This relationship provides a "hard and fast" backstop for defining the significance of the findings with less subjectivity than when the outcomes are judged using "clinically significant" determinations. Another use of the *P* value is to indicate how incompatible the data are with a specified statistical model.[14] If the research question is answered from an omnibus or overall test (ie, a test for the significance of several parameters at once) that examines a null hypothesis with more than 1 equal sign, the *P* value is helpful in guiding investigation of underlying differences. For example, a study may examine 3 interventions—a novel treatment, standard treatment, and placebo—in which the omnibus test examines whether there is a difference among the 3 compared groups.

P values are also helpful for proper post hoc evaluation through conservative adjustment (ie, the Bonferroni adjustment) or theory-based methods like the Tukey test[15] or Scheffé procedure.[16] These approaches may be useful in studies that involve multiple comparisons to help reduce the likelihood of false positives, statistically significant findings that occur by chance. *P* values also guide the testing for presence of interaction effects in statistical models. Exploratory analyses are often based on identification and selection of variables based on *P* values. For example, automated methods of model building (ie, stepwise approaches) are executed and interpreted based on *P* values and preset criteria for selection of variables. Advanced statistical approaches, like genome-wide association study or machine-learning techniques, build their algorithms and validate their training through use of *P* values.

The most important disadvantage of the *P* value and null hypothesis statistical testing is that these approaches do not answer the important questions: How big of a difference was observed between the compared groups? How strong is the association between groups? How important is the observed result? Equally important, the *P* value is inherently unstable. Repeat experiments sampling from the same population, even when statistical power is high, produce *P* values with a large degree of variability.[17] Additional problems with reliance on *P* values to describe study results include the scientific irrationality of selecting a specific threshold for significance and the limited evidence provided by the *P* value as a measure of the strength of evidence for or against

Downloaded from academic.oup.com/book/58841 by guest on 17 October 2026

a hypothesis. These problems contribute to issues of false-positive and false-negative study results, and the inability to replicate findings. Thus, authors are advised to avoid solely reporting the results of statistical hypothesis testing with *P* values. *P* values should never be presented alone without the data that are being compared. If *P* values are reported, follow standard conventions for decimal places: for *P* values less than .001, report as "$P < .001$"; for *P* values between .001 and .01, report the value to the nearest thousandth; for *P* values greater than or equal to .01, report the value to the nearest hundredth; and for *P* values greater than .99, report as "$P > .99$." For studies with exponentially small *P* values (eg, genetic association studies), *P* values may be reported with exponents (eg, $P = 1 \times 10^{-5}$).

The American Statistical Association, among other professional organizations, has recommended several alternatives to null hypothesis statistical testing and reliance on *P* values for the reporting and interpretation of research results.[18] These methods include the use of effect size, confidence intervals, likelihood ratios, graphical representation of data, meta-analytical approaches, and bayesian analysis. The use of effect size metrics and confidence intervals are presented as examples of alternatives to null hypothesis statistical testing and the *P* value.

The effect size metric is a measure of the difference between groups or the strength of the relationship between 2 or more variables. Many effect size measures exist and they are generally divided into 1 of 2 "families": (1) difference between groups (*d* family) or (2) measures of association (*r* family). The choice of the appropriate measure depends on the research question, study design, type of variables under analysis, and distribution of the data.[19] The first effect size metric that was introduced was the Cohen *d*,[20,21] which is calculated as the difference in means between 2 groups divided by the pooled standard deviation. The effect size metric, *d*, represents standard deviation units. A significant contribution by Cohen was to provide suggestions for the interpretation of the result, with *d* of 0.2 representing a small effect, 0.5 a medium effect, and 0.8 a large effect.[22] Cohen also provided meaningful interpretations of the effect size value. For instance, Cohen suggested that a medium effect size is "likely to be visible to the naked eye of a careful observer." A small effect size is "to be noticeably smaller than medium but not so small as to be trivial." A large effect size is "to be the same distance above medium as small was below it."[22] Additional examples of effect size measures that belong to the *d* family include the Glass Δ, Hedges *g*, risk ratio, and odds ratio. The effect size metrics that belong to the *r* family are standardized measures of association and are variations of the correlation coefficient. The more common measures include the Pearson product moment correlation (*r*), Spearman rank correlation (ρ), and Kendall τ. Authors are responsible for selecting the correct effect size metric and correctly interpreting their study effect size relative to the specific research question.

Downloaded from academic.oup.com/book/58841 by guest on 17 October 2026

To fully interpret the effect size and study results, investigators need to provide confidence intervals around the effect size. The width of the confidence interval describes the precision of the estimate and informs the degree of confidence regarding where the true effect lies.[23] The wider the confidence interval, the less precise the estimate and less confidence in the results. Inspection of the upper and lower boundaries of the confidence interval allows for inferences to be made about the likely effect size in the population and whether the observed results are compatible with clinically meaningful effects. Too often, confidence intervals are incorrectly used as a proxy for the *P* value, with investigators declaring and readers inferring "statistical significance" or not by examining whether the lower boundary of the confidence interval crosses the null value. Instead, investigators and readers should focus on whether the confidence interval includes clinically meaningful effects. Moreover, the results from a study must be evaluated and interpreted with knowledge of similar research from the past. Rarely is a single study definitive, regardless of the magnitude of the effect size, width of the confidence interval, or size of the *P* value. Scientific knowledge is a cumulative process, and reporting results as an effect size with confidence intervals allows for meta-analytic thinking or the steady accumulation of knowledge.[17]

Conclusion

The purpose of the Results section is to convey the data and information required to answer the research questions presented in the Introduction and defined in the Methods section. The information should be reported objectively, logically, according to the prespecified research protocol, and without interpretation. The focus of results reporting should be on describing the magnitude of the observed effects, the precision of the effect estimates, and whether the results are compatible with clinically meaningful effects.

References

1. EQUATOR Network. Accessed March 21, 2023. https://www.equator-network.org/about-us
2. Moher D, Hopewell S, Schulz KF, et al; Consolidated Standards of Reporting Trials Group. CONSORT 2010 Explanation and Elaboration: updated guidelines for reporting parallel group randomised trials. *J Clin Epidemiol*. 2010;63(8):e1-e37. doi:10.1016/j.jclinepi.2010.03.004
3. von Elm E, Altman DG, Egger M, Pocock SJ, Gøtzsche PC, Vandenbroucke JP; STROBE Initiative. The Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) statement: guidelines for reporting observational studies. *J Clin Epidemiol*. 2008;61(4):344-349. doi:10.1016/j.jclinepi.2007.11.008

Downloaded from academic.oup.com/book/58841 by guest on 17 October 2026

4. Simera I, Moher D, Hoey J, Schulz KF, Altman DG. A catalogue of reporting guidelines for health research. *Eur J Clin Invest*. 2010;40(1):35-53. doi:10.1111/j.1365–2362.2009.02234.x
5. Yueh B, Feinstein AR. Abstruse comparisons: the problems of numerical contrasts of two groups. *J Clin Epidemiol*. 1999;52(1):13-18. doi:10.1016/S0895-4356(98)00133–4
6. Altman DG. *Practical Statistics for Medical Research*. Chapman and Hall; 1991:466.
7. Guyatt GH, Osoba D, Wu AW, Wyrwich KW, Norman GR; Clinical Significance Consensus Meeting Group. Methods to explain the clinical significance of health status measures. *Mayo Clin Proc*. 2002;77(4):371-383. doi:10.4065/77.4.371
8. Jaeschke R, Singer J, Guyatt GH. Measurement of health status: ascertaining the minimal clinically important difference. *Control Clin Trials*. 1989;10(4):407-415. doi:10.1016/0197-2456(89)90005-6
9. Kallogjeri D, Spitznagel EL Jr, Piccirillo JF. Importance of defining and interpreting a clinically meaningful difference in clinical research. *JAMA Otolaryngol Head Neck Surg*. 2020;146(2):101-102. doi:10.1001/jamaoto.2019.3744
10. Yueh B. The threshold of clinical significance. *JAMA Otolaryngol Head Neck Surg*. 2020;146(2):98-100. doi:10.1001/jamaoto.2019.3741
11. Fisher RA. *Statistical Methods for Research Workers*. Oliver and Boyd; 1925.
12. Piccirillo JF. Improving the quality of the reporting of research results. *JAMA Otolaryngol Head Neck Surg*. 2016;142(10):937-939. doi:10.1001/jamaoto.2016.2670
13. Feinstein AR. P-values and confidence intervals: two sides of the same unsatisfactory coin. *J Clin Epidemiol*. 1998;51(4):355-360. doi:10.1016/S0895-4356(97)00295-3
14. Wasserstein RL, Lazar NA. The ASA statement on *p*-values: context, process, and purpose. *Am Stat*. 2016;70(2):129-133. doi:10.1080/00031305.2016.1154108
15. Braun HI, ed. *The Collected Works of John W. Tukey: Volume VIII: Multiple Comparisons*. Chapman and Hall; 1994.
16. Scheffé H. *The Analysis of Variance*. John Wiley and Sons, Inc; 1959.
17. Cumming G. The new statistics: why and how. *Psychol Sci*. 2014;25(1):7-29. doi:10.1177/0956797613504966
18. Wasserstein RL, Schirm AL, Lazar NA. Moving to a world beyond "$p < 0.05$." *Am Stat*. 2019;73:1-19. doi:10.1080/00031305.2019.1583913
19. Ellis PD. *The Essential Guide to Effect Sizes: Statistical Power, Meta-Analysis, and the Interpretation of Research Results*. Cambridge University Press; 2015.
20. Cohen J. *Statistical Power Analysis for the Behavioral Sciences*. Academic Press; 1969.
21. Kirk RE. The importance of effect magnitude. In: Davis SF, ed. *Handbook of Research Methods in Experimental Psychology*. Blackwell; 2003:83-105. doi:10.1002/9780470756973.ch5
22. Cohen J. A power primer. *Psychol Bull*. 1992;112(1):155-159. doi:10.1037/0033-2909.112.1.155
23. Kallogjeri D, Francis DO, Piccirillo JF. Use of confidence intervals to improve the quality of research results reporting and interpretation. *JAMA Otolaryngol Head Neck Surg*. 2019;145(6):491-493. doi:10.1001/jamaoto.2019.0793

Downloaded from academic.oup.com/book/58841 by guest on 17 October 2026

CHAPTER 15

Writing a Convincing Discussion Section

Jody W. Zylke, MD

Downloaded from academic.oup.com/book/58841 by guest on 17 October 2026

KEY POINTS

- The purpose of the Discussion section is to interpret the study for readers.
- The Discussion should begin with a statement of the key study finding and conclusion, with consideration of statistical and clinical significance.
- Authors should comment on the most likely explanation for the results and alternative explanations, while avoiding speculation as much as possible.
- Results of related studies in the literature should be compared and contrasted.
- Authors should acknowledge the strengths and limitations of the study.
- Relevant clinical, economic, and policy implications and future research directions can receive brief mention.
- Authors should avoid introducing new results, raising unrelated issues, or expressing opinions.
- A final paragraph should provide a clear "take-home" statement of the main study conclusion.

A scientific manuscript can be thought of as a package. The Methods are the box—the framework that provides the structure for the study. The Results are the contents—the surprise that awaits at the end of the investigation. The Discussion is the ribbon that ties it all together.

Content and Structure

The Discussion section is usually the last or one of the last sections that an author writes. In many ways, the Discussion section should be the easiest to write, as the hard work has already been done. Authors have reviewed the

literature before beginning the study, designed the study with a specific hypothesis in mind, conducted the investigation, and analyzed the results. The strengths and limitations may have been clear when designing the study or may become more apparent during its conduct and analysis. All that remains is to integrate these features into a few concise paragraphs that interpret the data and put the study in perspective for readers. In some ways, the Discussion section is the opposite of the Introduction section, which moved from the general topic under consideration to the specific question addressed in the study. In contrast, the Discussion section begins with the specific study results and then places them within the broader context of what is already known about the subject. However, reflecting on the broader context can be challenging. Authors need to interpret their results in a manner that is consistent with the data and without overinterpreting what they have found. They need to put their study in context without being boastful or arrogant. Few studies are truly novel, perfectly conducted, and free of bias, and few culminate with unambiguous and overwhelmingly strong results. Thus, objectivity and modesty are essential.

Purpose

The main purpose of the Discussion section is to interpret the findings for readers—both in terms of the current study and in the context of prior related research and investigation. Having spent so much time from conception to completion of the research endeavor, the importance and relevance of the results will be obvious to authors; however, they should not assume these will be obvious to readers. Authors should write the Discussion section from the perspective of a reader and not as an investigator. Readers will want to know what conclusions can appropriately be drawn from the results and the possible explanations. They will want to know how the results compare to relevant literature and the strengths and limitations of the data. Most important, they want to know why the results matter and the implications of the results for current clinical practice and future research.

Appropriate Interpretation of Study Results

The most difficult part of writing a good Discussion section is to determine the appropriate study conclusion. Several considerations will help accomplish this goal.

First, identify the key result. This is usually the prespecified main outcome or the data that directly address the hypothesis for which the study was conducted.

Downloaded from academic.oup.com/book/58841 by guest on 17 October 2026

Second, determine whether that result is statistically significant (or not), given the prespecified statistical threshold of the study or traditional statistical interpretation. Also, consider the strength of the results from a statistical perspective. For example, a relative risk of 1.2 will require a very different interpretation than a relative risk of 4.3. A main result that includes an effect size with a wide confidence interval will require a more measured interpretation than one with a narrow confidence interval.

Third, consider the clinical importance of the findings. Sometimes the clinical importance and statistical significance of a result differ. A statistically significant odds ratio may not be clinically important or significant if, for example, the absolute improvement in outcome is small. A non–statistically significant result that is close to the threshold for statistical significance but may have reached statistical significance in a larger study deserves careful and perhaps guarded comment.

Fourth, carefully choose the language needed to accurately convey the findings. Causal language would be appropriate for a clinical trial, while reporting an association would be appropriate for most observational studies, unless rigorous methods specifically designed to support causal inferences are included. A strong result may justify use of words such as "demonstrate"; a weaker result may require words such as "suggest."

Fifth, be sure to acknowledge any important limitations to interpretation of the study results, such as application to a specific population (eg, adults over 65 years) or location (eg, rural health care setting). If there were important limiting design elements (such as a single center), these should be included. The conclusion should not go beyond the findings of the study (for example, by suggesting that the results from a study conducted in one city apply to patients throughout an entire country).

Having established the study conclusion, the initial paragraph of the Discussion section can be written, which should state the key finding and conclusion. If the research question was complex, it may be useful to remind the reader of the study hypothesis or context first. The key finding does not need to reiterate the quantitative data that were generated. Subsequent paragraphs may highlight other important results, such as secondary or subgroup analyses or findings that were unusual or unexpected. Secondary or subgroup results may or may not support the primary result, and so the pattern of results (ie, secondary outcomes that are not statistically significant but in the direction of the primary outcome) may be important to consider. However, every outcome that was reported in the Results section need not be revisited in the Discussion section. Relevant secondary findings should not be given as much weight as the primary outcome, and limitations of these outcomes should be clearly acknowledged.

For example, in a multicenter, prospective observational cohort study of very low-birth-weight infants, researchers investigated the association between

Downloaded from academic.oup.com/book/58841 by guest on 17 October 2026

the primary exposure of red blood cell (RBC) transfusion and a secondary exposure of anemia and the occurrence of necrotizing enterocolitis (NEC). The authors found an adjusted cause-specific hazard ratio for transfusion that was not statistically significant but a statistically significantly increased hazard ratio for anemia, although with a wide confidence interval. The conclusion of the study, presented in the first sentence of the Discussion section, focused on the primary outcome: "RBC transfusion was not an independent risk factor for NEC." The secondary outcome was clearly important but with less confidence in the result and was addressed in the second paragraph of the Discussion section using more moderated language: "In addition, the results suggest that severe anemia may be an important potential risk factor for NEC."[1]

After presenting the most important results in the first few paragraphs of the Discussion, possible reasons for the findings should be addressed. Do the results of the study support or refute the hypothesis? What is the most likely explanation, and what are possible alternative explanations for the findings? The Discussion should not be too speculative, however. Pathophysiologic or mechanistic explanations that might support the results should be included, but extensive discussion of this nature is usually distracting rather than enlightening.

Placing the Results in Context and Addressing Implications

The Discussion section should also place the findings within the context of the existing literature. There is no best place to position the literature review. It can be summarized in a separate paragraph, or the relevant literature may be interwoven with discussion of the individual study findings. A comprehensive review of all previous studies is rarely possible. Rather, authors should focus on studies that are most relevant in terms of content and most rigorous in terms of study design, size, or representativeness. For instance, it may be helpful to include a brief discussion (ie, a paragraph or 2) explaining how the results of the study compare with other studies that have similar findings, and to include a brief discussion (ie, a paragraph or 2) explaining how the study findings contrast with previous studies that have different findings. This approach may help readers understand possible explanations for consistent or discordant findings. Inclusion of quantitative results from the cited studies may be helpful. Highlight differences in study design, study sample, or type of measurement that may explain conflicting findings across studies. For example, if previous studies did not find an association between an exposure during pregnancy and congenital anomalies, but a larger study examining exposure in each trimester found an association only with first-trimester exposure, a possible mechanism is suggested. The literature review can also help readers understand whether the study being reported is primarily confirmatory or appreciate the novel contribution made.

Downloaded from academic.oup.com/book/58841 by guest on 17 October 2026

When discussing the work of previous investigators, authors should provide a factual, objective description rather than critical presentation.

The Discussion section should also delineate the implications of the study. If the study is preliminary or has many limitations, perhaps the only implications are for further study in a larger sample. If the study is well designed with a statistically significant result, implications for clinical practice should be detailed. Some investigations may have implications pertaining to economic or policy considerations, which can be highlighted in a balanced, objective manner. It may also be important to indicate what the results do not imply, so that readers and other scientists do not overinterpret the results. Study findings often need to be extended or replicated in other populations. However, it is not sufficient to simply say, "further research is required"; be specific about what the next step should be.

Study Strengths and Limitations

Another important component of the Discussion section is acknowledgment of the strengths and weaknesses of the study, which should each be summarized in a paragraph or 2. A few sentences devoted to the strengths of the study—for example, the study design (ie, clinical trial), sample (ie, large or nationally representative), or analysis (ie, propensity score matching to control for confounders)—are usually sufficient. The list of limitations should be relatively comprehensive; being upfront about the limitations of the study demonstrates authors' objectivity, honesty, and humility about their work. Acknowledgment of limitations also may prevent potentially embarrassing exchanges in the letters column when readers write in about potential flaws in the study. Limitations often include the study design (ie, retrospective observational study), study sample (ie, small), and measures (ie, self-report). Whether the sample is representative of the population from which it was drawn is important to include, as well as whether the results are generalizable or limited to certain patient groups. Possible sources of bias, such as recall bias, should be discussed, and the ways bias might have affected the results considered. The power of the study should be explicitly discussed if a study has null or neutral findings. Present evidence from the study or the literature to support or refute the limitations if possible.

Concluding Paragraph

Although in general repetition is to be avoided in the Discussion section, the final paragraph is an exception. The concluding statement should reinforce the

Downloaded from academic.oup.com/book/58841 by guest on 17 October 2026

primary findings of the study. The conclusion may consist of a single or a few sentences and may or may not be set off with a heading. In some journals, such as *JAMA,* a Conclusion subhead is used and authors are asked to repeat the conclusion, using the same language as is used in the conclusion of the Abstract. This reinforces the main finding and take-home message of the study.

Other Considerations

When finalizing the Discussion section, authors also should be sure to consider the following. The Discussion section should not introduce new methods, results, or analyses. It should not raise issues that are not directly related to the topic. The Discussion is not the place for authors to express their opinions, especially if the topic is controversial—this type of text should be reserved for opinion articles.

Discussion sections vary in length and structure in different journals, so authors should consult the instructions for authors and look at examples in the journal of interest. The length of the section will depend on the results and the previous literature available to review, but in general it is best to keep it as short and concise as possible.

Conclusion

Writing a Discussion section can help authors think critically about their work and help readers understand the study and its place in the scientific literature. A well-done Discussion section not only serves to tie the manuscript together but can provide the bow on top.

Reference

1. Patel RM, Knezevic A, Shenvi N, et al. Association of red blood cell transfusion, anemia, and necrotizing enterocolitis in very low-birth-weight infants. *JAMA*. 2016;315(9):889-897. doi:10.1001/jama.2016.1204

Downloaded from academic.oup.com/book/58841 by guest on 17 October 2026

CHAPTER 16

Referencing and Using Reference Managers

Pamela L. Shaw, MSLIS, MS, Kristi Holmes, PhD, and Philip Greenland, MD

Downloaded from academic.oup.com/book/58841 by guest on 17 October 2026

KEY POINTS

- References attribute ideas and results to their original source and can demonstrate the flow of ideas in the scholarly literature, the emergence of new research domains, and the influence of research on policy, clinical practice, media attention, and public engagement.
- Authors should include important previously published work as references in the manuscript but avoid citing obvious facts that an informed reader would be expected to know.
- References that support the findings and that counterbalance the findings in a report should be included. It is important to present an even-handed approach to the evidence.
- Referencing has evolved to reflect increased attention on evolving research practices and greater emphasis on open processes.
- Authors should follow journal instructions for formatting and for the number of references.
- Reference management tools are widely available and can reduce errors and increase productivity, but there is an initial investment in time to learn the functions of the tool.
- A wide variety of reference management tools are available, and there is no best tool for everyone. Libraries may make an institutional decision in selecting reference management tools, but authors should consider several key differences when selecting a personal reference manager.

General Considerations

Referencing the literature is a critical component of medical and scientific writing. References help demonstrate the influence of prior articles on a given work

and provide a way to attribute ideas and results to their original sources. References can help readers understand the development of ideas in the scholarly literature and the emergence of new research domains. Also, leveraging citation counts in bibliographic indexes and social media attention metrics can serve as a critical indicator of use of the referenced work, which is particularly important in understanding the influence of research on clinical practice, policy, media attention, and public engagement.[1-3] Accurate referencing allows readers to find relevant publications closely associated with the topic of the published report. References are also important to demonstrate that authors are familiar with the relevant previous research on the topic being studied and that those findings and ideas have been appropriately considered and incorporated into the report.

Some basic questions about using references in a submitted manuscript include how many references should be cited and what should be referenced. The instructions for authors of some major medical journals may describe how many references are considered acceptable for a specific type of manuscript; for example, *JAMA* suggests 50 to 75 references for a meta-analysis, and the *New England Journal of Medicine* suggests up to 40 references for an original research article. The following suggestions may be useful for authors in determining what references to include and what not to include when preparing a manuscript.

Since citations to previous work suggest a degree of familiarity with the previous research on the topic, authors should include references for any major article on the topic that served as critical background for the new manuscript. It is impossible to demonstrate that there is a gap in the literature that a new manuscript will address unless the authors can show that important previously published articles have not covered the specific topic being addressed. Authors must search the literature carefully and thoroughly for previous reports that are related to the topic of the manuscript they are preparing. Omission of a critically important previously published report on the topic of the manuscript could be interpreted by reviewers or editors as a lack of true familiarity with the subject matter or perhaps as evidence of a lack of thoroughness. Therefore, it is important for authors to cite relevant literature to demonstrate command and sufficient knowledge of the subject area. Examples of important citations might include reports of major clinical trials, authoritative clinical practice guidelines, recent meta-analyses, or reports from important and influential groups such as the US National Academy of Medicine or the World Health Organization. One practical way for authors to know if they have included the key and important references is to ask a colleague who is knowledgeable about the subject area to review the manuscript before submitting it to a journal. Any important omissions of key references could be added at this stage of manuscript preparation.

Downloaded from academic.oup.com/book/58841 by guest on 17 October 2026

While authors want to avoid key omissions, it is also important to avoid excessive citations. If a point is well known and widely accepted, it does not need to be cited, and often does not need to be stated in the manuscript. An example would be that the disease tuberculosis is caused by *Mycobacterium tuberculosis*. Another example would be that cardiovascular disease is a leading cause of morbidity and mortality in men and women in most countries. These are well-known facts that might be omitted, but if included, they would not need to be supported with citations. However, in a manuscript about new tuberculosis treatments, it would be important to mention and cite previous work relevant to specific therapies. Similarly, in a manuscript about new treatments for heart failure, it may be helpful to include current information about the prevalence of disease to indicate the number of patients who may be eligible for the treatment, supported with key references. Referencing should also seek to be balanced and include all relevant opinions on a given topic. This is especially important in a discussion section of a manuscript where both previous supportive and contradictory work should be cited. From a practical point of view, addressing these different sides of a given question will help place the new findings reported in the manuscript in proper context and provide balance in the interpretation.

Authors should ensure that references included in the manuscript are as current as possible, especially when reporting background information, such as basic data on epidemiology, incidence, prevalence, health care spending, costs of treatments, or lost productivity. Contemporary references make the manuscript as meaningful as possible for readers and demonstrate that the literature review is current. It is also a good practice for authors to search carefully within the target journal for previously published articles that are relevant to the topic of the manuscript being submitted to the journal. Awareness and citation of such articles helps the reviewers and editors recognize that previous work on the topic of the manuscript was considered relevant to the journal; it also may help the editors by indicating possible reviewers. However, it is not necessary to cite articles from the target journal without good reason. Editors may question such a practice and could be concerned about efforts to manipulate the review process.

Several other practical points should be considered. If a journal's instructions for authors state a specific limit to the number of references, authors should adhere strictly to this instruction. These are not "suggestions" to be considered; they are instructions to follow. Editors might well assume that authors who greatly exceed the citation limits described in the author instructions have not read them or lack attention to important detail. This also may create a negative perception about the manuscript that is avoidable. On the other hand, when no specific instruction is given, it is possible that the journal may limit the number of references even when the manuscript is favorably reviewed and being seriously considered for publication.

Downloaded from academic.oup.com/book/58841 by guest on 17 October 2026

In addition, because the purpose of including a citation is to establish precedence and provide additional background, it is important to avoid use of "in press" or "in submission" citations. Very few journals will allow such citations, and they fail to accomplish the main purpose of a citation. Preprint servers can serve as a means of establishing precedence of new research and serve as a valuable mechanism to communicate an interim research product.[4] (See also Chapter 40, Preprints, Preprint Servers, and Biomedical Publication.) It is reasonable to cite those preprints as references if they are relevant. If these preprint sources are cited, they should be clearly denoted as preprints. Authors can also cite an abstract of research that has been presented at a formal meeting, if the research has not yet been published and provided they indicate the name of the presenter(s) and meeting and the date of presentation in the reference.

Importantly, authors should never cite a reference that they have not read and should not cite a general review article as a source for a specific data point (such as mortality rates or disease incidence or prevalence). Authors should always examine the original primary source report and find the fact they need to cite.

Formatting References

A properly formatted reference provides all the information necessary to identify and find a referenced work. Book citations generally include information such as the author, the title of the book, and original and electronic publication information (if the book is available electronically). For a peer-reviewed journal article, citations generally include information such as the author, article title, journal title, date of publication, volume and issue number, page numbers or e-locators, and a persistent identifier (PID). Persistent identifiers are unique alphanumeric character strings that can refer to a physical object, a digital object, and even a person. Incorporation of a PID in a reference provides a lasting, unambiguous link between the text and referenced research object. Persistent identifiers also serve as an important component of bibliographic and attention metrics, providing a direct way to track use of the object, as well as helping to facilitate interoperability. Digital object identifiers (DOIs) are the most frequently used PIDs for both interim (eg, preprints) and final digital research publications (eg, journal articles) and are frequently incorporated as a referencing best practice for a wide range of research products. When citing information from a website, authors should provide a complete reference, including the publisher or producer of the website, author(s) (if provided), the title of the information being cited, the date the information was released, the date the information was accessed, and a uniform resource locator (URL) that links to the website. Authors should also retain a copy (ie, screenshot or printout) of the material, as information on websites may change over time.

Downloaded from academic.oup.com/book/58841 by guest on 17 October 2026

The References section of the *AMA Manual of Style*[5] is an excellent resource for reference documentation and formatting. This authoritative and regularly updated resource provides numerous examples of how to cite print and electronic references for journal articles, books, monographs and special reports, websites, news and social media, audio, video, transcripts, meeting presentations, databases, repositories, preprints, legal references, and unpublished documents. Another excellent resource to understand the diversity of primary source materials is *Citing Medicine: The NLM Style Guide for Authors, Editors, and Publishers*.[6] This authoritative resource provides guidance on formatting bibliographic citations across a wide range of resources and usages and includes a discussion of citation rules and examples of the specific citations. Each *Citing Medicine* chapter addresses a separate bibliographic format, including published print documents, unpublished material, audio and visual files, and internet resources. Journal instructions for authors also usually include examples of proper citation for that specific journal. Examples of reference formats used in the JAMA Network journals for some commonly cited materials are shown in **Table 16-1**.

Table 16-1. Examples of Common Reference Types, Formatted Using the *AMA Manual of Style*

Reference type	Example of reference
Journal article	Leening MJ, Berry JD, Allen NB. Lifetime perspectives on primary prevention of atherosclerotic cardiovascular disease. *JAMA*. 2016;315(14):1449-1450. doi:10.1001/jama.2016.1654
Online-only journal article	Gomes T, Tadrous M, Mamdani MM, Paterson JM, Juurlink DN. The burden of opioid-related mortality in the United States. *JAMA Netw Open*. 2018;1(2):e180217. doi:10.1001/jamanetworkopen.2018.0217
Article published online ahead of print	Adalja AA, Toner E, Inglesby TV. Priorities for the US health community responding to COVID-19. *JAMA*. Published online March 3, 2020. doi:10.1001/jama.2020.3413
Book in print	Guyatt G, Rennie D, Meade MO, Cook DJ, eds. *Users' Guides to the Medical Literature: A Manual for Evidence-Based Clinical Practice*. 3rd ed. McGraw-Hill; 2015.
Book online	Guyatt G, Rennie D, Meade MO, Cook DJ, eds. *Users' Guides to the Medical Literature: A Manual for Evidence-Based Clinical Practice*. 3rd ed. McGraw-Hill; 2015. Accessed January 18, 2021. https://jamaevidence.mhmedical.com/content.aspx?bookid=847&sectionid=69030714
Legal case	*Green v Douglas*, 12 B4d 11 (Juvenile Dom 2010). See the *AMA Manual of Style*[5] for additional guidance.
Document on government website	About the USPSTF. US Preventive Services Task Force. March 2019. Accessed January 18, 2021. https://www.uspreventiveservicestaskforce.org/uspstf/about-uspstf Federal, Provincial and Territorial Advisory Committee on Population Health. *Statistical Report on the Health of Canadians*. Statistics Canada; 1999. Accessed January 18, 2021. https://www150.statcan.gc.ca/n1/en/pub/82-570-x/4227736-eng.pdf?st=n2LuLQKJ
Preprint	Bar DZ, Atkatsh K, Tavarez U, Erdos MR, Gruenbaum Y, Collins FS. Biotinylation by antibody recognition—a novel method for proximity labeling. *bioRxiv*. Preprint posted online August 11, 2016. doi:10.1101/069187

Downloaded from academic.oup.com/book/58841 by guest on 17 October 2026

As with many aspects of manuscript preparation, authors should review a journal's instructions for authors and follow the specific directions for reference formats.

Using Reference Management Software

Reference management software is a boon to authors and should be used to the greatest extent possible. These software tools help authors find, collect, and organize large numbers of references in a single application interface. They improve efficiency and reduce errors in referenced documents and provide a way, through interoperability with word processing software, to cite references in-text and to build a bibliography without having to type each reference in the document. Authors can easily copy and move large blocks of text along with references and rely on the software to reorder and renumber references automatically.

Reference managers save authors time by providing a library of journal or publisher reference styles, or the ability to create a custom style to suit the publisher's requirements. Reference management software should help authors to work collaboratively from a single shared library of references. Reference managers also should be easy to learn, provide adequate training documentation, and possess user interfaces that are logical and user-friendly. The best reference managers can identify duplicate references in libraries and assist the user in removing these duplicates; allow users to bulk edit multiple references at once; and find reference updates by remote search of online reference databases and automatic import of updated information.

Many good reference managers are available, offered as open-source (free) software or for purchase or institutional license. For authors at academic institutions, the choice of a reference manager is often made by the institutional library unless the author wishes to buy a specific product directly. A few guidelines for selecting a reference manager are listed in **Table 16-2**.

Emerging Referencing Practices

Evolving research practices and greater emphasis on open processes has motivated citation practices that consider interim research products, as well as the greater range of research products created during research. Generally, citations should reflect the style specified by the publication and include the creator, title, publication year, publisher, and PID. This information allows the reader to clearly distinguish critical details about the referenced digital object. Interim research products such as preprints, protocols, and study registrations are encouraged by the National Institutes of Health to speed the dissemination

Downloaded from academic.oup.com/book/58841 by guest on 17 October 2026

Table 16-2. Factors to Consider in Selecting a Reference Management Tool

Criteria	Considerations
Operating system	Does the software offer a Windows, Mac, Linux, or browser-based mobile version?
Where data are saved and stored	Is the software installed as a desktop client? Are references stored on a machine or available anywhere via the cloud?
Availability and cost	Does the author's organization provide access? What version is available?
Interoperability	How easy is it to retrieve metadata from publication indexes?
Ability to handle citations from sources other than journal articles and books	Are reference types beyond periodical publications and monographs included? Is the user able to create records manually?
Interface and user experience	Does the software interface promote ease of use?
Update frequency and maintenance	Is the software well maintained with regular updates and bug fixes? Is the documentation sufficient to support ongoing use of the tool?
Collaboration potential	Can references be easily shared with collaborators, and does the software integrate with common collaborative tools used by teams?

and enhance rigor.[7] The References section of the *AMA Manual of Style*[5] and *Citing Medicine*[6] are excellent resources to guide referencing of such products. Data set and software citation practices vary across disciplines; however, community standards have been developed through FORCE11 community in the Joint Declaration of Data Citation Principles[8] and the Software Citation Principles.[9]

Conclusion

Appropriate and meaningful citation of research products accomplishes several critical goals. Meaningful referencing helps to support proper attribution and credit, support collaboration and reuse of data, enable reproducibility of findings, foster faster and more efficient research progress, and provide the means to share data with future researchers. Resources to support this activity are found throughout this chapter and can also be available through librarians and other research resources.

References

1. Sarli CC, Dubinsky EK, Holmes KL. Beyond citation analysis: a model for assessment of research impact. *J Med Libr Assoc*. 2010;98(1):17-23. doi:10.3163/1536-5050.98.1.008

Downloaded from academic.oup.com/book/58841 by guest on 17 October 2026

2. Luke DA, Sarli CC, Suiter AM, et al. The Translational Science Benefits Model: a new framework for assessing the health and societal benefits of clinical and translational sciences. *Clin Transl Sci*. 2018;11(1):77-84. doi:10.1111/cts.12495
3. Deshpande A, Hood C, Leach B, Guthrie S. Existing indicators to measure the biomedical innovation ecosystem: a targeted landscape review for FasterCures. RAND Corporation; 2019. Accessed June 13, 2023. https://www.rand.org/pubs/working_papers/WR1312.html
4. Funk K. NIH preprint pilot expands to include preprints across NIH-funded research. National Institutes of Health. *Extramural Nexus*. February 8, 2023. Accessed June 13, 2023. https://nexus.od.nih.gov/all/2023/02/08/nih-preprint-pilot-expands-to-include-preprints-across-nih-funded-research/
5. Fischer L, Frank P. References. In: Christiansen S, Iverson C, Flanagin A, et al, eds. *AMA Manual of Style: A Guide for Authors and Editors*. 11th ed. Oxford University Press; 2020. Accessed September 11, 2023. https://academic.oup.com/amamanualofstyle/book/27941/chapter/207563234
6. Patrias K, Wendling DL, eds. *Citing Medicine: The NLM Style Guide for Authors, Editors, and Publishers*. 2nd ed. National Library of Medicine; 2007. Updated 2015. Accessed June 13, 2023. https://www.ncbi.nlm.nih.gov/books/NBK7256/
7. Reporting preprints and other interim research products. US National Institutes of Health. March 24, 2017. Accessed June 13, 2023. https://grants.nih.gov/grants/guide/notice-files/NOT-OD-17-050.html
8. FORCE11 Data Citation Synthesis Group. Joint Declaration of Data Citation Principles. FORCE11. 2014. Accessed June 13, 2023. https://force11.org/info/joint-declaration-of-data-citation-principles-final
9. Smith AM, Katz DS, Niemeyer KE; FORCE11 Software Citation Working Group. Software citation principles. *PeerJ Comput Sci*. 2016;2:e86. doi:10.7717/peerj-cs.86

Downloaded from academic.oup.com/book/58841 by guest on 17 October 2026

CHAPTER 17

Effective Use of Figures and Tables in Scientific Articles

David L. Schriger, MD, MPH, and
Stephen M. Schenkel, MD, MPP

Downloaded from academic.oup.com/book/58841 by guest on 17 October 2026

KEY POINTS

- Figures and tables in a scientific article present key evidence, support inferences and conclusions, and contribute to a clear, logical, and cohesive report.
- Figures display relationships and change; tables display exact quantities.
- The ideal scientific report contains just enough illustration through figures and tables to ensure clarity and concise presentation of key information.
- The optimal data display will often include elements of both figures and tables.

Figures and tables are essential elements of scientific articles and are critically important for effectively and efficiently presenting scientific data and other information. The thought and effort expended in the design of tables and figures should match their importance as communication tools. Properly used, tabular and graphical elements present key evidence, support inferences and conclusions, and contribute to a clear, logical, and cohesive article.

This chapter reviews the effective use of figures and tables, including how to choose the optimal format: a figure, a table, or a hybrid of the two. (For detailed guidance specific to tables and figures, see Chapter 18, Creating Effective and Efficient Tables, and Chapter 19, Effective Use of Figures and Graphs in Scientific Publications. For additional information, see also Chapter 4.0, Tables, Figures, and Multimedia, in the *AMA Manual of Style*.[1])

General Principles

The creation and use of graphical elements in scientific manuscripts, while guided by scientific principles, is very much an art. Although there is no exact recipe for each type of manuscript, authors should heed several theoretical principles and pragmatic considerations regarding the creation of figures and tables.

Ensure That One Figure or Table Compellingly Shows the Main Results

In virtually all scientific manuscripts, the most important findings usually can be communicated in a single figure or table that should be the centerpiece of the manuscript. This figure or table would be the most important visual shown in a presentation of the research. In many instances this element will be a figure because a well-designed figure can succinctly present the key information that complements the text. Figures can show trends in the data over time, compare distributions of important continuous outcomes, depict the results of individual participants, or a combination of the above. For most studies (except those with a very small sample size), a figure, in contrast to a table, is the only format that shows data at the unit of analysis and the only format that depicts paired data point-by-point.[2] However, when the primary outcome is simple, compelling, and binary (eg, proportion of study participants alive), a table of key results with the primary outcome clearly labeled and prominently featured may be the most appropriate graphical element. Whatever the format, care should be taken to design an illustrative figure or table that stands alone to clearly convey the research findings.

Create a Set of Coordinated, Comprehensive Graphic Elements

Effective use of figures and tables requires that each graphic is prepared appropriately, that the information is clearly presented, and that the figures and tables are ordered logically, are properly interrelated, and are not redundant or excessive. Graphical elements should follow the internal logic of the manuscript and be consistent with the order of information presented in the Methods and Results sections. The figures and tables should augment, rather than duplicate, information in the text.

Downloaded from academic.oup.com/book/58841 by guest on 17 October 2026

For most research manuscripts, effective presentation could proceed across 4 or 5 figures and tables. For example, a scientific manuscript reporting the results of an interventional clinical trial often will include the following:

- Figure 1, a flow diagram appropriate for the study design (see the EQUATOR Network for design-specific examples[3]) showing the recruitment, randomization, and retention of participants, or the development of cohorts;
- Table 1, showing baseline characteristics of each group in the study sample;
- Two figures or tables showing quantitative results with 1 clearly illustrating the primary study outcome; and
- If relevant, another table or figure showing adverse events, subgroup analyses, or specific examples.

Depending on the volume of study data and complexity of the study methods and analyses, additional tables and figures reporting sensitivity analyses, ancillary analyses, or post hoc analyses may be presented either in the main manuscript or in a supplement. In all cases, judgment is required, because excessive use of tables or figures in the main article may obscure the primary message.

There is less standardization of the figures and tables in observational studies than in interventional trials because designs vary widely. Nevertheless, limiting the presentation to a reasonable number of graphics (perhaps a total of 4 to 5, depending on the complexity of the study and the amount and types of data being presented) leads to a streamlined and accessible presentation that minimizes distraction. For many observational studies, a flowchart should be considered as an initial figure. This single feature establishes both the flow of the study participants and the details in the design (eg, assembly of the cohort, key exposure variables, and completeness of follow-up) and functions as an outline and overview of the study. A Table 1 that characterizes the study sample remains an essential element. It is important to not mix baseline variables with any adjusted variables in this initial table. Two figures or tables will usually suffice to present the main findings of the research, at least 1 of which, ideally, is a figure that depicts the data in detail. Observational studies may have substantial supplementary tables and figures that include additional data, stratified analyses, ancillary approaches, and sensitivity analyses. The degree to which each of these graphical elements adds insight or nuance to the primary message determines whether it should be in the main manuscript or the supplement.

Follow the Guidelines of the Journal

Selection and presentation of figures and tables should align with the usual practices of the journal to which authors plan to submit their manuscript.

Downloaded from academic.oup.com/book/58841 by guest on 17 October 2026

Journals have specific requirements for manuscript preparation and often have guidance regarding preparation of figures and tables. See, for example, the detailed guidance provided in the JAMA Network's Instructions for Authors.[4] Authors should review articles published in the target journal and read the journal's instructions for authors to determine the number, size, complexity, and characteristics of tabular and graphical elements. A correctly formatted manuscript that follows the journal instructions, even though potentially time consuming to create, may be more likely to merge as intended within the journal's tracking system and serves to provide editors and peer reviewers with a manuscript that is consistent with journal style and requirements, such as types and numbers of graphics. While some journals may recreate, redraw, or otherwise assist with preparation of figures, this cannot be assumed.

Choose the Optimal Visual Format

In a scientific article, the choice of figure or table should be governed by the type, purpose, and complexity of the information and data being presented and the concepts being conveyed. On occasion the results of some studies are so simple that they can be conveyed most efficiently with text; however, most studies involve more complex relationships among data that require figures and tables for optimal illustration.

Tables are numbers arranged on a rectilinear grid that facilitates comparison and pattern recognition. Figures are useful when comparison among groups or over time is of primary importance.[5] Tables are useful when the exact values are more important than the relationships among them.[6] (For additional information, see also Box 4.1-1, Guidelines for Using Text, Tables, and Figures to Display Numerical Data, in Chapter 4.0, Tables, Figures, and Multimedia, in the *AMA Manual of Style*.[1])

Tables

The example table, **Table 17-1**, effectively shows a binary comparison in 2 different cohorts for the primary analysis.[7] The comparison is straightforward and compelling and readily understood in a tabular form and therefore a table is chosen for display. Uncertainty is represented as a 1-sided confidence interval and portrayed as an integral element in the table. Labeling identifies the primary outcome and allows inclusion of secondary outcomes. Main comparisons are arranged left to right following the standard English language inclination to read information horizontally along rows instead of vertically within columns.

Downloaded from academic.oup.com/book/58841 by guest on 17 October 2026

Table 17-1. Example of Binary Comparison in 2 Different Cohorts for the Primary Analysis
Intubation Characteristics and Outcomes of Patients in a Study of the Effect of Rocuronium vs Succinylcholine on Out-of-Hospital Endotracheal Intubation Success

	No./Total no. (%)		Absolute difference (95% CI), %[a]	*P* value[b]
	Rocuronium group	Succinylcholine group		
Primary outcome (successful first-attempt intubation)				
Per-protocol analysis	455/610 (74.6)	489/616 (79.4)	−4.8 (1-sided 97.5% CI, −9.0 to ∞)[c]	
Randomized group analysis	456/613 (74.4)	489/617 (79.2)	−4.8 (1-sided 97.5% CI, −9.1 to ∞)[c]	
Secondary outcomes				
Prespecified analyses				
Cormack-Lehane grade[d]				
I (best view)	375/609 (61.6)	346/616 (56.2)	5.4 (−0.3 to 10.9)	.06
II	125/609 (20.5)	173/616 (28.1)	−7.6 (−11.5 to −3.7)	<.001
III	81/609 (13.3)	72/616 (11.7)	1.6 (−2.9 to 6.2)	.49
IV (worst view)	28/609 (4.6)	25/616 (4.0)	0.6 (−1.5 to 2.6)	.60

[a]The estimated difference between the groups was calculated with a 2-sided 95% CI using a generalized estimated equation model, in which center was specified as the clustering factor.

[b]Not corrected for multiple comparisons.

[c]The estimated difference between the groups was calculated with a 1-sided 97.5% CI using a generalized estimated equation model, in which center was specified as the clustering factor. The margin for noninferiority was set at −7%. A lower bound of the CI that did not exceed this margin indicated noninferiority.

[d]Reflects glottis visualization. Range, 1-4; higher scores indicate less glottis visualization.

Reproduced from Guihard et al.[7]

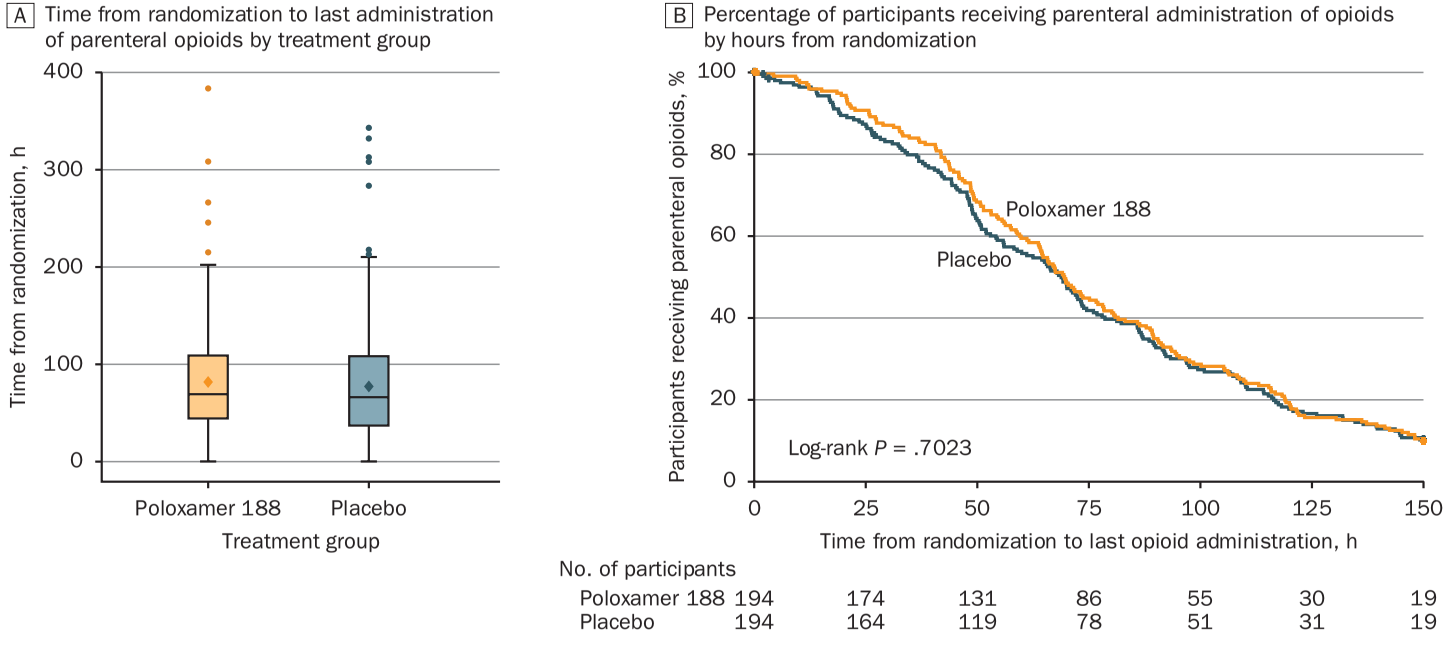
Scientific investigations may generate large amounts of data. Tables can both display and obscure that data. The latter occurs when the core data are surrounded by an excessive amount of less important data, when prespecified outcomes are not reported, or when the table layout is designed to selectively overemphasize data that support a specific interpretation. These tendencies should be avoided; at best they may be perceived as poor design, at worst as possible misrepresentation of data. Large volumes of complex data may be better summarized in figures with supplemental or archival tables providing actual values.

Figures

In the example in **Figure 17-1**, paired panels from a single figure highlight the primary outcome of a study in 2 different ways and highlight relationships, depict differences over time, and illustrate the overall result.[8] The box

Downloaded from academic.oup.com/book/58841 by guest on 17 October 2026

Figure 17-1. Example of Box Plots and a Kaplan-Meier Curve to Highlight the Primary Outcome of a Study in 2 Different Ways



Reproduced from Casella et al.[8]

Downloaded from academic.oup.com/book/58841 by guest on 17 October 2026

plots in Panel A illustrate the variation in findings, including both the overall results and the tails of extreme measures; in this way, individual variation is captured within the context of a composite result. Panel B presents a traditional Kaplan-Meier curve that shows how the outcome changes over time in each group. The 2 panels provide complementary views of the data that together allow enhanced understanding of variability and change over time.

Figures may include statistical graphs, maps, diagrams, matrices, algorithms, illustrations, digital images, photographs, or other clinical images. (For a more detailed discussion of figures, see Chapter 19, Effective Use of Figures and Graphs in Scientific Publications. For additional information, see also Chapter 4.0, Tables, Figures, and Multimedia, in the *AMA Manual of Style*.[1]) Figures clarify complex concepts including theoretical models (eg, variables and pathways in mediation analyses) and analytic approaches (eg, analytic interrelationships in network meta-analyses). In some studies, figures represent or illustrate actual data, including radiographs or photographs of anatomy at various levels of magnification. Figures foster multiple comparisons and complex considerations and can serve to signal which of many potential comparisons are the most important. Patterns indicated by lines, symbol type, color, and faceting all contribute.[6] Specific research disciplines may have developed unique graphical formats that allow readily accessible shorthand interpretation of the underlying findings for those most familiar. Examples of this include Rankin Scale Score comparisons in stroke,[9] Manhattan plots in genetics,[10] and network meta-analysis plots.[11]

Titles, Legends, and Footnotes

A title introduces a table or figure and provides the minimum detail needed to understand what is reported. A legend is descriptive text that appears below a table or figure. A legend for a table typically provides expansions for abbreviations or acronyms, and footnotes provide additional explanation for specific table elements. A legend for a figure adds the essential, global details that enable a better understanding of what is being reported. Even with thoughtfully written titles, legends, and footnotes, it can be difficult to develop a figure or a table that is both self-explanatory and includes all the information needed for proper interpretation. Care must be taken not to overwhelm the display with excessive commentary in the legend. Footnotes help address this issue and can provide important but nonessential information. Notes that briefly summarize reported scales, illuminate research methodology, and clarify missing data all help figures and tables stand on

Downloaded from academic.oup.com/book/58841 by guest on 17 October 2026

their own while permitting reading both at a glance and in depth. See the example legend and footnotes in Table 17-1.

The Figure-Table False Dichotomy

The idea that authors must choose between a figure and a table when preparing graphics is pragmatically true but theoretically false. Journal publishers often have different processes for preparing tables and figures for publication, necessitating that each element is classified and labeled as a table or a figure. From a theoretical perspective, however, figures and tables lie along a continuum, and hybrid forms combining elements of both may be an optimal way to present data for clear and efficient communication.

In the example in **Figure 17-2** of a subgroup analysis, a table of values provides precise data for the multiple comparisons and relationships among the different groups.[12] The data are arranged horizontally (from left to right), from data based on stratified results portrayed as n/N (%) to ratios to within-group *P* values to between-group (interaction) *P* values. The single graphical element (the forest plot) naturally draws the eye, readily summarizes the hazard ratios, and allows vertical comparison in a natural manner that augments the left-to-right horizontal flow of the tabular material.

The corollary can also take place, when the graphical presentation is augmented with the precise values of a table. The table of the numbers of study participants at risk of falling below the *x*-axis of a Kaplan-Meier curve is one common example. (See Panel B in Figure 17-1.) Investigators should feel free to combine whatever graphical elements most clearly convey their data.

The addition of other forms of graphical elements, such as cell shading, color, bolding, italics, and shapes, can call attention to patterns and findings, provided these elements do not overemphasize selective findings or clutter an important graphical message. (Examples can be found in Chapter 4.0, Tables, Figures, and Multimedia, in the *AMA Manual of Style*.[1])

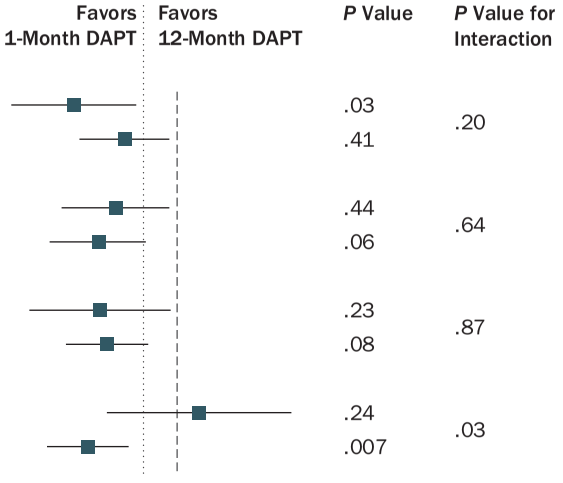
Conclusion

General principles guide the development of figures and tables for a manuscript. The primary findings should ideally be summarized in a single graphical element, a figure if the primary outcome is not binary. Figures and tables should be presented logically, be properly interrelated, avoid redundancy, and be readily understood in isolation. These graphical elements should be designed and presented with the same care as the text of the article. Authors should follow the guidance journals offer regarding preparation and submission of tables and figures.

Downloaded from academic.oup.com/book/58841 by guest on 17 October 2026

Figure 17-2. Example of Table and Forest Plot for a Subgroup Analysis

	No./Total (%)					
	1-Month DAPT (n = 1500)	12-Month DAPT (n = 1509)	HR (95% CI)	Favors 1-Month DAPT	Favors 12-Month DAPT	*P* Value	*P* Value for Interaction
Age, y							
≥75	10/448 (2.26)	25/499 (5.08)	0.44 (0.21-0.92)			.03	.20
<75	25/1052 (2.41)	30/1010 (3.02)	0.80 (0.47-1.36)			.41	
Acute coronary syndrome							
Yes	16/565 (2.88)	23/583 (4.02)	0.72 (0.38-1.36)			.44	.64
No	19/935 (2.05)	32/926 (3.49)	0.59 (0.33-1.03)			.06	
STEMI							
Yes	9/291 (3.15)	14/270 (5.26)	0.60 (0.26-1.38)			.23	.87
No	26/1209 (2.18)	41/1239 (3.36)	0.65 (0.40-1.06)			.08	
Severe chronic kidney disease							
Yes	9/82 (11.22)	5/84 (5.97)	1.93 (0.65-5.75)			.24	.03
No	26/1418 (1.86)	50/1425 (3.56)	0.52 (0.32-0.84)			.007	



Reproduced from Watanabe.[12]

Downloaded from academic.oup.com/book/58841 by guest on 17 October 2026

ACKNOWLEDGMENT

The example table and figures shown in Table 17–1 and Figures 17–1 and 17–2 are based on a previously published Table and Figures.[7,8,12]

References

1. Christiansen S, Manno C. Tables, figures, and multimedia. In: Christiansen S, Iverson C, Flanagin A, et al, eds. *AMA Manual of Style: A Guide for Authors and Editors*. 11th ed. Oxford University Press; 2020. Accessed August 17, 2023. https://www.amamanualofstyle.com
2. Schriger DL. Graphic portrayal of studies with paired data: a tutorial. *Ann Emerg Med*. 2018;71(2):239-246. doi:10.1016/j.annemergmed.2017.05.033
3. EQUATOR Network. Accessed August 17, 2023. https://www.equator-network.org/
4. How do I? format my manuscript. Instructions for Authors. JAMA. Accessed August 17, 2023. https://jamanetwork.com/journals/jama/pages/instructions-for-authors
5. Wilkinson L. *The Grammar of Graphics (Statistics and Computing)*. 2nd ed. Springer; 2005.
6. Gelman A, Pasarica C, Dodhia R. Let's practice what we preach. *Am Stat*. 2002;56(2):121-130. doi:10.1198/000313002317572790
7. Guihard B, Chollet-Xémard C, Lakhnati P, et al. Effect of rocuronium vs succinylcholine on endotracheal intubation success rate among patients undergoing out-of-hospital rapid sequence intubation: a randomized clinical trial. *JAMA*. 2019;322(23):2303-2312. doi:10.1001/jama.2019.18254
8. Casella JF, Barton BA, Kanter J, et al. Effect of poloxamer 188 vs placebo on painful vaso-occlusive episodes in children and adults with sickle cell disease: a randomized clinical trial. *JAMA*. 2021;325(15):1513-1523. doi:10.1001/jama.2021.3414
9. Chen HS, Cui Y, Zhou ZH, et al; ARAIS Investigators. Effect of argatroban plus intravenous alteplase vs intravenous alteplase alone on neurologic function in patients with acute ischemic stroke: the ARAIS randomized clinical trial. *JAMA*. 2023;329(8):640-650. doi:10.1001/jama.2023.0550
10. Walker GJ, Harrison JW, Heap GA, et al; IBD Pharmacogenetics Study Group. Association of genetic variants in NUDT15 with thiopurine-induced myelosuppression in patients with inflammatory bowel disease. *JAMA*. 2019;321(8):773-785. doi:10.1001/jama.2019.0709
11. Ferreyro BL, Angriman F, Munshi L, et al. Association of noninvasive oxygenation strategies with all-cause mortality in adults with acute hypoxemic respiratory failure: a systematic review and meta-analysis. *JAMA*. 2020;324(1):57-67. doi:10.1001/jama.2020.9524
12. Watanabe H, Domei T, Morimoto T, et al; STOPDAPT-2 Investigators. Effect of 1-month dual antiplatelet therapy followed by clopidogrel vs 12-month dual antiplatelet therapy on cardiovascular and bleeding events in patients receiving PCI: the STOPDAPT-2 randomized clinical trial. *JAMA*. 2019;321(24):2414-2427. doi:10.1001/jama.2019.8145

Downloaded from academic.oup.com/book/58841 by guest on 17 October 2026

CHAPTER 18

Creating Effective and Efficient Tables

David L. Schriger, MD, MPH

Downloaded from academic.oup.com/book/58841 by guest on 17 October 2026

KEY POINTS

- Creating a table is similar to writing prose. The first step is to determine what information is to be conveyed.
- The hallmark of a good table is that its structure is homologous to its purpose, which may be for archival information or for presentation of research data.
- The title of the table should convey the main purpose, and subheadings should be used to help readers navigate complex tables. The primary comparisons should be horizontal and prominent.
- Less is more when creating tables. The tables should be edited carefully to remove all material that is extraneous to the table's main messages and to remove all nonessential digits from the remaining entries.
- The table should be comprehensible in isolation. The meaning of each cell in the table should be clearly evident for all cells, including what quantities the numbers represent, the number of observations on which the value is based, and the units of measurement.

The presentation of data and other information in scientific reports in biomedical journals should be as efficient and clear as possible. Tables are commonly used for this purpose and are important tools for presenting key information effectively and in detail. Tables that are well thought-out, appropriately constructed, and properly used can highlight the key findings and important data in a scientific report and contribute substantially to the communication of a clear, cohesive message in the article. In contrast, tables that are inadequately constructed may detract from overall quality by interfering with clear communication of the overall message of the scientific report. This chapter presents guidelines for creating effective tables in manuscripts submitted to biomedical journals. (For additional guidance and examples, see Section 4.1, Tables, in the *AMA Manual of Style*.[1])

The hallmark of a good table is that its structure is homologous to its purpose. Biomedical journal articles may include tables that have different purposes. There are 2 types of tables: archival and presentation. Archival tables are structured to optimize information retrieval. For example, an alphabetical organization of the 50 US states facilitates finding information about a specific state but does not foster comparison by geographic proximity or by population size. In scientific journal articles, archival tables include information that augments information in the main report and often are placed in supplementary material.

Recommendations for Standard Presentation Tables

This chapter focuses on presentation tables, which are the most common type of tables used in reports in biomedical journals. In contrast to archival tables, presentation tables are designed to communicate one or more concepts or comparisons. For that reason, the first step in creating a presentation table is to list hierarchically the concepts the table is intended to convey. Sometimes the purpose of the table is singular and straightforward, such as describing the study participants. Other tables are designed to communicate multiple concepts, such as a primary comparison between groups and secondary comparisons among subgroups. A general rule is that the data in tables should be presented and arranged so that the primary comparisons are horizontal; readers scan across the data columns to see the difference among groups. Secondary concepts, such as differences among subgroups, are conveyed vertically, but within each subgroup, the between-group comparison remains horizontal. The logical, nested, repetition of columns and rows is a keystone of well-organized presentation tables.

Unlike archival tables, which are used to display all available information, for presentation tables, there is an inverse relationship between the size of a presentation table and its readability. The urge to present all available data should be tempered by this knowledge, and the placement of nonessential material in supplementary tables will increase the probability that readers derive the key information the main tables are intended to communicate.

Presentation tables should be self-contained and self-explanatory. Readers should not need to refer to the text to understand the table. Several details will help ensure that this will be the case:

- The title of the table should focus on the key concept to be gleaned from the table.
- Every data cell should be designed to ensure that the reader can easily discern the group identifier, number of observations the data point is based on, unit of measurement (eg, mg/dL or person-years),

Downloaded from academic.oup.com/book/58841 by guest on 17 October 2026

and the statistical nature of the data point (mean, median, count, variance, etc). To avoid redundancy, these data descriptors should be presented at the highest level that is accurate. For example, if the denominator (N) for every row in a column is constant, the N should appear once in the column header rather than repeated in every cell. If the N is the same for most rows in a column, a footnote (such as a superscript letter) can be placed in the header leading to a footnote explanation in the table legend reading "unless otherwise stated," and the Ns that differ from the column N can be stated in those cells in forms such as "No. (%)"; "mean (SD), No."; "median (IQR), No."; and similar forms. The same principles apply to the depiction of units of measurement and statistical quantities.

- Every term in a table that is not common knowledge should be defined. Authors need to consider a journal's audience. For example, a table in an ophthalmological research report will require more definitions and explanatory footnotes if published in a general journal than if published in an ophthalmology journal. All scales used for data presented in a table should be defined in footnotes that indicate the range, direction, and clinical meaning of values included in the table. For example, if the mean APACHE II score in a table is 28, the footnote explanation might read: "The APACHE II score ranges from 0 to 71 with higher values indicating greater severity of illness and a higher probability of imminent mortality. A score of 25 represents a predicted mortality of 50%." Authors should also consider including the minimal clinically important differences of the values, if known.
- All noncount descriptive statistics, such as means and medians, should be presented with some measure of the spread of the data, such as standard deviation or 1st and 3rd quartiles, respectively. Standard errors of the means and confidence intervals, which estimate the variability of the population mean, not the variability of the data, should accompany comparative statistics (difference measures, ratio measures, and model coefficients) but not descriptive statistics such as means. With rare exception, *P* values should always be accompanied by the differences and confidence intervals on which they are based.
- Number precision should be given careful attention. The principles of precision and significant figures should be followed, but even when justified by these rules, extra decimal digits make tables cumbersome, intimidating, and less likely to be read. For example, while it might be statistically justifiable to report the mean systolic blood pressure in 2 treatment groups of 100 patients each as 136.2 and 137.1, in most cases reporting 136 and 137 is sufficient given the reliability of the measurement and the arguable clinical importance of decimal differences.

Downloaded from academic.oup.com/book/58841 by guest on 17 October 2026

Table requirements vary among journals, and authors should read the instructions for authors and review tables published in the journal to which they plan to submit their manuscript to understand the expectations and format for tables in the journal. Several types of tables commonly appear in reports of biomedical research; annotated example tables accompany the following recommendations.

Tables Reporting Characteristics of the Sample

The typical Table 1 in a research report provides a description of the study participants (see the annotated example table in **Figure 18-1**[2]). For case series and other single-group studies, the table will be 2 columns wide, with 1 column containing the row descriptors (the technical term is *stub*), such as age, race and ethnicity, etc, and the other column containing the data. Such a table helps readers evaluate the external validity of a study (ie, how the results of the study might apply to their population of interest). When a study reports on more than 1 group, this table also provides insight into internal validity, as comparison among groups allows readers to understand how closely matched the groups were at baseline. These validity considerations guide the content of the table. When constructing the table, the authors must determine what variables are necessary to adequately characterize the sample and, for multigroup studies, what variables are necessary to communicate whether differences in outcome are likely to be due to differences in baseline characteristics. Typical best practices include the following:

- For multigroup studies, an "overall" or "total" column usually is not needed. This column adds little value as it makes the table bulkier without adding new information.
- Analytic statistics such as *P* values generally should not be included in this descriptive table. For nonrandomized cohort studies, a difference measure and confidence interval can be provided to illustrate between-group differences.
- The ordering of study groups (in columns) should be consistent across all tables and figures. For example, in *JAMA*, groups are ordered with the exposure of greatest intensity (such as active drug) in the columns on the left, and the placebo, standard care, or lowest intensity group in the columns on the right.
- Since these are presentation tables, ordering should be used to highlight the most important data. For example, if presenting the frequency of a series of comorbidities, the most common ones should be listed first, rather than listing by other ordering, such as alphabetically.

Downloaded from academic.oup.com/book/58841 by guest on 17 October 2026

Figure 18-1. Annotated Example of a Table Reporting the Characteristics of the Sample

1 **Table 1. Baseline Characteristics of Participants in a Study of the Effect of Single-Fraction vs Multifraction Radiotherapy on Ambulatory Status Among Patients With Spinal Canal Compression From Metastatic Cancer**

Characteristic	2 No. (%)	
	Single-fraction radiotherapy group (n = 345)	Multifraction radiotherapy group (n = 341)
Age		
Median (range), y	70 (23-96)	70 (33-95)
3 ≥75 y	106 (31)	119 (35)
Sex		
Men	255 (74)	248 (73)
Women	90 (26)	93 (27)
4 Site of primary cancer		
Prostate	152 (44)	152 (45)
Lung	66 (19)	66 (19)
Breast	39 (11)	40 (12)
Gastrointestinal	35 (10)	38 (11)
Kidney	11 (3)	12 (4)
Skin	9 (3)	6 (2)
Bladder	7 (2)	4 (1)
Other (ie, gynecologic, head and neck, sarcoma, unspecified)	26 (8)	23 (7)
5 Nonskeletal metastases	159 (46)	156 (46)
No. of spinal cord compression sites		
Single	303 (88)	311 (91)
Multiple	42 (12)	30 (9)
7 WHO performance status[a]	6 (n = 343)	(n = 337)
0-1 (Best)	97 (28)	94 (28)
2	88 (26)	81 (24)
3	114 (33)	121 (36)
4 (Worst)	44 (13)	41 (12)
Ambulatory status		
8 Grade 1 (ambulatory without the use of walking aids)	76 (22)	77 (23)
Grade 2 (ambulatory with walking aids)	152 (44)	146 (43)
Grade 3 (unable to walk)	91 (26)	90 (26)
Grade 4 (absence or flicker of motor power in any muscle group)	26 (8)	28 (8)

[a]WHO performance status of 0 indicates able to carry out all normal activity without restriction; 1, restricted in strenuous activity but ambulatory and able to carry out light work; 2, ambulatory and capable of all self-care but unable to carry out any work activities and are up and about for greater than 50% of waking hours; 3, symptomatic and in a chair or in bed for greater than 50% of the day but not bedridden; and 4, completely disabled, cannot carry out any self-care, and totally confined to bed or chair.

Downloaded from academic.oup.com/book/58841 by guest on 17 October 2026

Figure 18-1 Annotations

1. The title clearly and fully explains what is being presented and why. The purpose and content of this table are understandable without consulting the text of the article.

2. Since most cells are the same format, that format, No. (%), is indicated here as the default for each cell, except where indicated. The data row for age is median (IQR) and that is indicated in the row stub as "Median (range, y)."

3. The authors recognized that patients aged 75 years or older may represent a higher risk group, so they chose to show the number and proportion of study participants in this age group.

4. The primary cancer sites are sorted by frequency to clearly indicate which sites predominate.

5. For some binary variables, the data are presented for both outcomes (eg, sex and number of spinal cord compression sites), but for other binary variables, only 1 outcome is presented (eg, nonskeletal metastases). The benefit of presenting only 1 outcome is a smaller, more approachable table, but for some entries readers will prefer to directly see both options.

6. Some participants did not have a World Health Organization (WHO) performance score, so the number (n) for this section is listed here to make clear that it differs from the total number (N) in each column.

7. Footnote a is used to fully explain the WHO performance scale, and the "Best" and "Worst" are included in the table row heading to provide basic orientation for values on this scale.

8. Descriptions are included next to noninformative categories such as Grade 1, Grade 2, etc, to indicate the meaning of the grades. This information also could have been presented in a footnote but is easily understood by inclusion in the row headings of the table.

- Mean (SD) should be used for presenting data that have a normal distribution.
- Median (interquartile range [IQR]) should be used instead of mean (SD) when data are skewed or have high or low kurtosis (non-normal).
- The +/– notation (as in "mean +/– SD") should be avoided; this notation implies a symmetry that may or may not be present. "Mean (SD)" should be used.
- For certain items (eg, creatinine, systolic blood pressure), the percentage of participants with values above *x* or below *y* may be more informative than a mean (SD) or median (IQR) because unbalanced distribution of such participants is a greater threat to internal validity than a small difference in means.
- For propensity analyses and other designs that study a subset of the data, the table should present the complete sample data for each group with a difference measure and the propensity-balanced data with the standardized mean difference (SMD).
- It is helpful to consult the journal instructions for authors or a reference manual (such as the *AMA Manual of Style*) to ensure that descriptors such as race and ethnicity are presented in the optimal manner (eg, in alphabetical order and not in order of proportion).

Tables Reporting Results

Typically, Table 2—and possibly Tables 3, 4, and 5—in a research report contain the primary and secondary study results (see the annotated example table in **Figure 18-2**[3]). Some results are best presented in tables, others in figures. (See

Downloaded from academic.oup.com/book/58841 by guest on 17 October 2026

Figure 18-2. Annotated Example of a Table Reporting Results

1

Table 2. Primary and Secondary Efficacy Outcomes

Characteristic	2 No. (%)[a] Immediate pushing (n = 1200)	Delayed pushing (n = 1204)	3 Absolute risk difference (95% CI)[b]	Relative risk (95% CI)[c]	*P* Value
4 **Primary outcome**					
Spontaneous vaginal delivery	1031 (85.9)	1041 (86.5)	−0.6 (−3.4 to 2.1)	0.99 (0.96 to 1.03)	.67
Prespecified secondary outcomes					
Total duration of the second stage of labor, min					
5 Median (IQR)	79 (45 to 134)	113 (84 to 167)			
Mean (SD)	102.4 (79.6)	134.2 (76.3)	−31.8 (−36.7 to −26.9)		<.001
6 Duration of active pushing, min	[n = 1198]	[n = 1200]			
Median (IQR)	58 (29 to 114)	49 (25 to 100)			
Mean (SD)	83.7 (76.8)	74.5 (70.7)	9.2 (5.8 to 12.6)		<.001
Type of delivery					
7 Operative vaginal	76 (6.3)	71 (5.9)	0.4 (−1.5 to 2.4)	1.1 (0.7 to 1.7)	.75
Vacuum-assisted vaginal	55 (4.6)	56 (4.7)	−0.1 (−1.8 to 1.6)	1.0 (0.7 to 1.4)	.93
Forceps-assisted vaginal	21 (1.8)	15 (1.3)	0.5 (−0.5 to 1.5)	1.4 (0.7 to 3.0)	.38
Cesarean	93 (7.8)	91 (7.6)	0.2 (−1.9 to 2.3)	1.0 (0.9 to 1.1)	.55
Postpartum hemorrhage	27 (2.3)	48 (4.0)	−1.7 (−3.1 to −0.4)	0.6 (0.3 to 0.9)	.03

Abbreviations: IQR; interquartile range; NICU, neonatal intensive care unit.

[a]Unless otherwise indicated.

8

[b]Calculated from binomial distribution.

[c]Obtained from generalized estimating equations models, which were used to account for study site.

Downloaded from academic.oup.com/book/58841 by guest on 17 October 2026

Figure 18-2 Annotations

1. The title indicates that this table reports primary and secondary outcomes.

2. Most items are No. (%) so that is the default, as indicated in the top heading. The row stubs contain this information for rows with a different data format, such as "Total duration of second stage of labor, min." This is indicated by footnote a and explained in the table legend.

3. Absolute measures are least likely to be misinterpreted and should be included in all outcome tables even if the prespecified outcome is a ratio measure.

4. Subheadings are used to identify and separate the different types of outcomes (eg, primary and secondary).

5. Authors should decide whether presenting mean (SD) adequately characterizes the distribution or whether additional measures, such as median, interquartile range (IQR), or range, should be included.

6. The n = 1198 and n = 1200 entries make it clear that the number of study participants with data for duration of pushing differs from the overall number of participants.

7. Indentation is used to indicate nesting of outcomes by type of delivery.

8. The methods used to calculate the 95% CIs and *P* values are indicated.

Chapter 17, Effective Use of Figures and Tables in Scientific Articles, for a detailed description of use of tables vs figures.) Tables that report results will be more variable in form than the typical Table 1 with study participant characteristics or a table reporting adverse events, making it challenging to provide specific advice. The key priority is to establish what organization of rows and columns best conveys the information. A few general principles include the following:

- For larger tables, subheadings should be used to divide the table into sections that help orient the reader. Such subheadings can, and should, be used to differentiate primary outcomes from secondary, exploratory, and post hoc outcomes. Subheadings also can be used to differentiate different types of outcomes (patient-centered, laboratory values, etc).
- Absolute between-group differences (and their confidence intervals or credible intervals) should be presented even if the prespecified outcome is a relative measure, in which case both should be presented.
- If the table has many rows, consider converting it to a figure (for example, adding a dot and whisker illustration of each row's main comparison) to facilitate understanding of the key message.

Tables for Reporting Adverse Events

Reports of clinical trials and comparative effectiveness studies generally should include a specific table that includes adverse events (see the annotated example table in **Figure 18-3**[4]). Although the general concepts and style discussed for the other tables also apply, several other factors should be considered for tables reporting adverse events:

Downloaded from academic.oup.com/book/58841 by guest on 17 October 2026

Figure 18-3. Annotated Example of a Table Reporting Adverse Events

1

Table 3. Adverse Events in the Safety Population[a]

Characteristic	No. (%) of Patients: Fremanezumab monthly dosing (n = 290)	Fremanezumab single higher dose (n = 291)	Placebo (n = 293)
All events			
≥1 Adverse event	192 (66.2)	193 (66.3)	171 (58.4)
≥1 Treatment-related adverse event	138 (47.6)	137 (47.1)	109 (37.2)
≥1 Serious adverse event	3 (1.0)	3 (1.0)	7 (2.4)
Any adverse event leading to study discontinuation	5 (1.7)	5 (1.7)	5 (1.7)
Death	0	1 (0.3)	0
Adverse event type[b]			
General disorders and administration site conditions			
Injection site pain	87 (30.0)	86 (29.6)	76 (25.9)
Injection site induration	71 (24.5)	57 (19.6)	45 (15.4)
Injection site erythema	52 (17.9)	55 (18.9)	41 (14.0)
Injection site hemorrhage	3 (1.0)	9 (3.1)	6 (2.0)
Fatigue	2 (0.7)	6 (2.1)	4 (1.4)
Infections			
Upper respiratory tract infection	16 (5.5)	11 (3.8)	15 (5.1)
Nasopharyngitis	11 (3.8)	11 (3.8)	9 (3.1)
Urinary tract infection	7 (2.4)	10 (3.4)	4 (1.4)
Bronchitis	6 (2.1)	4 (1.4)	3 (1.0)
Sinusitis	4 (1.4)	2 (0.7)	8 (2.7)
Gastrointestinal disorders			
Nausea	4 (1.4)	7 (2.4)	5 (1.7)
Protocol-defined adverse events of special interest			
Hepatic enzyme increased	2 (0.7)	1 (0.3)	0
Blood bilirubin increased	1 (0.3)	0	1 (0.3)
Ophthalmic events of at least moderate intensity	0	0	0
Hy's law events	0	0	0
Anaphylaxis	0	0	0
Severe hypersensitivity reactions	0	0	1 (0.3)

[a]Adverse events were collected at each visit via inquiry and clinical laboratory tests. The safety population included all patients who were randomized and received at least 1 dose of study drug. If a patient had multiple types of adverse events, they were counted once for each type. One patient randomized to receive placebo inadvertently received 1 dose of fremanezumab, 225 mg.
[b]Adverse events shown include those reported in more than 2% of patients in any group.

2, 3, 4, 5

Figure 18-3 Annotations

1. The title indicates the purpose of the table and the footnote explains which patients comprise the safety population.

2. All data are reported as No. (%), so a single identifier for the entire table is adequate.

3. Treatments are ordered from left to right in a logical way that is consistent with the order presented in the text and other tables and figures.

4. Inclusion of a footnote that explains how an adverse event was determined to be treatment-related or was serious would be helpful. For this article, the criteria were included in the Supplement.

5. Footnote b explains the criteria for including an adverse event in the table.

Downloaded from academic.oup.com/book/58841 by guest on 17 October 2026

- Since most studies are not powered to measure differences in adverse events, the table should be descriptive and statistical testing should be avoided unless prespecified.
- Events should be organized from most serious at the top to least serious at the bottom.
- The method for identifying events should be described in a footnote (but should also be reported in the Methods section of the main text).
- If events are categorized as related or unrelated to the treatment, the methods used for classification should be explained in a footnote (but should also be reported in the Methods section of the main text).
- For rows that could be interpreted as either mutually exclusive or nested, an explanation should be provided regarding which of these it is.

Conclusion

A well-constructed presentation table reveals its purpose through its title and structural organization. The table should be comprehensible without consulting the text of the report. For every cell in the table, the number (N), the unit of measurement, and the meaning of the value should be provided and easily determined. Tables should be carefully edited to remove all information that is not central to the main purpose. Material that is nonessential for conveying the main messages of the report can be included in supplementary tables. When creating tables, authors should consult the instructions for authors of the journal to which they plan to submit their manuscript, and they should review the journal for examples of published tables that convey information efficiently and effectively.

ACKNOWLEDGMENT

The annotated example tables shown in Figures 18-1, 18-2, and 18-3 are based on previously published tables.[2-4]

References

1. Christiansen S, Manno C. Tables. In: Christiansen S, Iverson C, Flanagin A, et al, eds. *AMA Manual of Style: A Guide for Authors and Editors*. 11th ed. Oxford University Press; 2020. Accessed September 12, 2023. https://www.amamanualofstyle.com
2. Hoskin PJ, Hopkins K, Misra V, et al. Effect of single-fraction vs multifraction radiotherapy on ambulatory status among patients with spinal canal compres-

Downloaded from academic.oup.com/book/58841 by guest on 17 October 2026

sion from metastatic cancer: the SCORAD randomized clinical trial. *JAMA*. 2019;322(21):2084-2094. doi:10.1001/jama.2019.17913
3. Cahill AG, Srinivas SK, Tita ATN, et al. Effect of immediate vs delayed pushing on rates of spontaneous vaginal delivery among nulliparous women receiving neuraxial analgesia: a randomized clinical trial. *JAMA*. 2018;320(14):1444-1454. doi:10.1001/jama.2018.13986
4. Dodick DW, Silberstein SD, Bigal ME, et al. Effect of fremanezumab compared with placebo for prevention of episodic migraine: a randomized clinical trial. *JAMA*. 2018;319(19):1999-2008. doi:10.1001/jama.2018.4853

Downloaded from academic.oup.com/book/58841 by guest on 17 October 2026

CHAPTER 19

Effective Use of Figures and Graphs in Scientific Publications

Mary (Nora) L. Disis, MD, and Denise L. Cecil, PhD

Downloaded from academic.oup.com/book/58841 by guest on 17 October 2026

KEY POINTS

- Simple data can be described in the text and do not require a figure.
- The choice of graphic is dictated by the study design, distribution of data, and sample size.
- All panels of a single figure should be focused on the same theme or take-home message.
- Authors may consider adding a schematic diagram to provide an overall description of the study.
- Graphics with color enhance the visual appeal of dense data.

One hallmark of an excellent scientific publication is being able to read and comprehend the premise and results of the article by solely evaluating the data displays, including the tables and especially the figures and figure legends, presented in the manuscript. Visual representation of data is a key feature of any manuscript. According to one study, the density of figures within a manuscript and the methods of visual display that authors choose are associated with the scientific influence as measured by the citation rate of that publication.[1] The investigators analyzed nearly 8 million figures from more than 650 000 manuscripts deposited in PubMed Central over a multiyear period and determined that manuscripts with a higher number of citations are associated with a greater density of figures and a greater number of figures that include plots and diagrams. The trend in higher density figures composed of several panels is increasing over time and can be attributed to the evolving complexity of scientific questions, the numerous technologies and methods available to address a problem or hypothesis, and the availability of software that facilitates the creation of complex figures for publication.[1] A well-designed figure or suite of figures in a scientific manuscript can significantly enhance understanding of the data presented.

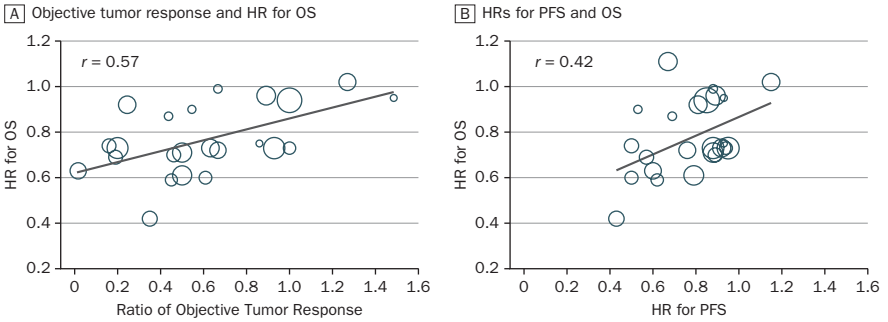
Effective Use of Figures and Graphics

Figures should be designed to improve understanding of information in the manuscript. The first step in considering figures for a scientific publication is determining whether a graphic is needed to effectively convey the message. The purpose of a figure is to present complex data more simply and to underscore the most important information in the manuscript. Visual representation of key data will enhance long-term retention of the information over text alone.[2] Well-designed figures make the manuscript easier to read, understand, and remember. Figures should not be repetitive of information that is provided in text form or a table. An example of a poor use of a figure would be one added for the description of the clinical response rate in a trial of a new agent. An author might state in the text, "Among the patients included in the study, 30% achieved a complete response, 40% a partial response, and 30% of individuals demonstrated progressive disease (Figure 1)," where Figure 1 is a bar graph of the 3 percentages. The response rates are simple descriptive data, and the text and graph are repetitive of each other. Presentation of simple data does not require a figure. In addition, while pie charts and Venn diagrams may be useful to illustrate concepts, they should not be used to graphically represent empirical or numeric data because they lack precision and may be misleading. (There are numerous examples of acceptable figure presentations for display of simple and complicated data in the *AMA Manual of Style*[3] and in the Table of Figure Requirements in the JAMA Network Instructions for Authors.[4] See also Chapter 17, Effective Use of Figures and Tables in Scientific Articles.)

If a figure is multipanel, the graphs, plots, and diagrams presented should all be part of the same question addressed by the data. Combining multiple disparate themes within a single figure by adding multiple panels reduces the clarity of the take-home message. Multipanel figures can become "data dumps" inclusive of not only key information but also other types of data that would be best relegated to supplemental figures (such as an example of the assay method used or a series of comprehensive controls). Often, the clarity of the figure is inversely associated with the number of panels used to construct the figure. When contemplating the construction of figures or graphics to include in a publication, it is important to consider the study design and the type of data generated. An excellent example of using a graphic display to deliver information on multiple aspects of an analysis is shown in **Figure 19-1**. These graphs describe a meta-analysis aimed at defining appropriate clinical end points for phase 2 trials.[5] The panels are clearly labeled and show a correlation of various treatment effects. The individual data points depict not only the number of trials evaluated, but also the number of patients in each trial contributing to the analysis by the size of the circles. The bold line and *r* value visually indicate the strength of the correlations.

Downloaded from academic.oup.com/book/58841 by guest on 17 October 2026

Figure 19-1. Well-Designed Graphs Can Convey Multiple Aspects of an Analysis

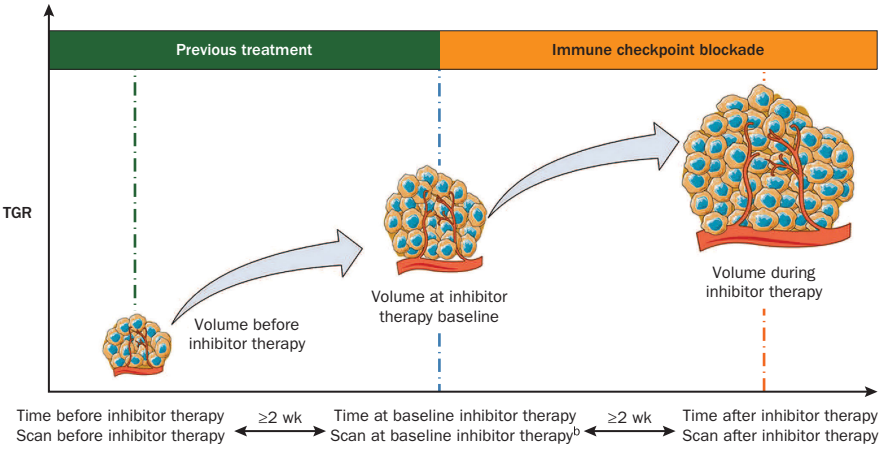


The Figure shows several aspects of correlations of relative treatment effects from a meta-analysis. Individual studies analyzed are represented by a specific data point. The number of patients in each trial is reflected by the size of the data point. The correlation between variables is depicted visually by the bold line as well as analytically via the *r* value. Each panel is clearly labeled as A and B. HR indicates hazard ratio, OS indicates overall survival, and PFS indicates progression-free survival.

Reproduced from Ritchie G et al.[5]

In presentations of clinical trials or large biomarker studies, flowcharts or decision trees are critical to clearly indicate how patients were enrolled, progressed through the study, and were treated, or how decisions were made about which samples should be analyzed by a specific test. Often, for complex trials, a diagram of the study schema is a helpful visual representation of the experiment.[6] **Figure 19-2** is a creative and visually striking description of a

Figure 19-2. Diagrams of Complex Studies Promote Understanding and Retention of Information Provided in a Manuscript



The Figure depicts the tumor growth rate (TGR) over time while a patient is receiving a specific therapy. The axes are well labeled and the green and gold bars across the top of the graph provide the treatment course at a glance. Tumor growth is depicted visually. The schema allows for quick understanding of multiple aspects of the study prior to reading the more detailed data analysis presented in the manuscript.

Reproduced from Ferrara R et al.[7]

Downloaded from academic.oup.com/book/58841 by guest on 17 October 2026

retrospective multicenter study attempting to define a new pattern of cancer progression after treatment, called hyperprogression. The figure depicts the variation in tumor growth rate (TGR) over time and plots the change observed in relation to treatment.[7] The authors clearly labeled the timeline on the *x*-axis and use colored bars at the top of the graph for a quick summary of treatment. The TGR is shown on the *y*-axis, but the authors used a picture of cancer growth to reinforce their message. At a glance, this schema figure provides a strong foundation for understanding the data that will be discussed in the manuscript. These structural figures—diagrams, flowcharts, and decision trees—are key elements of the manuscript and provide a visual roadmap for the design of the study and the flow of work.

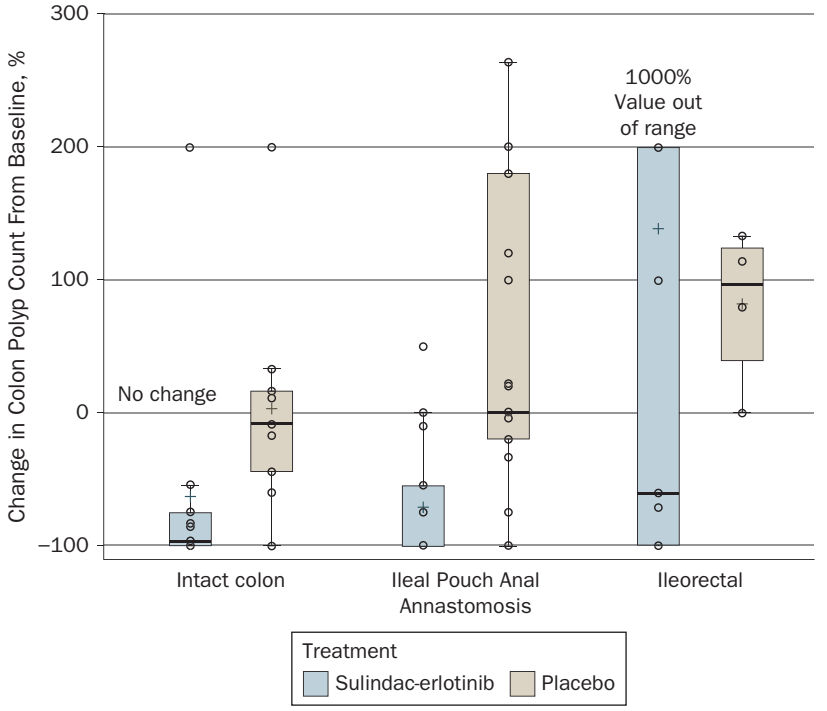
Choice of Figures and Graphics

The choice of graphics is also dictated by the distribution of data and the sample size. The goal is to represent the information in the most accurate and complete manner possible. A single variable that changes over time or comparison of multiple variables that change over time is best depicted by a line graph. A histogram is optimal for showing sampling distribution. Comparing different populations from large data sets would best be suited to box plots. Smaller sample sizes are suited to scatterplots in which individual data points can be evaluated as a group, clearly showing the outliers from the mean or median.[8] **Figure 19-3** is an example of data derived from a clinical trial with a small sample size. The trial involved an experimental treatment applied to a unique patient population with multiple locations of disease.[9] The authors provided a box-plot graph that is dense with information, yet very easy to interpret. Data are presented by change in polyp count with the intervention by specific location of disease. Individual patient data are depicted with open circles, yet cumulative results are available in an overlay plot showing median, range, and data points out of the range. Giving each treatment group a unique color allows demonstration of the effects of the experimental intervention by tumor location. This type of plot is called a Tukey plot with whiskers and outliers and is ideally suited for such small sample sizes.

Another popular type of figure found in the medical literature is a survival plot, which is constructed on time-to-event data. The most common type of survival plot is the Kaplan-Meier curve, which is used to describe the length of survival after an intervention. Kaplan-Meier plots can be graphed to offer much information, not only survival in groups over time but also shaded areas around each curve that represent confidence interval bands. An additional important component often added is a small table beneath the Kaplan-Meier graph that shows the number of individuals at risk by time. Giving some

Downloaded from academic.oup.com/book/58841 by guest on 17 October 2026

Figure 19-3. Choosing the Most Appropriate Type of Graphic Design for a Specific Data Set



The graph represents data from a small clinical trial. The open circles depict each individual patient in a specific group represented by disease location. The box and whisker plot (or Tukey plot) divides the data into quartiles, showing the median, range, and outlier data. In this case, the whiskers extend to the minimum and maximum values. Colors are effectively used to separate treatment groups.

Reproduced from Samadder NJ et al.[9]

thought to the study design and the level of data generated should guide the choice of appropriate visual data display.

Enhancing Interpretation of Figures and Graphics

Color in a figure or graph can enhance the visual appeal of dense data, as shown in Figure 19-3, and can act as an aid to group similar data sets across a multipanel figure with coordinated colors. The use of color adds visual interest to the publication and holds attention, as shown in Figure 19-2. Too many colors, however, can be distracting, especially if the color themes are not coordinated with specific data sets and change in every figure. Colors should be distinct from each other so that the separate data lines can be easily interpreted. In addition, the color palette selected should not create problems for readers who have difficulty distinguishing colors on the red and green axis.

Downloaded from academic.oup.com/book/58841 by guest on 17 October 2026

Figures, especially multipanel figures, need to provide a map to enhance interpretation of the data. One component of that map is careful and complete numbering of the figure, panels, and subpanels. Each individual panel in the figure must have its own denotation and be mentioned in the figure legend as well as discussed in the text.

Another component of the map is the figure legend. Figure legends are not meant to take the place of the Results section of the manuscript and should not reiterate results. Figure legends are a guide to the figure, describing the variables on each axis and defining the experimental groups and how these groups are depicted. The text in the legends should provide enough information to be able to understand the graph and interpret the data. Legends should be short, compact, and easy to understand.

Conclusion

Careful consideration of the type of figure and graphic suited to the data presented should be one of the first steps in the preparation of a manuscript. Software tools that provide a generous selection of graph and figure formats are widely available and easy to use. Effective visual display of data will enhance understanding of the information in the article and may increase the long-term influence of the work on the scientific community.

ACKNOWLEDGMENT

The example figures shown in Figures 19-1, 19-2, and 19-3 are based on previously published figures.[5,7,9]

References

1. Lee P, West JD, Howe B. Viziometrics: analyzing visual information in the scientific literature. *IEEE Trans Big Data*. 2017;4(1):117-129. doi:10.1109/TBDATA.2017.2689038
2. Carney RN, Levin JR. Pictorial illustrations still improve students' learning from text. *Educ Psychol Rev*. 2002;14:5-26. doi:10.1023/A:1013176309260
3. Christiansen S, Iverson C, Flanagin A, et al. *AMA Manual of Style: A Guide for Authors and Editors*. 11th ed. Oxford University Press; 2020. Accessed March 21, 2023. https://www.amamanualofstyle.com
4. Table of figure requirements. Instructions for Authors. JAMA Network. Accessed January 18, 2021. https://jamanetwork.com/journals/jama/pages/instructions-for-authors#SecTableofFigureRequirements
5. Ritchie G, Gasper H, Man J, et al. Defining the most appropriate primary end point in phase 2 trials of immune checkpoint inhibitors for advanced solid cancers: a systematic review and meta-analysis. *JAMA Oncol*. 2018;4(4):522-528. doi:10.1001/jamaoncol.2017.5236

Downloaded from academic.oup.com/book/58841 by guest on 17 October 2026

6. Franzblau LE, Chung KC. Graphs, tables, and figures in scientific publications: the good, the bad, and how not to be the latter. *J Hand Surg Am*. 2012;37(3):591-596. doi:10.1016/j.jhsa.2011.12.041
7. Ferrara R, Mezquita L, Texier M, et al. Hyperprogressive disease in patients with advanced non–small cell lung cancer treated with PD-1/PD-L1 inhibitors or with single-agent chemotherapy. *JAMA Oncol*. 2018;4(11):1543-1552. doi:10.1001/jamaoncol.2018.3676
8. Weissgerber TL, Milic NM, Winham SJ, Garovic VD. Beyond bar and line graphs: time for a new data presentation paradigm. *PLOS Biol*. 2015;13(4):e1002128. doi:10.1371/journal.pbio.1002128
9. Samadder NJ, Kuwada SK, Boucher KM, et al. Association of sulindac and erlotinib vs placebo with colorectal neoplasia in familial adenomatous polyposis: secondary analysis of a randomized clinical trial. *JAMA Oncol*. 2018;4(5):671-677. doi:10.1001/jamaoncol.2017.5431

Downloaded from academic.oup.com/book/58841 by guest on 17 October 2026

Downloaded from academic.oup.com/book/58841 by guest on 17 October 2026

PART 4

Specific Types of Articles

Downloaded from academic.oup.com/book/58841 by guest on 17 October 2026

Downloaded from academic.oup.com/book/58841 by guest on 17 October 2026

CHAPTER 20

Clinical Trials

Neil M. Bressler, MD

Downloaded from academic.oup.com/book/58841 by guest on 17 October 2026

KEY POINTS

- The title of a randomized clinical trial usually should follow a format such as "Effect of A vs B on C in Patients With D: A Randomized Clinical Trial."
- Authors should include the clinical trial registry identifier; a data sharing statement; supplementary material that includes the trial protocol and the statistical analysis plan, including all amendments; and the CONSORT checklist.
- The Methods and Results sections should follow the CONSORT checklist, and a CONSORT flow diagram should be included.
- The Discussion should summarize the primary outcome; any secondary outcomes needed to understand the clinical relevance of the primary outcome; a safety summary; a synthesis of the risk-benefit ratio; limitations of the study including any chance, bias, or confounding issues; and generalizability of the results to clinical practice.

Clinical trials have a special place in biomedical publications because their findings, especially from primary outcome reports, are at or near the top of the evidence-based medicine hierarchy and, more than other research designs, may influence clinical care.[1] Randomized clinical trials (RCTs) have this special place because effective randomization minimizes bias for both known and unknown confounders. Prespecified eligibility and exclusion criteria may minimize selection bias and ascertainment bias. Well-designed protocols and systematic data collection can minimize information bias. Furthermore, study design and investment in personnel and other strategies, such as telephone or text reminders of follow-up visits, often are incorporated in the design of clinical trials to attempt to minimize loss to follow-up, which otherwise might introduce information bias as well.

A clinical trial is defined by the International Committee of Medical Journal Editors (ICMJE), based on concepts from the World Health Organization,

as any research project that prospectively assigns human participants or groups of humans to an intervention or a comparison group to study the cause-and-effect relationship between that intervention (eg, a new drug for glioblastoma) and a health outcome (eg, survival).[2] This cause-and-effect relationship often provides the scientific evidence needed for physicians and other health care professionals to change clinical practice. The clinical trial must be registered at an appropriate online public registry (as discussed below). While the interventions are varied and might involve a drug, a surgical procedure, a device, a behavioral treatment, an educational program, or a dietary intervention, an investigation of an intervention without a comparison group could not, by design, determine a cause-and-effect relationship and therefore would not be considered a clinical trial.

Reporting Clinical Trials

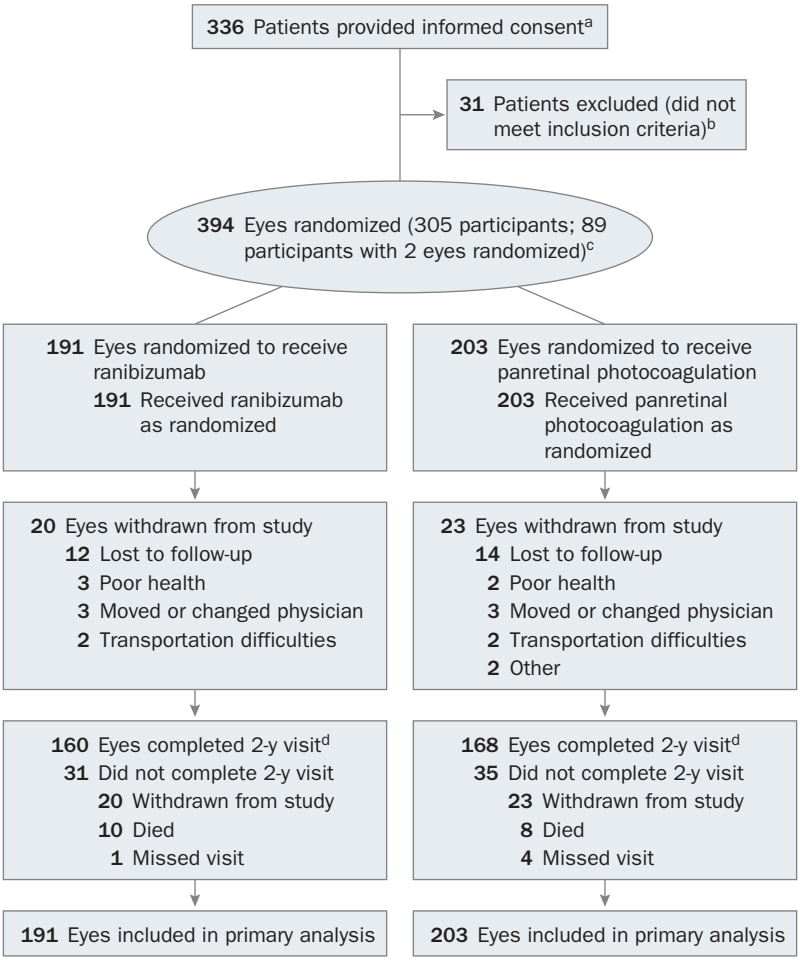
Reports of clinical trials typically are more structured and potentially more straightforward than many other reports of original research. Manuscripts that report the results of clinical trials should be accompanied by the trial protocol and statistical analysis plan for the trial as supplemental material, including any amendments, and also should include a Consolidated Standards of Reporting Trials (CONSORT) flow diagram (**Figure 20-1**) in the manuscript to show the flow of participants through the trial.[3]

In addition, many journals encourage authors to submit the CONSORT checklist, which provides details about how the trial was designed, analyzed, and interpreted. Journals ask authors to submit a completed CONSORT checklist to aid in editorial review and decision, but the checklist is not typically published. The CONSORT checklist is part of the Enhancing the Quality and Transparency of Health Research (EQUATOR) reporting guidelines,[4] which include checklists and extensions of the CONSORT statement with details and additional considerations for various types of RCT designs, such as noninferiority trials, equivalence trials, pragmatic trials, and trials that focus on patient-reported outcomes,[5] among others.

Even though clinical trial protocols may occupy hundreds of pages, manuscripts that report on the primary outcome, or important secondary outcomes, typically follow the journal guidelines for original research investigations. For instance, the guidelines for the JAMA Network journals recommend that clinical trials should be limited to 3000 words of text and no more than 5 tables or figures.[6] Nevertheless, some authors of clinical trials may be concerned at the potentially difficult challenge of providing the primary outcome report of a trial that could change clinical practice within a specific word limit, although more detailed methodology or results that are needed to support the report and follow the guidelines of the CONSORT statement often can be included within

Downloaded from academic.oup.com/book/58841 by guest on 17 October 2026

Figure 20-1. Example of a Profile of a Randomized Clinical Trial, Typically Figure 1, of a Randomized Clinical Trial's Primary Outcome Report[11]



This Figure shows the flow of participants through a trial of panretinal photocoagulation vs intravitreous ranibizumab for proliferative diabetic retinopathy.

[a]Participants were not formally screened prior to obtaining informed consent.

[b]Information was not collected on specific reasons for exclusion.

[c]Participants who had both eyes included in the study had 1 eye randomly assigned to receive ranibizumab and 1 eye to receive panretinal photocoagulation.

[d]Two-year completed visits include those that occurred between 644 and 812 days (between 92 and 116 weeks).

Reproduced from Gross et al.[11]

supplementary material available online within links in the report. Authors should recognize that the report of the clinical trial typically is not a report on every aspect of the study or every analysis.[7] However, for initial reports of clinical trials, it is important to include all prespecified primary outcomes and secondary outcomes in a manner that is consistent with the trial protocol. All

Downloaded from academic.oup.com/book/58841 by guest on 17 October 2026

outcomes should be addressed in the Abstract, Methods, Results, and Discussion sections in the order presented in the trial protocol. If analyses of any secondary outcomes are not to be included in a report, these should be listed with an indication of when and where those findings will be addressed.

Specific Components of Manuscripts Reporting Clinical Trials

Details for preparation of individual sections of a manuscript are provided in other chapters. (See also Chapter 10, Creating an Informative and Effective Title; Chapter 11, Writing an Informative Abstract; Chapter 12, Writing a Compelling Introduction; Chapter 13, Writing the Methods Section; Chapter 14, Presenting the Results Section; and Chapter 15, Writing a Convincing Discussion Section.) However, several specific details should be included in manuscripts that report the results of RCTs.

TITLE

The title of an RCT should clearly indicate the intervention that was evaluated and perhaps the comparator, as well as the primary outcome and the disease entity or study population, such as "Effect of A vs B on C in Patients With D." To help identify the RCT, given its importance to clinical practice, the title or subtitle routinely should include "A Randomized Clinical Trial." However, because all RCTs by design are prospective and study participants are assigned prospectively, the term "prospective" is not needed; for example, "Effect of Continuous Glucose Monitoring on Glycemic Control in Adolescents and Young Adults With Type 1 Diabetes: A Randomized Clinical Trial."[8] In addition, because RCTs in some fields are known by and often referred to by the trial name or acronym, the subtitle may include that information, such as "Effect of Ticagrelor Monotherapy vs Ticagrelor With Aspirin on Major Bleeding and Cardiovascular Events in Patients With Acute Coronary Syndrome: The TICO Randomized Clinical Trial."[9]

ABSTRACT

Most journals that publish clinical trials require authors to prepare a structured abstract, wherein the statements of the abstract are supported by the complete report (as discussed below). Although the abstract format and requirements may vary among journals, key details about the trial should be reported, and generally include the following:

- A clearly stated objective of the trial
- Specific information about the intervention (eg, dose and duration) and the comparator (eg, active intervention or placebo)

Downloaded from academic.oup.com/book/58841 by guest on 17 October 2026

- The dates the study was conducted, including the date of final follow-up; for secondary analysis of an RCT, the dates of that analysis should be included
- Numbers of participants randomized to each group
- The proportion that completed the study
- Description of the primary outcome(s) and key secondary outcome(s), and the measurements used for their assessment
- Data for the main outcomes, with absolute rates and between-group comparisons of absolute rates whenever possible
- Data on adverse events
- A concise, appropriately circumspect conclusion that is supported by the data
- Trial registration identifier

Some journals provide an even shorter iteration of the study findings, such as a section of Key Points, that indicates (1) what the main question or objective of the RCT was; (2) the main findings that answered that main question; and (3) the meaning or clinical relevance of those findings. Journals also may use other mechanisms to efficiently summarize and communicate the study findings, such as a visual abstract, or may include a brief summary for social media to help disseminate the RCT results. The information in these types of summaries is usually based on information included in the abstract.

INTRODUCTION

The Introduction sets the stage for the objective or study question of the clinical trial; it is not a narrative review of the disease under investigation. The Introduction should provide context for the current study by briefly describing previous important RCTs that have addressed similar research questions and should clearly indicate the gap in knowledge that the current RCT will address. The Introduction also should include a clear statement of the primary objective of the RCT and the study hypothesis being tested. If a manuscript is reporting a secondary analysis of a previously reported RCT, this should be made clear in the Introduction with a reference to the primary report.

METHODS

Similarly, the Methods section of a manuscript reporting an RCT provides an opportunity to report the following:

- The number and location of clinical sites, institutional review board or research ethics committee review and approval and informed consent issues, data monitoring, and links to the trial protocol and statistical analysis plan

Downloaded from academic.oup.com/book/58841 by guest on 17 October 2026

- Description of the study population with principal inclusion/exclusion criteria and demographics assessed of trial participants
- Key aspects of the study design (as suggested in the CONSORT reporting guideline), including randomization, follow-up schedule and dates, primary outcome (eg, median diastolic blood pressure), primary outcome time (eg, 2 years after randomization), and any centralized resource staff such as medical monitors or a group of centralized functional outcome assessors
- Key aspects of the intervention, comparator(s), and the comparison group(s)
- Outcomes including the following:
    - The primary outcome(s) and the time point(s) for assessment of the primary outcome(s)
    - Key secondary outcomes from the protocol that are needed to support the interpretation of the primary outcome (if other secondary outcomes are not reported an explanation should be provided)
    - Safety outcomes including prespecified adverse events of interest, and any additional safety outcomes relevant to the interpretation of the risk-benefit ratio of the trial
    - Any amendments and their rationale

The Methods should end with a detailed description of the statistical analyses with a link to the statistical analysis plan, along with items relevant to the CONSORT checklist, including the following:

- How the sample size was estimated
- Adherence to the intention-to-treat principle
- Imputation methods used for missing data
- How treatment group differences, effect sizes, confidence intervals, and *P* values were managed
- Any per-protocol analyses undertaken
- Any preplanned subgroup analyses and their interactions relative to the primary outcome result
- A clear description of any post hoc analyses that were conducted
- Any amendments and their rationale

RESULTS

The Results section requires the following:

- The beginning and ending dates of randomization and date of final follow-up
- Balance of principal baseline characteristics (usually presented as Table 1 in the manuscript)

Downloaded from academic.oup.com/book/58841 by guest on 17 October 2026

- Follow-up with reference to the flow diagram (usually Figure 1)
- Findings for the primary and secondary outcomes following the order presented in the Methods section

To ensure internal consistency in the manuscript, the primary outcome and secondary outcomes, as well as any other outcomes, should be reported using the same order and organizational framework as used in the Methods section. The results should be reported with absolute rates for the primary outcomes, and between-group absolute differences or between-group relative comparisons (such as relative risk or hazard ratios) should be accompanied by confidence intervals. In addition, the Results section also should include a detailed presentation of adverse events.

However, RCTs may have issues that challenge this otherwise straight forward reporting, such as when there is unanticipated dropout of enrolled participants, early termination of the trial, end points that may not be clinically relevant even though they meet with regulatory approval, ambiguous primary results, or secondary end points that are not completely consistent with the primary outcome.[7] In these cases, the reporting of these aspects must be objective and placed in context with the prespecified trial design in a transparent and appropriately circumspect fashion. For these unforeseen circumstances, the data and the related factual information should be included in the Results section (eg, in the case of early termination of the trial, the reasons this occurred and the number of patients enrolled at the time of termination compared with the target enrollment), and the implications of these events for study interpretation should be described in the Discussion section.

DISCUSSION

The Discussion should provide the following:

- A summary of the primary outcome and any secondary outcomes needed to understand the clinical relevance of the primary outcome
- A summary of the safety concerns
- A synthesis of the risk-benefit ratio
- Findings placed in context of related studies
- Limitations of the study, especially chance, bias, and confounding issues
- Generalizability of these results to clinical practice and others not included as study participants
- Conclusions

The results of the clinical trial should be placed in context with the findings from other clinical trials and findings from relevant observational research studies. The conclusion at the end of the manuscript can be identical to or

Downloaded from academic.oup.com/book/58841 by guest on 17 October 2026

consistent with the conclusions and relevance section of the Abstract. Of note, reporting conclusions of an RCT should not necessarily end with a guideline for incorporating the results in clinical practice; that aspect usually will be for another report, when results of other similarly designed clinical trials from other investigators, perhaps in other parts of the country or the world, are available and synthesized in a systematic review with meta-analysis, and by clinicians and patients who evaluate and synthesize the RCT results and superimpose their clinical judgment and values when determining guidelines for how to apply these results to a patient's individual care.

Other Issues to Consider

STATISTICAL VS CLINICAL SIGNIFICANCE OR CLINICAL RELEVANCE

Many journals, including *JAMA* and the JAMA Network journals, use specific language to differentiate between statistical significance and clinical importance. During study design, investigators make assumptions about what represents a statistically significant result for the primary outcome (with effect sizes and measures of error or variance or with a frequentist design, usually a P value $< .05$). However, comparative findings should not be presented with P values alone. Regardless of whether a difference is clinically relevant, investigators should describe the primary outcome differences of treatment A vs treatment B in terms of statistically significant or nonstatistically significant differences, with an estimate of uncertainty, such as 95% confidence intervals around that point estimate difference. Whether that difference is clinically important depends on many other issues that may or may not have been reported in pertinent references prior to the start of the trial. Ideally, experts have defined a priori the magnitude of a primary outcome that would represent a minimal clinically important difference. Such differences should be referenced to determine if statistically significant differences for the primary outcome also represent clinically relevant differences. (See also Chapter 14, Presenting the Results Section.)

TRIAL REGISTRATION

The trial registration (registry name, trial ID, and URL) must be included (typically at the end of the Abstract or in the Methods section). The trial must have been registered before onset of patient enrollment, with registration in a publicly available trials registry that is acceptable to the ICMJE (ie, the registry must be owned by a not-for-profit entity, be publicly accessible, and require the minimum registration data set as described by ICMJE).[2] All clinical trials, regardless of when they were completed, must be registered before submission of a manuscript based on the trial.[2,6] Authors of trials who did not register the trial

Downloaded from academic.oup.com/book/58841 by guest on 17 October 2026

until after patient enrollment began should clearly indicate this information to the journal at the time of manuscript submission. Some journals may have policies and specific criteria to evaluate manuscripts from trials that were registered late or have not been registered to determine whether those studies could be eligible for consideration by the journal. This may require retrospective registration and explanation of why registration was not done prospectively, to be included in the Methods section of the manuscript.

Secondary data analyses of primary (parent) clinical trials should not be registered as separate clinical trials but instead should reference the trial registration number of the primary trial.

DATA SHARING

A data sharing statement should be provided for reports of clinical trials. (See also Chapter 39, Data Sharing, for additional information.) The ICMJE maintains that there is an ethical obligation to share data responsibly that have been generated by clinical trials because, among other reasons, by design, the study participants have put themselves at risk to participate in the trial.[10] Authors should be aware that requirements for data sharing vary among journals, from mandating data sharing as a condition for considering a manuscript for publication to only requiring a statement about whether authors are willing to share data.

Conclusion

Randomized clinical trials have a special place in biomedical publications because their content, especially reports of their primary outcomes, often can influence clinical practice in small or profound ways. Reporting results of clinical trials presumably should be straightforward, with inclusion of the clinical trial registry ID, supplementary material that includes the trial protocol, the statistical analysis plan, and the CONSORT checklist. This approach guides the well-defined content to be included in the Methods section, results that include the CONSORT flow diagram, and discussion of the clinical trial findings. With careful attention to the topics discussed in this chapter, the systematic reports of randomized clinical trials can provide high-quality evidence that can change clinical practice in a way that can improve the public health.

ACKNOWLEDGMENT

The example figure shown in Figure 20-1 is based on a previously published Figure.[11]

Downloaded from academic.oup.com/book/58841 by guest on 17 October 2026

References

1. Simel DL, Rennie D, eds. *The Rational Clinical Examination: Evidence-Based Clinical Diagnosis*. McGraw-Hill; 2009. Accessed March 22, 2023. https://jamaevidence.mhmedical.com/content.aspx?bookid=845&sectionid=70850924
2. Clinical trials registration. International Committee of Medical Journal Editors. Accessed March 22, 2023. https://www.icmje.org/about-icmje/faqs/clinical-trials-registration/
3. CONSORT 2010 flow diagram. CONSORT. Accessed January 18, 2021. http://www.consort-statement.org/
4. EQUATOR reporting guidelines. Instructions for Authors. JAMA Network. Updated March 3, 2023. Accessed March 22, 2023. https://jamanetwork.com/journals/jama/pages/instructions-for-authors#SecEQUATORReportingGuidelines>
5. Mehran R, Baber U, Dangas G. Guidelines for patient-reported outcomes in clinical trial protocols. *JAMA*. 2018;319(5):450-451. doi:10.1001/jama.2017.21541
6. Clinical trial. Instructions for Authors. JAMA Network. Updated March 3, 2023. Accessed March 22, 2023. https://jamanetwork.com/journals/jama/pages/instructions-for-authors#SecClinicalTrial
7. Bauchner H, Golub RM, Fontanarosa PB. Reporting and interpretation of randomized clinical trials. *JAMA*. 2019;322(8):732-735. doi:10.1001/jama.2019.12056
8. Laffel LM, Kanapka LG, Beck RW, et al; CGM Intervention in Teens and Young Adults with T1D (CITY) Study Group; CDE10. CGM Intervention in Teens and Young Adults with T1D (CITY) Study Group; CDE10. Effect of continuous glucose monitoring on glycemic control in adolescents and young adults with type 1 diabetes: a randomized clinical trial. *JAMA*. 2020;323(23):2388-2396. doi:10.1001/jama.2020.6940
9. Kim BK, Hong SJ, Cho YH, et al; TICO Investigators. Effect of ticagrelor monotherapy vs ticagrelor with aspirin on major bleeding and cardiovascular events in patients with acute coronary syndrome: the TICO randomized clinical trial. *JAMA*. 2020;323(23):2407-2416. doi:10.1001/jama.2020.7580
10. Taichman DB, Backus J, Baethge C, et al. Sharing clinical trial data: a proposal from the International Committee of Medical Journal Editors. *JAMA*. 2016;315(5):467-468. doi:10.1001/jama.2015.18164
11. Gross JG, Glassman AR, Jampol LM, et al; Writing Committee for the Diabetic Retinopathy Clinical Research Network. Panretinal photocoagulation vs intravitreous ranibizumab for proliferative diabetic retinopathy: a randomized clinical trial. *JAMA*. 2015;314(20):2137-2146. doi:10.1001/jama.2015.15217

Downloaded from academic.oup.com/book/58841 by guest on 17 October 2026

CHAPTER 21

Meta-Analyses

Christopher C. Muth, MD

Downloaded from academic.oup.com/book/58841 by guest on 17 October 2026

KEY POINTS

- Meta-analysis should be reserved for scenarios in which uncertainty exists after considering the individual studies available and when combining studies could potentially generate new information that might help resolve this uncertainty.
- Systematic reviews and meta-analyses should be prospectively registered, and reporting guidelines such as those provided in the PRISMA statement should be utilized.
- Heterogeneity of the underlying studies should be considered when deciding whether meta-analyses should be performed; if the studies are too heterogenous, a systematic review without meta-analysis may be more appropriate.
- Assessment of the quality and risk of bias of the underlying studies that contribute to the meta-analysis is critical, and sensitivity analyses excluding studies of low quality and high risk of bias should be considered.
- Interpretation of the findings of meta-analyses should consider not only statistical significance but also whether the size of the effect estimate is clinically important and, in most cases, generally should avoid causal inferences in reporting the findings.

In the hierarchy of research study designs, systematic review with meta-analysis is frequently considered to be at the top of the evidence pyramid. While the appropriateness of this can be debated,[1] the advantages of systematic reviews with meta-analyses are that they involve a comprehensive search to identify all relevant evidence and then synthesize the evidence with a statistical pooling of results across studies to yield an effect estimate that, in many cases, is more precise and often more generalizable than the estimates derived from any individual study.

Meta-analyses can be performed with or without a preceding systematic review and can involve data from randomized trials or observational studies.

Meta-analyses can be conducted at the patient level using individual patient data or at the study level using summary data as reported in each component study.

Why Conduct a Meta-Analysis?

A meta-analysis should not be performed simply because more than one study exists that addresses a particular research question. Rather, meta-analysis should be reserved for scenarios in which uncertainty exists after considering the individual studies available and when combining studies could potentially generate new information that might help resolve the uncertainty. Situations in which meta-analyses can be particularly helpful are (1) when attempting to reconcile discrepant findings across studies or (2) to provide increased precision around an effect estimate by combining data from individual studies. In the case of discrepant findings among individual studies, meta-analysis can provide a summary effect estimate that is representative of the larger body of evidence and perhaps more generalizable to a broader range of patients. In instances when individual studies fail to yield statistically significant results, perhaps due to small sample sizes and imprecise effect estimates, pooling data using meta-analysis allows researchers to increase the number of patients analyzed. In this way, study power is increased and authors may be able to obtain a more precise estimate that may achieve statistical significance in aggregate.

It may be less informative to conduct a meta-analysis when a single study or a few large well-conducted studies have already provided informative and convincing estimates of treatment effects. Because large studies are generally given more weight when combined with other smaller studies involving fewer patients, they tend to drive the overall effect estimate when meta-analyzed, thus rendering the meta-analytic process less informative. If the individual studies comprising the literature are heterogenous or of poor quality, a meta-analysis may also be less useful. There is also some concern that repeating meta-analyses as more and more randomized clinical trials are published, further narrowing the confidence interval, may provide little or no clinically important information. At *JAMA* and some other journals, these repetitive analyses that fail to provide new insights may be viewed as lacking sufficient novelty to warrant publication.

Methodological and Reporting Details

Prior to conducting a systematic review and meta-analysis, it is good practice to prospectively register the study at a registry such as PROSPERO.[2] This helps ensure that results are reported with fidelity to the protocol (similar to trial

Downloaded from academic.oup.com/book/58841 by guest on 17 October 2026

registration for randomized clinical trials) and may also help reduce unintentional duplication of systematic review and meta-analytic efforts by researchers.

There are also formal guidelines for reporting systematic reviews and meta-analyses. The Preferred Reporting Items for a Systematic Review and Meta-Analysis (PRISMA) statement[3] has been endorsed by many medical journals and may be a helpful resource to authors conducting meta-analyses of clinical trials. Several PRISMA extension statements are also available for specific subtypes of meta-analyses, such as studies using individual patient data or studies of diagnostic test accuracy. Meta-analyses of observational studies can follow the Meta-Analysis of Observational Studies in Epidemiology (MOOSE) reporting guidelines.[4] It is important to be familiar with PRISMA, MOOSE, and other reporting guidelines before conducting the meta-analysis, rather than just prior to submission of the manuscript.

If a systematic review is performed, the search strategy should be exhaustive, the search should be as current as possible, and the search terms used should be provided to allow assessment of appropriateness and reproducibility. Ideally, multiple databases should be queried, including sources of unpublished data when relevant. Study inclusion and exclusion criteria should be clearly outlined, and a flowchart can be used to illustrate the various stages at which studies were excluded and the reasons why. Each step in the study selection and data collection process (eg, assessment of study eligibility, extraction of study data from reports) should ideally be performed independently by more than 1 individual to reduce the risk of error and bias and to enhance reproducibility, with disagreements generally resolved through discussion.

Because the strength of conclusions drawn from meta-analyses relies on the validity of the underlying studies being pooled, it is critical that all included studies be formally assessed for quality and risk of bias. A tool such as the Cochrane Collaboration's tool for assessing the risk of bias[5] facilitates assessment of multiple domains, including random sequence generation, allocation concealment, blinding of participants and personnel, blinding of outcome assessment, incomplete outcome data, and selective reporting. Publication bias may occur if, for example, the results of positive (and not negative) studies are more frequently published, and this can be formally assessed using a funnel plot or other test.

Once studies have been identified as candidates for inclusion in a meta-analysis, the main methodological question centers around whether it is appropriate to pool the studies, and if so, how this should be done. If the designs of the individual studies vary substantially (eg, vastly different patient populations, interventions, or outcomes), researchers may decide that the data from these studies are too heterogenous to be pooled. In this case, the findings may be more appropriately summarized as a systematic review without meta-analysis. (See also Chapter 22, Review Articles.) If studies are of poor quality,

Downloaded from academic.oup.com/book/58841 by guest on 17 October 2026

researchers should not pool the results. If studies are pooled, the method used to pool the data (eg, fixed-effects or random-effects meta-analysis) and a quantification of the magnitude of heterogeneity (eg, I^2 statistic) should be reported. Subgroup analyses or meta-regression may be used to better understand any potential sources of heterogeneity. (For more information, see Section 19.3.6, Meta-Analyses, in the *AMA Manual of Style*.[6])

Interpretation of Results

Meta-analysis at its core is an observational analysis using statistical techniques to aggregate data across varying studies in an attempt to draw novel inferences. Because of the complexities inherent in such aggregation (such as statistical heterogeneity and variation among included studies in terms of study populations, interventions, and other aspects of care and follow-up), meta-analysis, including meta-analysis of randomized clinical trials, can support inferences similar to those made using other observational research designs. Thus, in most cases, findings from meta-analyses generally should be reported using language that describes associations and avoids causal language or interpretation (ie, exposure-outcome relationships should be described as "associated with" or "relationships between," rather than "effect of," "efficacy of," or "impact of"), unless rigorous methods specifically designed to support causal inferences are included.

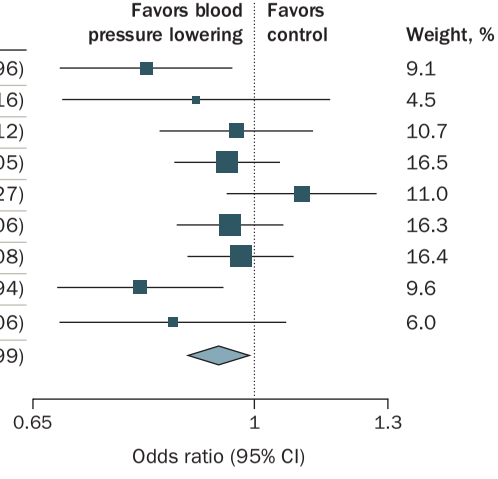
As with other research designs, interpretation of the findings of a meta-analysis should consider not only statistical significance but also whether the size of the observed estimated difference in outcome (ie, effect size) is clinically relevant. If investigators converted effect sizes into standardized units to facilitate pooling across studies, then converting the aggregate effect estimate back to units that are meaningful to clinicians may aid in interpretation. If some of the underlying studies were of poor quality and had high risk of bias, sensitivity analyses excluding these studies and focused on high-quality studies at low risk of bias should also be performed.

The synthesized findings of the meta-analysis can be displayed in a forest plot, which is the graphical representation of the results of the individual studies included and the pooled results (**Figure 21-1**).[7] Visual inspection of the forest plot generated by meta-analysis may facilitate interpretation in multiple ways. First, the forest plot allows an understanding of the contributions of each individual study to the overall results and may help identify whether the results are driven by one or a few large studies. Second, it allows quick assessment of the variability across studies. If all the point estimates of the individual studies tend to hover around the same pooled effect estimate, investigators usually can be more confident about the validity of the aggregate estimate than if the pooled estimate seems to represent an average of extreme outliers on either

Downloaded from academic.oup.com/book/58841 by guest on 17 October 2026

Figure 21-1. Example of a Forest Plot for a Meta-Analysis

Study	Participants with dementia or cognitive impairment/total No.		Absolute risk reduction (95% CI), %	Odds ratio (95% CI)	Weight, %
	Blood pressure lowering group	Control group			
PROGRESS,[23] 2003	276/3051	334/3054	1.89 (0.39 to 3.39)	0.81 (0.68 to 0.96)	9.1
SCOPE,[24] 2003	113/2477	125/2460	0.52 (–0.68 to 1.71)	0.89 (0.69 to 1.16)	4.5
HYVET-COG,[6] 2008	485/1687	486/1649	0.72 (–2.36 to 3.81)	0.97 (0.83 to 1.12)	10.7
PRoFESS,[26] 2008	795/7531	832/7518	0.51 (–0.48 to 1.50)	0.95 (0.86 to 1.05)	16.5
TRANSCEND,[7] 2011[a]	454/2642	412/2589	–1.27 (–3.28 to 0.74)	1.10 (0.95 to 1.27)	11.0
ON TARGET (Dual),[7] 2011	1240/7461	657/3801	0.67 (–0.80 to 2.13)	0.95 (0.86 to 1.06)	16.3
ON TARGET (ARB),[7] 2011	1279/7566	657/3801	0.38 (–1.09 to 1.85)	0.97 (0.88 to 1.08)	16.4
SPRINT MIND,[12] 2019	287/4278	353/4285	1.53 (0.42 to 2.64)	0.80 (0.68 to 0.94)	9.6
HOPE-3,[13] 2019	584/811	612/815	3.08 (–1.20 to 7.37)	0.85 (0.68 to 1.06)	6.0
Test for overall effect: $z = -2.28$; $P = .02$ Heterogeneity: $\tau^2 = 0.00$; $\chi^2 = 12.60$; $P = .13$; $I^2 = 36.1\%$			0.71 (0.19 to 1.2)	0.93 (0.88 to 0.99)	



The individual studies included in the analysis are listed, with the numerator and denominator for the outcomes of interest, the absolute risk differences, and the relative differences expressed as odds ratios. The odds ratios and confidence interval for each study are plotted, with the size of the squares reflecting the weight of each study in the analyses and the diamond representing the overall estimate of the association.

Reproduced from Hughes et al.[7]

Downloaded from academic.oup.com/book/58841 by guest on 17 October 2026

side. If there are studies with extreme results, and especially if these outlying studies are of poorer quality with high risk of bias, investigators should consider sensitivity analyses excluding these studies to obtain a more valid pooled effect estimate.

Common Problems and Errors in Manuscripts Reporting the Results of Meta-Analyses

Some common problems with meta-analyses can be avoided with careful planning during the design phase, whereas other problems may need to be addressed as issues arise. Research questions that are too broad or imprecisely defined may yield search results that are heterogenous and not appropriate for pooling. Using a framework to clearly define the population, intervention, comparison group, and outcome of interest (ie, the PICO framework) can help generate focused and clinically relevant search results.

Failure to prospectively register the study is another potential problem that can be addressed with some forethought. Although technically reporting guidelines, the PRISMA or MOOSE statements can also be consulted early in the design phase of the study to ensure that all relevant aspects are addressed as the study is prospectively planned and registered.

When reporting methodological details and search results, critical details that should be provided but are often overlooked include study selection criteria (along with a flow diagram describing the reasons for study exclusion at each stage of the process) and quality and risk of bias assessment of the individual studies. Once studies have been identified, common problems include unwarranted pooling of data or failure to perform appropriate sensitivity analyses focused on high-quality studies; as noted above, meta-analyses of studies that are too heterogenous or of poor quality should not be performed. If pooling is performed, the rationale for pooling (and the techniques used) should be explained and a measure of heterogeneity should be provided.

In interpreting the findings, authors should attempt to understand whether results are driven by any single individual study and consider possible reasons for discrepant findings among individual studies. Overinterpretation should be avoided, and instead, authors should try to place the results in appropriate clinical context and within the existing body of literature.

Conclusion

Meta-analyses, when conducted well and performed to address a question about which substantial uncertainty exists, can yield important information

Downloaded from academic.oup.com/book/58841 by guest on 17 October 2026

and make useful contributions to the scientific literature beyond what would be possible from considering individual studies alone.

ACKNOWLEDGMENT

The example figure shown in Figure 21-1 is based on a previously published Figure.[7]

References

1. Berlin JA, Golub RM. Meta-analysis as evidence: building a better pyramid. *JAMA*. 2014;312(6):603-605. doi:10.1001/jama.2014.8167
2. PROSPERO: international prospective register of systematic reviews. University of York Centre for Reviews and Dissemination. UK National Institute for Health Research. Accessed March 21, 2023. https://www.crd.york.ac.uk/PROSPERO
3. Preferred reporting items for systematic reviews and meta-analyses: the PRISMA statement. EQUATOR Network. Updated March 6, 2023. Accessed March 21, 2023. https://www.equator-network.org/reporting-guidelines/prisma
4. Meta-analysis of observational studies in epidemiology: a proposal for reporting. EQUATOR Network. Updated September 26, 2013. Accessed March 21, 2013. https://www.equator-network.org/reporting-guidelines/meta-analysis-of-observational-studies-in-epidemiology-a-proposal-for-reporting-meta-analysis-of-observational-studies-in-epidemiology-moose-group
5. Higgins J, Thomas J, eds. *Cochrane Handbook for Systematic Reviews of Interventions*. Version 6.2; 2021. Accessed March 21, 2023. https://training.cochrane.org/handbook/current
6. Christiansen S, Iverson C, Flanagin A, et al. *AMA Manual of Style: A Guide for Authors and Editors*. 11th ed. Oxford University Press; 2020. Accessed March 21, 2023. https://www.amamanualofstyle.com
7. Hughes D, Judge C, Murphy R, et al. Association of blood pressure lowering with incident dementia or cognitive impairment: a systematic review and meta-analysis. *JAMA*. 2020;323(19):1934-1944. doi:10.1001/jama.2020.4249

Downloaded from academic.oup.com/book/58841 by guest on 17 October 2026

CHAPTER 22

Review Articles

Phil B. Fontanarosa, MD, MBA

Downloaded from academic.oup.com/book/58841 by guest on 17 October 2026

KEY POINTS

- Reviews are important types of articles in biomedical journals; provide up-to-date, state-of-the-science summaries of the literature; and may include systematic reviews, narrative reviews, scoping reviews, or other types of review articles.
- Authors of review manuscripts should have a comprehensive understanding of the topic, be aware of whether other reviews on the same or closely related topics have been published recently, and have in-depth knowledge of the practical applications related to the clinical, policy, and research applications and implications of the topic of the review.
- Before beginning manuscript preparation, authors should determine the types of reviews published by the journal to which they are planning to submit their manuscript and be knowledgeable about the specific journal format and requirements for reviews.
- Guidelines for reporting certain types of reviews are available and may be useful for authors in organizing their review manuscripts and ensuring that key elements are included.

Reviews are important types of articles in biomedical journals and provide up-to-date, state-of-the-science summaries of the literature. Depending on the journal, reviews may address a wide variety of topics relevant for the readership, such as clinical medicine, public or global health, health policy, biomedical research, or other topics. This chapter describes several types of reviews, discusses factors authors should consider before and when writing a review, and provides guidance on preparing review manuscripts for submission to biomedical journals.

Types of Reviews

Journals publish various types of reviews. Some of the most common review articles include systematic reviews, narrative reviews, scoping reviews, umbrella reviews, clinical guidelines, position statements from professional organizations, and reporting guidelines. Other review-type articles may be designated with different terms or descriptions, such as rapid review, living review, special communication, special article, or seminars, among others. (See also "Reviews," in Section 1.0, Types of Articles, in the *AMA Manual of Style*.[1])

The following are some common types of reviews in biomedical journals.

SYSTEMATIC REVIEWS

Systematic reviews are critical assessments of the literature and data sources pertaining to a topic and provide an evidence-based, balanced, objective evaluation of the current state of the knowledge base.[2,3] Systematic reviews in clinical journals generally address a specific question or issue relevant for the journal readership and may involve a focused topic emphasizing factors such as cause, diagnosis, prognosis, therapy, or prevention.[2] Systematic reviews require a complete systematic search of the literature using multiple databases, covering many years, and generally include grading the quality of the cited evidence. In some journals, such as *JAMA*, systematic reviews with meta-analysis are published as original research articles, because these reports usually provide new results from pooled data estimates. (See also Chapter 21, Meta-Analyses.) Systematic reviews without meta-analysis are usually published as review articles.[2]

NARRATIVE REVIEWS

Narrative reviews in biomedical journals may address a wide range of topics, such as in clinical medicine, public health, health policy, or medical research, and are scholarly, thorough, evidence-based, and well-referenced.[2] These reviews of clinical topics provide an up-to-date summary of the evidence for clinicians on a topic of interest, often from the perspective of experts in these disciplines. The focus of narrative reviews on clinical topics may be to provide an update of the current understanding of the physiology of the disease or condition, diagnostic considerations, and treatment.[2] These reviews often address a specific question or issue that is relevant for clinical practice. Narrative reviews do not require (but may include) a systematic literature search but should be based on a thorough assessment of the most recently available evidence. These reviews should be objective and balanced and should avoid selective inclusion

Downloaded from academic.oup.com/book/58841 by guest on 17 October 2026

of evidence that only supports one position related to an issue. Recommendations should be supported with evidence and should rely on recent systematic reviews and guidelines, if available.[2]

SCOPING REVIEWS

Scoping reviews are an increasingly common approach to evidence synthesis. Methodological guidance and resources are available to assist authors with planning, conducting, and reporting these reviews.[4,5] Some objectives of scoping reviews may include evaluating the amount, variety, and nature of available evidence on a topic; determining the potential value of undertaking a systematic review; summarizing findings from an evidence base with methodological variability; or identifying gaps in the literature that may be helpful in planning future studies.[4,5]

UMBRELLA REVIEWS

Umbrella reviews are systematic assessments of multiple systematic reviews or systematic reviews of meta-analyses on a specific topic.[6] Umbrella reviews are only useful when many systematic reviews with or without meta-analyses on a specific topic have been published. These review types provide a summary overview of the quality of included systematic reviews, including assessment of sample sizes, effect sizes, measures of uncertainty, heterogeneity, and potential bias.[6]

CLINICAL GUIDELINES

Clinical guidelines have been defined as "statements that include recommendations intended to optimize patient care that are informed by a systematic review of evidence and an assessment of the benefits and harms of alternative care options."[7] These articles may reflect national evidence-based recommendations, such as those from the US Preventive Services Task Force regarding clinical preventive services, or may represent official recommendations from professional organizations regarding topics related to clinical practice and health care delivery, such as those from the American Heart Association. For these review-type articles, journals may have ongoing relationships with the organizations that produce the clinical guidelines and may have agreements regarding publication of these reports.

Factors to Consider Before Writing a Review

Authors of review manuscripts should have a comprehensive understanding of the topic, including the totality of the evidence base and the existence of

Downloaded from academic.oup.com/book/58841 by guest on 17 October 2026

landmark or classic reports on the topic. In addition to the collective knowledge and experience of the authors regarding the review topic, thorough literature searches are essential to identify and capture the totality of evidence. Another important consideration is that authors should be aware of whether other reviews on the same or closely related topics have been published recently. This will help determine whether the review the authors are considering writing is necessary, and if so, how the knowledge and information from the review will add to existing reviews. Collaborating with a medical librarian is helpful to ensure that the available evidence on a topic is identified and retrieved in literature searches[8] and to identify recent reviews on similar or related topics.

Authors should have in-depth knowledge of the practical applications related to the topic of the review, not only involving the available evidence but also regarding the clinical, policy, and research applications and implications. Authors of reviews should have sufficient experience and expertise with the subject matter of the review to be able to prepare a high-quality, comprehensive review manuscript that will be recognized as authoritative, meaningful, and useful and that will be positioned appropriately within the current context of clinical practice or policy discussions related to the topic of the review.

Authors should carefully examine reviews published in the journal to which they are considering submitting a review manuscript. Doing so will enable authors to determine the types and scope of topics included in reviews the journal publishes and assess whether a review on a similar or closely related topic as that of the planned review has been published recently. Evaluating these published reviews also will enable authors to determine the review article format, understand the methodological rigor and depth required for the review, examine the types and typical components of tables and figures, and assess other overall aspects of the review. This may include, for example, the usual content and nature of the Discussion section of the review and the types of materials typically included as supplemental information.

Authors should be aware that journals may have special considerations regarding submission of reviews. For some journals, reviews are invited by the journal editors, whereas for some other journals, authors are required to contact the journal (or editor of the review section) prior to submission of a review manuscript. These presubmission inquiries may require authors to submit a letter expressing interest in submitting a review and may request that authors submit an outline of the proposed review, describe the underlying evidence on which the review will be based, and report any potential conflicts of interest authors may have involving the topics that will be covered in the review manuscript. Following evaluation of this information, the journal editors may inform the authors that they are not interested in considering the proposed topic or manuscript, in which case the authors should accept the decision and consider another journal for their review manuscript. Alternatively, the editors may inform the authors that they are interested in considering the proposed

Downloaded from academic.oup.com/book/58841 by guest on 17 October 2026

review manuscript and may provide additional suggestions for the authors to consider. In these cases, authors should understand that this expression of interest only indicates that the journal editors are interested in the topic of the review and are willing to evaluate the full manuscript but does not represent a commitment or a guarantee that the manuscript will be accepted for publication.

Journal Guidelines for Reviews

Authors should consult the instructions for authors of the journal to which they are considering submitting a review before they begin manuscript preparation considering that journals not only publish different types of reviews, but often have very specific requirements for various types of reviews. In general, authors should avoid preparing a review using their own individual approach or their preferred format without considering the requirements of the target journal. In some cases, it may not be possible to retrofit the content of the review and reformat the completed manuscript to fulfill a specific journal's criteria and requirements. It can also be problematic when authors use their own format for a review that is not consistent with the journal's requirements and format and then expect editors to make an exception for a specific manuscript. As with all scientific writing, authors of reviews should avoid promotional language and primarily citing their own work. In addition, some journals will not consider reviews by authors with related financial conflicts of interest.

Most journals provide information in the instructions for authors related to the types of reviews the journal publishes and include guidelines about the requirements for review manuscripts. These may include details about the following:

- Abstract format
- Specific sections to include in the manuscript
- Length of the manuscript (overall, and possibly by manuscript section)
- Recommendations for tables and figures
- Limits on number of references
- Content to include in supplemental materials (eg, lengthy detailed tables, supporting information, videos)
- In some journals, limits on the number of authors
- Requirements for disclosures of conflicts of interest

The following examples of guidelines for review manuscripts from 3 journals illustrate some of these differences.

Downloaded from academic.oup.com/book/58841 by guest on 17 October 2026

JAMA

JAMA publishes systematic reviews and narrative reviews.[2] In the instructions for authors, systematic reviews are described as "critical assessments of the literature and data sources pertaining to clinical topics, emphasizing factors such as cause, diagnosis, prognosis, therapy, or prevention."[2] These manuscripts should include the following sections: Structured Abstract, Introduction, a detailed Methods section, Results (which may include subsections, depending on the specific topic, such as Pathophysiology, Clinical Presentation, Assessment and Diagnosis, Treatment, and Prognosis), Discussion, and Conclusions. The maximum manuscript length is 3000 words of text, with no more than a total of 5 tables and/or figures and no more than 50 to 75 references.[2]

Narrative reviews are described as "providing an up-to-date review for clinicians on a topic of general common interest from the perspective of internationally recognized experts in these disciplines."[2] The manuscript should include the following: Structured Abstract, Introduction, Methods (if included), Discussion/Observations (with the following subsections, if appropriate: Pathophysiology, Clinical Presentation, Assessment and Diagnosis, Treatment, and Prognosis), and Conclusions. The typical length is 2000 to 3500 words (maximum), with no more than a total of 5 tables and/or figures, and no more than 50 to 75 references.[2]

NEW ENGLAND JOURNAL OF MEDICINE

The *New England Journal of Medicine* publishes clinical practice reviews and other review manuscripts. According to the information in the author center, a clinical practice review "offers evidence-based review of topics relevant to practicing primary care and specialist physicians (but written for general audience, so may include material considered too introductory for specialists)."[9] The manuscripts should have a maximum of 2500 words with a maximum of 2 authors, and must include information regarding the clinical problem, strategies and evidence, areas of uncertainty, guidelines from professional societies, and authors' conclusions and recommendations. The manuscript may have a "small number of tables and figures" and up to 50 references.[9]

"Other reviews" are described as offering "an evidence-based review covering a wide variety of potential clinical and mechanistic subjects." These manuscripts have a maximum length of 3000 words, with a maximum of 3 authors, a maximum of 5 figures and tables, and up to 75 references.[9]

ANNALS OF INTERNAL MEDICINE

Annals of Internal Medicine publishes several types of reviews and the information for authors provides guidelines for preparing these manuscripts, including

Downloaded from academic.oup.com/book/58841 by guest on 17 October 2026

for systematic reviews and meta-analyses, rapid reviews, living reviews, and narrative reviews.[10] A rapid review is described as "a form of knowledge synthesis in which components of the systematic review process are simplified or omitted to produce information in a timely manner."[10] A living review "is a systematic review that is routinely updated at defined intervals, incorporating relevant new evidence as it becomes available."[10] These reviews should have the following: "clearly formulated questions; methods sections that describe sources and searches, selection criteria, data extraction and assessment, and synthesis methods; results that synthesize rather than catalog evidence, with flow charts and other graphics as necessary; and discussions that mention limitations of the review."[10]

Narrative reviews are described as "review articles without detailed structured methods to identify, collect, appraise, and interpret information that are often summarized descriptively in a narrative form. Narrative reviews are especially suitable for describing cutting-edge and evolving developments and underlying theory."[10] These manuscripts should include the term "a narrative review" as a subtitle, an unstructured abstract of 275 words or less, text length of 3500 words or less (excludes abstract and references), 75 or fewer references, no more than 4 tables or figures (combined), and a box listing 3 to 7 take-home points that link back to the original questions that the review set out to answer.[10] This journal also considers and publishes other types of reviews, including position papers, which are "official statements from professional organizations on issues related to clinical practice, health care delivery, and public health," and clinical practice guidelines.[10]

OTHER JOURNALS

As these examples demonstrate, the types and format of reviews vary substantially among journals, and many journals have their own specific criteria and requirements for review manuscripts. For instance, in some journals, reviews on clinical topics may include specific sections like those used in some textbook chapters, such as Pathophysiology, Epidemiology, Clinical Presentation, Assessment and Diagnosis, Treatment, and Prognosis. Following the information for authors about reviews in the target journal will help ensure that authors prepare their review manuscripts in accordance with the journal's required format and manuscript components.

Preparation of Review Manuscripts

Even though the specific details regarding requirements for preparation of reviews vary from journal to journal, authors may find several general approaches helpful for writing a review manuscript. Guidelines for reporting for certain

Downloaded from academic.oup.com/book/58841 by guest on 17 October 2026

types of reviews have been rigorously developed and may be useful for authors in organizing their review manuscripts and ensuring that key elements are included. Guidelines and checklists for reporting elements in review articles are available from the EQUATOR Network[11] and include, for example, guidelines for systematic reviews and meta-analyses,[12] for scoping reviews,[5] for literature searches in systematic reviews,[13] and for systematic reviews with a focus on health equity.[14]

In addition to the details in these reporting guidelines, the following general principles and suggestions for writing review manuscripts, based on the *JAMA* Instructions for Authors,[2] represent an approach authors could consider when preparing review manuscripts. These suggestions are not meant to be comprehensive or all-inclusive, but rather provide potential starting points for consideration when preparing sections of the review manuscript.

TITLE

The title for a review manuscript should include a description of the primary topic of the review. Specific terms should be used, and the title generally should not be overly broad. The type of review (eg, "Systematic Review") could be indicated in the subtitle. (See also Chapter 10, Creating an Informative and Effective Title.)

INTRODUCTION

The Introduction should clearly describe the question or issue the review will address and, for clinical topics, explain the importance of the topic for general medical practice, specialty practice, or public or global health. It is helpful to begin with a general summary of the clinical issue (eg, breast cancer), briefly summarize the disease epidemiology (eg, prevalence, incidence, mortality), and describe the specific aspect of the clinical problem the review will explore (eg, diagnosis of breast cancer). The Introduction should clearly indicate the focus of the material that will be covered in the review and may describe specific objectives or key questions the review will address. (See also Chapter 12, Writing a Compelling Introduction.)

METHODS

Depending on the journal requirements, a Methods section may be required for systematic reviews and may be helpful to include in narrative reviews. The Methods section should summarize the literature search conducted for the review and indicate the criteria used for inclusion and exclusion of articles. The characteristics of the literature searched and included in the review should be described, including the bibliographic databases and other sources that were

Downloaded from academic.oup.com/book/58841 by guest on 17 October 2026

searched (eg, PubMed/MEDLINE, Embase); search terms used; dates included in the search; screening process; language limitations; identification of other sources of material, such as subsequent reference searches of retrieved articles; and inclusion and exclusion criteria.

The search of the literature should reflect the most recently available evidence and information. For instance, if the initial literature search had been conducted several months earlier, the authors may need to repeat the search to determine if new relevant articles have been published, ideally with end dates of the search within a month or two before manuscript submission. For systematic reviews, the rating system used to evaluate the quality of the evidence should be specified. The methods used to evaluate study quality should be described, including number of quality raters, how agreement about quality ratings was assessed, and how disagreements on quality ratings were resolved.

The approach used for synthesizing the evidence should be described. The highest-quality evidence (randomized clinical trials, meta-analyses, systematic reviews, and high-quality prospective cohort studies) generally should receive the greatest emphasis. Other reviews and clinical practice guidelines ordinarily should not be used as the primary component of the evidence for the systematic review, although other relevant reviews and guidelines should be addressed in the Discussion section of the article. (See also Chapter 13, Writing the Methods Section.)

RESULTS

For systematic reviews and narrative reviews with a literature search, it is helpful to provide an indication of the evidence included in the review. The Results section could begin with a summary of the number of articles reviewed and included in the review, numbers of various types of studies included (eg, clinical trials, meta-analyses, cohort studies), the aggregate numbers of patients/participants represented by these studies, and a summary of the quality of the evidence. Details of the results of the evidence search can be reported in a flow diagram and details about the included individual studies (such as design, sample size, population, outcomes, effect sizes, measures of uncertainty, and study quality) can be reported in tables.

The major findings or observations from the review of the clinical issue or topic should be summarized in an evidence-based, objective, and balanced fashion. The highest-quality evidence available should receive the greatest emphasis, and more recent studies should be highlighted when appropriate. For key findings, providing quantitative data is useful, such as regarding epidemiological aspects (eg, changes in disease prevalence) or interventions (eg, summary or estimates of effect size). For clinical reviews that address treatment, findings generally should be based on the most recently available and highest level of evidence. Treatment options should be summarized in the text and presented

Downloaded from academic.oup.com/book/58841 by guest on 17 October 2026

in detail in tables along with an indication of the strength of evidence supporting the individual treatments. In general, treatment recommendations should be supported by a systematic review or a high-quality guideline. If possible, the costs for various treatments could be provided. (See also Chapter 14, Presenting the Results Section.)

DISCUSSION

The Discussion section of the review will vary depending on the journal style and requirements. In general, the Discussion should clearly explain the key findings of the review, describe how the review addressed the stated objectives (or questions posed, if applicable), and emphasize how the review contributes to advancing and summarizing current knowledge. For many reviews, it is helpful to summarize the key findings or primary messages from the review in the first paragraph of the Discussion, without listing detailed findings from all studies reviewed.

In the Discussion section, it is also helpful to provide a critical synthesis of data and information based on the results of the review, an assessment of the quality of studies summarized, and a description of how key findings could be interpreted and perhaps used to guide clinical practice or inform policy or future research. These statements should be supported by the evidence discovered in the review and should be balanced, objective, and circumspect. Discussion of the findings of the review in consideration of current guidelines or generally accepted conventional wisdom about a topic may be informative.

The limitations of the review and the available evidence base should be discussed, and gaps in evidence should be addressed. For some topics, a discussion of controversial or unresolved issues and topics in need of future research also may be included. (See also Chapter 15, Writing a Convincing Discussion Section.)

TABLES AND FIGURES

The effective use of tables and figures is an essential aspect of many reviews, serves to efficiently display and summarize the data and findings of the review, and provides the evidence base for discussion, explanation, and interpretation. While the type, level of detail, and number of tables and figures will vary depending on the individual journal and the characteristics of the individual review, some commonly used elements include the following. For systematic reviews and other reviews that include a literature search, a flow diagram that summarizes the details of the literature search and numbers of articles identified, reviewed, and included in the review should be included in the manuscript (or as supplemental material). The relevant sections of the PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-Analyses) flow diagram can

Downloaded from academic.oup.com/book/58841 by guest on 17 October 2026

be used as a guide for the flow diagram.[12] For systematic reviews, tables may be created to summarize the search results. For example, these tables may include a list of individual studies included in the review, perhaps with their year of publication, sample size, study methodology/design, interventions or exposure, key findings or outcomes, and quality assessment with an indication of risk of bias. If a systematic review includes a large number of studies, a table listing all studies and details may be better provided as a supplemental document rather than including this table in the main manuscript.

For narrative reviews on clinical topics, tables may display key findings of the review, major epidemiologic disease facts, major diagnostic tools available, major therapies available, and current clinical practice recommendations along with diagnostic and therapeutic uncertainty and controversies.[2] (See also Chapter 18, Creating Effective and Efficient Tables, and Chapter 19, Effective Use of Figures and Graphs in Scientific Publications.)

Conclusion

Review articles are commonly published in biomedical journals and provide up-to-date, state-of-the-science summaries of the literature, and may include systematic reviews, narrative reviews, or other types of reviews. Authors of review manuscripts should have a comprehensive knowledge of the topic and existing evidence base and should understand the types of reviews the journal to which the authors are planning to submit the manuscript publishes and the specific journal format and requirements for various types of reviews. Guidelines for reporting certain types of reviews are available and may be useful for authors in organizing their review manuscripts and ensuring key elements are included.

References

1. Fontanarosa PB. Types of articles. In: Christiansen S, Iverson C, Flanagin A, et al, eds. *AMA Manual of Style: A Guide for Authors and Editors*. 11th ed. Oxford University Press; 2020. Accessed July 21, 2023. https://academic.oup.com/amamanualofstyle/book/27941/chapter/207562717#406367260
2. Reviews. Instructions for Authors. JAMA Network. Updated April 4, 2024. Accessed April 10, 2024. https://jamanetwork.com/journals/jama/pages/instructions-for-authors#SecReviews
3. Murad MH, Montori VM, Ioannidis JPA, et al. How to read a systematic review and meta-analysis and apply the results to patient care: users' guides to the medical literature. *JAMA*. 2014;312(2):171-179. doi:10.1001/jama.2014.5559
4. Peters MDJ, Marnie C, Colquhoun H, et al. Scoping reviews: reinforcing and advancing the methodology and application. *Syst Rev*. 2021;10(1):263. doi:10.1186/s13643-021-01821-3

Downloaded from academic.oup.com/book/58841 by guest on 17 October 2026

5. Tricco AC, Lillie E, Zarin W, et al. PRISMA Extension for Scoping Reviews (PRISMA-ScR): Checklist and Explanation. *Ann Intern Med*. 2018;169(7):467-473. doi:10.7326/M18-0850
6. Belbasis L, Bellou V, Ioannidis JPA. Conducting umbrella reviews. *BMJ Med*. 2022;1(1):e000071. doi:10.1136/bmjmed-2021-000071
7. Institute of Medicine (US) Committee on Standards for Developing Trustworthy Clinical Practice Guidelines, Graham R, Mancher M, Miller Wolman D, Greenfield S, Steinberg E, eds. *Clinical Practice Guidelines We Can Trust*. Washington (DC): National Academies Press (US); 2011. doi:10.17226/13058
8. Rethlefsen ML, Murad MH, Livingston EH. Engaging medical librarians to improve the quality of review articles. *JAMA*. 2014;312(10):999-1000. doi:10.1001/jama.2014.9263
9. Article types. Author Center. *New England Journal of Medicine*. Accessed July 21, 2023. https://www.nejm.org/author-center/article-types
10. Information for Authors. *Annals of Internal Medicine*. Updated July 12, 2023. Accessed July 25, 2023. https://www.acpjournals.org/pb-assets/pdf/AnnalsAuthorInfo-1622139458027.pdf
11. EQUATOR Network. Accessed April 10, 2024. https://www.equator-network.org
12. The PRISMA 2020 statement: an updated guideline for reporting systematic reviews. EQUATOR Network. Updated January 16, 2024. Accessed April 10, 2024. https://www.equator-network.org/reporting-guidelines/prisma/
13. PRISMA-S: an extension to the PRISMA Statement for Reporting Literature Searches in Systematic Reviews. EQUATOR Network. Updated May 19, 2022. Accessed July 25, 2023. https://www.equator-network.org/reporting-guidelines/prisma-s/
14. PRISMA-Equity 2012 extension: reporting guidelines for systematic reviews with a focus on health equity. EQUATOR Network. Updated January 13, 2022. Accessed July 25, 2023. https://www.equator-network.org/reporting-guidelines/prisma-equity/

Downloaded from academic.oup.com/book/58841 by guest on 17 October 2026

CHAPTER 23

Brief Reports and Research Letters

Jody W. Zylke, MD

Downloaded from academic.oup.com/book/58841 by guest on 17 October 2026

KEY POINTS

- Shorter research articles include Brief Reports and Research Letters.
- Brief Reports are similar to full-length research articles but shorter.
- Research Letters vary in format from journal to journal.
- Topics for short reports may be more varied than full-length articles.
- The Methods and Results sections need to be relatively simple and the conclusion straightforward.

Original investigations are the behemoths in medical research and publishing. The studies they report cost the most money, and these articles occupy the most pages or online proportion of journal articles and often attract the most attention. However, that does not mean there is not room for smaller research reports in medical journals. In fact, many authors like and many readers may prefer short reports, as these articles are concise, focused, and easy to read, and sometimes the topics are provocative or creative. In addition, these types of articles, called Brief Reports and Research Letters in the JAMA Network journals and other journals, may represent an opportunity for an author to have work published in a high-profile journal.

How does an author know what type of article to write? Often the category of article is obvious, based on the type of study. A randomized clinical trial, for example, almost always needs to be a full-length report in the journal. But sometimes the type and length of article to prepare are not so obvious. Many factors need to be considered: Which outcomes should be reported, and in how many different articles? How many subgroup and sensitivity analyses are needed to thoroughly analyze the data and support the primary analysis? Sometimes it is best to write the manuscript as efficiently as possible, including key methods and results and a focused discussion, and then see the length of the manuscript. Trying to write a manuscript to fit a particular category can be constraining and may produce a report that either leaves out essential information or includes extraneous material. Determining the category for a study should not be a major source of concern for authors. A journal's

information for authors can be helpful, and authors can review the journal for articles published in specific categories. In addition, editors will advise authors to lengthen or shorten a manuscript based on editorial assessment and peer review or may decide a different journal category is more suitable. (For more information, see also Section 1.1, Research Reports, in the *AMA Manual of Style*.[1])

Brief Reports

Brief Reports usually follow the same structure as longer research reports (such as original investigations) and include a Title, Structured Abstract, Introduction, Methods, Results, and Discussion, and may include supplemental materials. Other chapters in this book about writing a manuscript (Chapter 12, Writing a Compelling Introduction; Chapter 13, Writing the Methods Section; etc) also apply to Brief Reports, except for length considerations. Brief Reports are shorter than full-length research reports; ie, they may be limited to 1000 to 1500 words of text (not including the Abstract) and usually have no more than a total of 3 data or graphic elements (tables or figures).

Some journals publish many Brief Reports. For some manuscripts that are submitted as Brief Reports, editors may ask for additional information about the study methods or request that authors conduct new analyses that require the manuscript to be lengthened to a full-length article. Or the editors may think that a full-length manuscript can be shortened (eg, by reducing the text devoted to study implications) and may recommend that it be shortened to a Brief Report.

Research Letters

Research Letters are highly focused, concise reports of original data and are generally published in the Correspondence section of a journal, even though these reports are more akin to regular research articles than letters to the editor. Research Letters are indexed in major bibliographic databases, may receive a substantial number of citations, and regularly attract the attention of the media.[2]

The format of Research Letters can be quite variable. Because of the short length, these articles can be challenging to write and differ the most from longer research studies. In some journals, Research Letters have a structure similar to full-length research articles; in other journals, Research Letters follow a different format. Some journals allow supplemental material; others do not. Authors should check the journal's information for authors and look at some examples in the journal before submitting a Research Letter.

Downloaded from academic.oup.com/book/58841 by guest on 17 October 2026

Topics of Research Letters tend to be more varied than the topics of regular research articles. Research Letter topics have included results of clinical studies as well as reports on health policy, scientific publishing, and technology that would be unusual topics for a full research article. Reports of longer-term follow-up or of secondary outcomes of trials previously published in the journal also may be suitable as Research Letters. Some journals may rarely publish single-case reports or case series as full-length articles but may publish these reports as Research Letters.

Although the types of reports that are published as Research Letters may vary from studies published elsewhere in the journal, the methodologic rigor required of accepted manuscripts is the same. Research Letters are expected to meet other journal requirements for original data (eg, originality, timeliness of data, and response rates for survey data). These reports undergo editorial evaluation and peer review and statistical review, as needed, and authors must respond to reviewers' and editors' comments during revision.

Certain types of studies are well suited for reporting as Research Letters. Studies that use well-established databases (such as the US National Health and Nutrition Examination Survey or the UK Biobank) can reference much of their methods, limiting the text that would otherwise be devoted to such description. Reports of secondary outcomes or long-term follow-up of previously published studies can similarly reference the study methods and perhaps baseline characteristics of the participants. Other types of designs that fit well in a short report are surveys, small crossover trials, and some cross-sectional and cohort studies. However, some designs do not work well. First reports of randomized clinical trials rarely can be summarized in a Research Letter, as there are too many reporting requirements. Meta-analyses are not suited to this format because usually they review more studies than can be accommodated in the limited number of references allowed for Research Letters.

Perhaps more important than the design, however, are the outcomes. In general, Research Letters have to report a fairly straightforward outcome, positive or negative, that can be summarized in a single concluding sentence. Studies with multiple outcomes or that require a fair amount of explanation or discussion do not lend themselves to the Research Letter format. Studies that use complex statistical analyses or require multiple sensitivity analyses to bolster the main analysis also cannot be adequately described within the limited length of a Research Letter.

But even with a study that may be well suited for the Research Letter format, some authors may hesitate to use this format because of the length restriction and may have difficulty writing in brief. Concise writing requires attention to every word. For example, authors frequently write "in the vast majority of cases," which can be written as "in most cases," using half the number of

Downloaded from academic.oup.com/book/58841 by guest on 17 October 2026

words. (See also Chapter 7, Advice on Writing for Biomedical Journals, and Chapter 9, Tone, Terminology, and Technical Aspects of Scientific Writing.)

Research Letter Format

Research Letters do not have an abstract but otherwise follow the same structure as a regular research article, with a Title, Introduction, Methods section, Results section, and Discussion. The length of these articles is limited; for instance, in some journals, it is limited to no more than 600 words of text with no more than 6 references and a maximum of 2 data displays (tables and/or figures). Depending on the journal, supplemental material may or may not be allowed or may only be permitted for necessary additional description of study methods. Exceptions may include protocols for small randomized clinical trials and copies of questionnaires for survey studies.

Research Letters begin with a title. In keeping with the concise nature of the articles, the titles tend to be pithy, without subtitles. The Introduction section of a Research Letter is usually only a few sentences, outlining what is known about the topic and what is not known that the study seeks to answer.

The Methods section should include the source of data, sampling, dates of the study, and statistical analysis. If relevant, institutional review board or ethics committee review and approval or exemption and participant informed consent must be stated. The most frequent mistake Research Letter writers make is to include insufficient detail about the methods. If an editor and reviewers cannot adequately determine if the study was appropriately conducted and analyzed, the chances for rejection increase.

The second most frequent mistake is to include insufficient detail in the Results section. The number of participants, basic demographic characteristics, and both the absolute and relative results, including the most important quantitative results, should be reported. Statements about results that are not presented in the text or tables and figures, such as subgroup or sensitivity analyses, should not be made. Tables should be concise and present relevant data, but should not be too wide or long, and figures usually should not have more than a few panels.

The Discussion section, like the Introduction, is very short. The initial sentence should summarize the most important results. If relevant, a comparison to previous literature, usually 1 or 2 key studies, might be included. The limitations of the study and implications for practice should follow, each limited to 1 or a few sentences. Implications should not go beyond the data. There is no need for a summary paragraph.

For some journals, Research Letters may have a limit on the number of authors and may have different authorship approaches than for other longer

Downloaded from academic.oup.com/book/58841 by guest on 17 October 2026

research reports (such as not including large groups of authors in the byline). Authors should consult the journal's instructions for guidance about authorship of these reports.

Author Requirements

Authors of Brief Reports and Research Letters must follow all submission requirements, such as reporting author contributions, disclosing any conflicts of interest, specifying the funding source, and delineating the role of the sponsor. Other persons who have contributed to the study (but do not meet authorship requirements to be listed as an author) could be mentioned in an Acknowledgment, with their permission.

Conclusion

Brief Reports and Research Letters present research studies in a concise format and complement the longer reports in some journals. For authors without the resources to conduct a large randomized clinical trial, who have performed a smaller study or one on a more unusual topic, or who can summarize the key methods and results of a study with few words, these articles may be a good option for getting published in a high-profile journal.

References

1. Christiansen S, Iverson C, Flanagin A, et al. *AMA Manual of Style: A Guide for Authors and Editors*. 11th ed. Oxford University Press; 2020. Accessed April 10, 2024. https://www.amamanualofstyle.com
2. Zylke JW. Research letters in *JAMA*: small but mighty. *JAMA*. 2013;310(6):589-590. doi:10.1001/jama.2013.8102

Downloaded from academic.oup.com/book/58841 by guest on 17 October 2026

CHAPTER 24

Letters to the Editor

Robert M. Golub, MD

Downloaded from academic.oup.com/book/58841 by guest on 17 October 2026

KEY POINTS

- When writing a Letter to the Editor, identify important questions to raise or points to make, but limit to no more than 1 or 2 key issues.
- Letters should be written in a professional scholarly style.
- All assertions should be supported with references.

Letters entertain you, letters make you smile. But they also perform a very important function, providing a forum for the scientific interaction between the authors of a published article and readers. The peer review system, which is the foundation for evaluating medical research studies and other types of articles, includes multiway dialogues among authors, editors, and expert peer reviewers in an iterative process that results in refinement of a manuscript, ultimately leading to publication. However, the process does not end at this point, because postpublication peer review is an integral part of scientific communication. At many journals this is manifest in Letters to the Editor.

Letters are not the exclusive venue for such interchanges. Journals frequently provide an online commenting function for some or all of their articles. This can take various forms, from completely open and unsupervised comments, to open but with some editorial control over what the journal considers inappropriate content, to moderated, to highly structured and curated.

This chapter focuses on Letters because they tend to be the most scholarly and informative interchanges, they are generally indexed on MEDLINE and other bibliographic databases, and the principles that apply to writing a good Letter also apply to writing an informed and useful online comment.

For clinical studies, Letters can raise questions about assumptions in the underlying research question or in the study design chosen to answer that question. Letters can question the analytic methods of the study; highlight perceived problems in study execution, presentation of the data, or interpretation of the findings; and suggest ways to place the findings in context. For published opinion articles, Letters can challenge the basis for the opinions. The assertions in

the Letters and the authors' replies should be well referenced, with the goal of the interchange being to augment readers' understanding of the issues and to allow them to reach their own conclusions.

This type of interaction is a vital part of a successful peer review process and is something journals are eager to promote. The editors seek Letters that raise reasonable and important questions about a study or its appropriate interpretation. As part of the responsibility that authors assume in return for having their articles published, they should be held accountable for responding to critical points.

To facilitate the submission of the highest quality Letters, these are some tips that may maximize the likelihood of getting a Letter published:

Do's

1. Letters are meant to be focused pieces and therefore usually have a limited word count and restriction on number of references, and often a restriction on number of authors. Because journals are interested in timely correspondence, there is often a deadline following publication of the article for submitting Letters. Adhering to these limits when writing a Letter is a very important starting point.
2. Recognize that the published Letter will be a scholarly article. Letters are indexed in journal publications, so journals take their content, including accuracy and professional quality, seriously.
3. Attempt to limit the Letter to 1 or 2 points that reflect the content of the published article. It is usually difficult to clearly and precisely raise more issues than this within the limits of the Letter format. Less focused Letters are less likely to receive priority for publication.
4. Support all assertions by peer-reviewed literature; generally, this should be primary research rather than review articles. Check the accuracy of cited data carefully. Describe the limitations in the literature that is cited (eg, denote case series as such).
5. Include conflict of interest disclosures in an Acknowledgment at the end of the Letter. These include potential conflicts of interest not just related to the specific content of the Letter, but also to the content of the journal's article and other related areas. A good way to think of this is to include any disclosures that would have been relevant had the Letter writer been the author of the journal article.
6. Recognize that Letters essentially in agreement with the authors without providing additional insights and Letters that point out study limitations that were adequately addressed in the article or accompanying editorial will generally have low priority.

Downloaded from academic.oup.com/book/58841 by guest on 17 October 2026

7. Realize that Letters that primarily highlight the writers' own research or are otherwise self-promotional will also generally have low priority. Supporting references are better if they are not limited to self-citation.
8. Be certain that the reference list is accurate. The editors and authors use these lists extensively.
9. Accept and expect the need for editing, especially for length and journal style. Realize that the article to which the Letter pertains was subject to similar editing.
10. Use civil and professional discourse.

Don'ts

1. Don't be anecdotal. While personal experience can have great value in patient care and hypothesis generation, it is generally not strong enough evidence to include in a published Letter.
2. Don't include unpublished data. Letters generally do not undergo external peer review, and journals generally cannot support unpublished data.
3. Don't submit Letters about articles published in other journals. Those Letters should be sent to the journals in which the original article was published.
4. Don't rehash arguments that have been made for years or decades (particularly in response to controversial sociopolitical issues).
5. Don't adopt a tone that might be misconstrued by the authors or readers to be in any way condescending or insulting. As scientific discourse, published disagreements should further the field. Ad hominem attacks in a Letter will generally lead to quick rejection, or in the rare case that the Letter is ultimately published will certainly be removed before acceptance. Don't write a Letter while upset or angry or, if that is done, put it aside for 24 hours and review it again objectively before sending it.

Conclusion

Journals strongly encourage readers to be active participants in the postpublication peer review process. These Letters help to advance the understanding of their articles, provide important challenges to other readers as well as to authors—and at times may even make you smile.

Downloaded from academic.oup.com/book/58841 by guest on 17 October 2026

ACKNOWLEDGMENT

This chapter is an updated version of the following previously published article: Golub RM. Correspondence course: tips for getting a letter published in *JAMA*. *JAMA*. 2008;300(1):98-99. doi:10.1001/jama.300.1.98

Downloaded from academic.oup.com/book/58841 by guest on 17 October 2026

CHAPTER 25

Editorials

Phil B. Fontanarosa, MD, MBA

Downloaded from academic.oup.com/book/58841 by guest on 17 October 2026

KEY POINTS

- Editorials may be written by the editors of the journal and used to communicate information about the journal, including journal policies, new initiatives or developments, or other issues, or they may be solicited by the editorial staff and written by authors who are not editors of the journal and may accompany research articles or other reports.
- An Editorial should present a cogent, cohesive, compelling, balanced, and evidence-based discussion of important insights that advance understanding of a current issue or that help explain an article that the Editorial is accompanying.
- Authors of Editorials should follow the journal guidelines for tone, content, length, and number of references; develop a meaningful title that indicates the topic being addressed; formulate and follow a logical framework for the discussion of key issues; and meet agreed on timelines for preparing and submitting the Editorial.

Virtually every scientific journal publishes Editorials or other opinion articles. The most effective Editorials are concise and detailed, authoritative and scholarly, and insightful and thought-provoking. Given these desirable attributes of Editorials and considering that many Editorials are written with tight timelines, this chapter is intended to provide guidance for writing effective and informative Editorials to accompany research articles.

Some Editorials are written by the editors of the journal and may be used to communicate information about the journal, including journal policies, new initiatives or developments, or other issues. These Editorials also may reflect the position of the journal editors regarding a current issue or related to a published article.

Editorials also may be solicited by the editorial staff and written by authors who are not editors of the journal, and they often accompany research articles or other reports. The views and perspectives of these Editorials are

intended to provide perspective and context to help with interpretation and application of the study findings, or to underscore important aspects of the study that have major implications for clinicians or researchers. These Editorials are intended to provide balance and caveats that help place the study finding in context and provide thoughtful and insightful information that goes beyond the issues covered in and raised by the authors of the article the Editorial accompanies. Because many readers might first read the Editorial to determine whether to read the article, a good Editorial will also provide a concise summary of the article it accompanies and highlight the implications of the study findings for clinical care, research, or health policy.

The goal of these types of Editorials is to present a cogent, cohesive, and compelling discussion of important insights that advance understanding of the article the Editorial is accompanying. It is important for these Editorials to accurately reflect the findings and data in the study.

Editorial Format and Content

The title of an Editorial is important and must be carefully prepared. The title should indicate the topic being addressed so that the Editorial will be identified in literature searches. The use of subtitles or questions in titles of Editorials can be effective in signaling the content discussed, imparting context, and perhaps drawing interest in reading the Editorial. However, as with the titles of other articles, titles of Editorials should not be trite or flippant, or possibly be construed as trivializing a disease process or condition.

Although the length and format of Editorials can vary by journal, most Editorials in general medical journals are relatively concise and usually occupy no more than approximately 2 printed or PDF pages. For example, in *JAMA*, this translates to approximately 1200 to 1300 words of text with approximately 10 references, or approximately 9 or 10 average-sized paragraphs. Most readers generally prefer short, concise Editorials rather than longer, complex Editorials.

A suggested approach to formulating a logical framework for an Editorial that accompanies and comments on a research report or another article includes the following:

- An introductory paragraph that introduces the topic, describes the issues, and includes a statement of the problem the accompanying study addresses
- A summary of the study, including the study design, numbers of study participants, and numerical data (such as absolute event rates) for the key outcomes; having this amount of detail helps to ensure

Downloaded from academic.oup.com/book/58841 by guest on 17 October 2026

that readers will not have to refer to the article to understand the Editorial
- A description of the key caveats and limitations of the study, especially those not acknowledged by the authors of the article the Editorial accompanies
- A balanced discussion that places the findings of the study in context with other relevant research
- Comments about the clinical or policy implications of the study findings, and perhaps discussion about the next steps in research
- A strong, evidence-based conclusion that presents a clear take-home message

Issues to Consider

For some journals, Editorials solely represent the opinions of the authors, whereas for other journals Editorials represent the position of the journal and a position that the journal editors agree with, similar to Editorials published in major newspapers that reflect the opinion of the publication or the Editorial page editors. Accordingly, some Editorials may include statements or disclaimers, such as "Editorials represent the opinions of the authors and not those of the journal" or "This Editorial represents the opinions of the authors and not necessarily those of the authors' organization or employer."

However, an invitation to write an Editorial is not a "license to preach." Authors should refrain from making unsubstantiated claims, leveling hypercritical or overly negative comments about the article about which they are commenting, or extrapolating the discussion far beyond the study findings. Editorialists also should avoid interjecting excessive opinion or attempting to use the Editorial platform to advance a personal or professional agenda.

Editorials within the same journal are generally fairly consistent in content, style, and tone. For instance, to ensure clarity, Editorials should avoid including highly technical language, jargon, or numerous abbreviations that may be familiar to some specialists or subspecialists in a certain discipline but will be confusing for many readers from other disciplines. Assertions that include data (eg, disease prevalence) or statements about specific facts derived from other sources should include appropriate current references. Statements about interpretation of the findings from the study the Editorial is accompanying should be appropriate based on study design. Inferences about causality usually should be reserved for findings from clinical trials; inferences from findings based on observational studies or meta-analyses generally should be described with noncausal language, in terms of associations or relationships, unless rigorous methods specifically designed to robustly support causal inferences are included.

Downloaded from academic.oup.com/book/58841 by guest on 17 October 2026

In addition, for most Editorials, readers will benefit much more from having an editorialist present a balanced discussion of the issues based on the available evidence, rather than presenting their personal perspective, opinion, or anecdotal experience about a topic. Accordingly, personal pronouns such as *I* or *we* with self-reference to the authors of the Editorial usually are not necessary to include.

Perhaps more important, journal editors have the responsibility to ensure that the content of the Editorial is balanced, objective, and as evidence based as possible.

To help ensure that Editorials are unbiased, editors routinely request that prospective authors disclose potential conflicts of interest at the time the author is invited to prepare an Editorial. The editors evaluate this information carefully to determine whether the invited author should prepare the Editorial, and they evaluate the content of the Editorial while considering any disclosure information.

Because of the relatively brief length of Editorials, every sentence is important. Writing and meaning must be clear, and terminology used must be carefully chosen and precise. (See Chapter 9, Tone, Terminology, and Technical Aspects of Scientific Writing.) For instance, the use of the collective or royal *we* to refer to society, the medical profession, or some other entity usually is ambiguous and should be replaced with the specific group to whom *we* would refer. Similarly, the term *provider* is ambiguous and may refer either to various types of clinicians, such as physicians, nurses, or other practitioners, or to various health care delivery entities, such as hospitals, clinics, or other sites, or at times may refer to both. This term should be avoided, and instead the group or entity referred to should be specified. Moreover, use of the term *provider* does not recognize the level of professionalism that should be accorded to physicians, especially in medical journals for which physicians are the primary audience.[1] *Stakeholder* is another commonly used term, but it has uncertain meaning and generally should be avoided. Instead, the individuals or groups to whom the author is referring should be explained in detail.

Authors of Editorials also should avoid overused terms and phrases. For instance, the term *impact* has become ubiquitous and so extensively overused that the meaning has been diluted. Although use of *impact* is not incorrect, more specific terminology usually could be considered in Editorials. For instance, when used as a verb (the primary definitions are "to fix firmly by or as if by packing or wedging," "to press together," and "to strike forcefully"),[2] the term *impact* (especially in past tense, as *impacted*) could be replaced with other more precise terms, like *affect* or *influence* (or *affected*). Likewise, when used as a noun (eg, "having an impact"; the primary definitions are "an impinging or striking" and "a forceful contact or onset")[2] or as a modifier, eg, "being impactful," other phrasing could be considered, such as "having a benefit" or "being beneficial." In addition, given the scholarly and circumspect tone that

Downloaded from academic.oup.com/book/58841 by guest on 17 October 2026

should characterize Editorials, hackneyed phrases, such as "paradigm shift" and "call to action," as well as embellished language, such as "urgently needed" and "dramatically increased," usually should be replaced with more appropriate terms.

Editorials should also follow norms for use of inclusive language. (More guidance on this is available in the Inclusive Language section of the *AMA Manual of Style*.[3])

Conclusion

Editorials are an important element of scientific journals and should help to foster informative and responsible discussion of the issues related to the articles they accompany. Thoughtfully prepared Editorials that use a logical framework along with concise and precise writing and a scholarly tone will be most effective in helping readers understand scientific advances and appreciate the related clinical, research, and policy issues.

ACKNOWLEDGMENT

This chapter is an updated version of the following previously published article: Fontanarosa PB. Editorial matters: guidelines for writing effective editorials. *JAMA*. 2014;311(21):2179-2180. doi:10.1001/jama.2014.6535

References

1. Beasley JW, Roberts RG, Goroll AH. Promoting trust and morale by changing how the word *provider* is used: encouraging specificity and transparency. *JAMA*. 2021;325(23):2343-2344. doi:10.1001/jama.2021.6046
2. Impact. *Merriam-Webster's Collegiate Dictionary*. 11th ed. Merriam-Webster Inc; 2003. Accessed November 8, 2023. https://www.merriam-webster.com/dictionary/impact
3. Christiansen S, Iverson C, Flanagin A, et al. *AMA Manual of Style: A Guide for Authors and Editors*. 11th ed. Oxford University Press; 2020. Accessed April 10, 2024. https://www.amamanualofstyle.com

Downloaded from academic.oup.com/book/58841 by guest on 17 October 2026

CHAPTER 26

Other Opinion Articles

Jody W. Zylke, MD

Downloaded from academic.oup.com/book/58841 by guest on 17 October 2026

KEY POINTS

- Opinion articles discuss a topic for which there is insufficient evidence and present the authors' point of view.
- It is important to be familiar with the journal and its opinion pieces prior to submitting such a report.
- Opinion articles most frequently address clinical topics or issues in policy, law, or ethics.
- The opinion article should be evidence based and discuss both sides of the issue as much as possible and should use logical, well-organized arguments.
- Authors may have more flexibility in terms of writing style and structure than with research articles.

Ideally in clinical medicine, there would be no need for opinions. Sufficient evidence would exist to inform the diagnostic and therapeutic decisions that physicians make daily. However, sufficient evidence is often not available, and physicians may rely on experience or the advice of experts, along with discussion with patients. In addition, many other influences on clinical practice—policy, law, ethics—may not lend themselves to research or even to a "best" answer and may be the subject of heated debate. One way physicians and other health professionals can obtain some assistance with making complex decisions or evaluating such issues is by reading opinion articles.

Many journals publish opinion articles. These may be called Viewpoints, Commentaries, Ideas, Opinions, or Perspectives. These articles differ from Editorials in that they may or may not be solicited by the editors and usually are not linked to another article in the journal. Some journals publish Letters to the Editor that are not linked to journal content and express the author's opinion, but these are shorter and not necessarily evidence based. At *JAMA*, opinion articles also differ from Special Communication articles in that the latter are longer and rely more on presenting data and existing research.

Any topic can be the subject of an opinion article, but the aspect of the topic addressed must be incompletely understood so that a personal view is warranted. Some opinion articles focus on clinical topics. These may include diagnostic or therapeutic interventions or public health approaches for which evidence is insufficient but the author thinks are worth considering based on cost, fewer adverse events, or ease of use. New angles on well-established clinical issues are another common subject of opinion articles. For example, a Viewpoint in *JAMA* addressed smoking cessation but focused on expanding the availability of over-the-counter medications.[1] New treatments being developed or future directions in research also may be topics of interest; an example of this type of article would be "Wearable Devices for Cardiac Rhythm Diagnosis and Management."[2] Authors may also highlight clinical or public health issues that they think deserve greater attention or clinical approaches that they wish to challenge.

Other opinion articles focus on health policy, health law, or ethics, particularly controversial policies or cases. These articles often discuss new policies, regulations, or laws or changes to existing ones, or evidence that a policy is having the desired effect or not. For example, many opinion articles have commented on health care systems, such as how to control health care costs, potential consequences of failing to do so, and avenues for improvement.

Opinion articles also consider matters specifically related to workforce issues, training, and practice, such as medical education or the patient-clinician relationship, or the controversial issue of maintenance of certification.[3]

A "Viewpoint on Viewpoints" in *JAMA Dermatology* offers suggestions for choosing a subject, including: (1) "pick a topic that is important, timely, and relevant"; (2) "take a position"; and (3) "aim to spark debate."[4]

Although anyone may submit an opinion piece, generally authors should have an in-depth knowledge of or experience in the field. Such experienced authors may mentor and coauthor with more junior coauthors.

However, authors should be wary of writing an opinion article if they have direct financial conflicts of interest. Readers might question the motivation of an author with a patent for a device writing in support of its use, for example. Many journals limit the number of authors for brief opinion articles. For example, in *JAMA* and the JAMA Network journals, the maximum number of authors for an opinion article is 3.

Authors should always review examples of opinion articles in the journal to which they are considering submitting and consult the journal's instructions for authors. Being familiar with opinion articles in a specific journal will give the author insight into the style of those articles. For example, Viewpoints in *JAMA* are formal in nature, with no clichés, and few quotes or case vignettes. *JAMA* is read by many types of clinicians and health care professionals throughout the world, so some of these policies have been adopted to ensure

Downloaded from academic.oup.com/book/58841 by guest on 17 October 2026

broad appeal of Viewpoints. In addition, it is important to be familiar with the content of the journal so that the submitted work is placed in context of previous publications in that journal.

Authors of opinion articles should be mindful of diversity and inclusion. For example, *JAMA* encourages diversity of gender, race, ethnicity, geographic location, and discipline for Viewpoint authors. (For additional guidance, see also the Inclusive Language chapter of the *AMA Manual of Style*.[5])

In general, there are fewer requirements for opinion articles than for research reports. For example, Viewpoints in *JAMA* are limited to less than 1200 words of text and 10 references. They do not require abstracts but may be published with a very short précis. Other authorship requirements, such as disclosing funding and conflicts of interest, also apply to Viewpoints and in many regards may be more important than disclosures in research reports.

Just as there are fewer requirements for opinion articles, there are also fewer recommendations for preparing one. All opinion articles must have a title. Without an abstract, the title takes on greater importance, as it must attract the reader's attention but should also be concise, informative, and scholarly. Although titles of research articles follow a pattern (eg, include what was measured and the disease/condition or population), titles of opinion articles can be more varied. Although the title of an opinion article may just state the topic or preview the author's perspective, sometimes it includes a play on words[3] or a question[3,6] or may have a subtitle to augment the main title.[1]

Unlike a research article with definite sections, no specific structure exists for an opinion article, which allows the author flexibility. Authors can interject some style or creativity. In general, to help orient readers, authors should "state the argument explicitly and early" and "use signposts to help readers understand the article's structure."[4] The first paragraph (or 2) usually identifies the problem and presents background information. In most cases, authors should avoid including anecdotes, personal experiences, or quotations, although on occasion, use of these may effectively illustrate a key point. The body of the text lays out the argument, supported by evidence. The discussion must be built on a foundation. Purely hypothetical arguments are rarely convincing. Articles should rely as much as possible on facts or evidence, even if preliminary. The strengths and weaknesses of the evidence should be reviewed. Although by definition an author of an opinion article favors a point of view, an argument is stronger if the issue can be discussed in a balanced fashion, with both sides considered and the pros and cons weighed. Original data, unpublished studies, or new calculations do not belong in an opinion article. In addition, the argument should be well organized and presented with a logical progression and cogent interconnectivity of ideas. Although authors may feel strongly about the point of view they are promoting, they should take care to use tempered language and never use terms that could be interpreted as inflammatory, derogatory, or insulting. A few headings may be used to help organize the text and assist

Downloaded from academic.oup.com/book/58841 by guest on 17 October 2026

readers, and a small table or figure may be added. A final paragraph summarizing the arguments with a strong take-home message should be included. Since restrictions on the number of references exist, only key references can be cited. Authors should not neglect important references published in the journal to which the opinion piece is submitted.

Opinion articles undergo internal review and sometimes external peer review. Revisions may be requested. Controversial opinion articles garner many views and citations. For example, a Viewpoint on COVID-19 infection published early in the pandemic has had more than 670 000 views and more than 1100 citations.[7]

For controversial topics, some journals may publish "point-counterpoint" or "dueling" opinion articles in which a question is posed and an author supports the affirmative position and another takes the opposite position.[8] With this approach, editors can cover these topics with balance.

Conclusion

Journals often focus on the cutting-edge studies they publish for academic researchers and the reviews and short clinical articles for practicing physicians. Opinion articles, which allow debate about and draw attention to current, unresolved, or novel issues, in many ways may be as important and influential for medicine, public health, and science.

References

1. Leischow SJ. Increasing smoking cessation in the United States: expanding the availability of over-the-counter medications. *JAMA*. 2019;321(6):541-542. doi:10.1001/jama.2018.21557
2. Ip JE. Wearable devices for cardiac rhythm diagnosis and management. *JAMA*. 2019;321(4):337-338. doi:10.1001/jama.2018.20437
3. Weinberger SE. Can maintenance of certification pass the test? *JAMA*. 2019;321(7):641-642. doi:10.1001/jama.2019.0084
4. Katz KA. A Viewpoint on Viewpoints: tips for authors from *JAMA Dermatology*. *JAMA Dermatol*. 2019;155(9):1003-1004. doi:10.1001/jamadermatol.2019.2233
5. Christiansen S, Iverson C, Flanagin A, et al. *AMA Manual of Style: A Guide for Authors and Editors*. 11th ed. Oxford University Press; 2020. Accessed April 10, 2024. https://www.amamanualofstyle.com
6. Hu FB, Otis BO, McCarthy G. Can plant-based meat alternatives be part of a healthy and sustainable diet? *JAMA*. 2019;322(16):1547-1548. doi:10.1001/jama.2019.13187
7. Paules CI, Marston HD, Fauci AS. Coronavirus infections—more than just the common cold. *JAMA*. 2020;323(8):707-708. doi:10.1001/jama.2020.0757
8. Bauchner H, Fontanarosa PB. The debut of dueling viewpoints. *JAMA*. 2012;307(14):1532. doi:10.1001/jama.2012.432

Downloaded from academic.oup.com/book/58841 by guest on 17 October 2026

Downloaded from academic.oup.com/book/58841 by guest on 17 October 2026

PART 5

Editorial Process and Peer Review

Downloaded from academic.oup.com/book/58841 by guest on 17 October 2026

Downloaded from academic.oup.com/book/58841 by guest on 17 October 2026

CHAPTER 27

Manuscript Assessment and Editorial Decision-Making

Robert Steinbrook, MD, and
Rita F. Redberg, MD, MSc

KEY POINTS

- A scientific journal is defined by the articles it publishes, as well as by those it declines.
- Editors assess manuscripts for originality, scientific accuracy, presentation, and interest to readers.
- A clinical journal may assess the likely influence and importance of studies; that is, are clinicians likely to do something differently based on the results?
- Editors consider the editorial priorities of the journal, other manuscripts under consideration, and whether the journal has published articles on similar topics.
- Authors may increase the chances a manuscript will be accepted when they follow the journal's instructions for authors.

Manuscript assessment and editorial decision-making are core responsibilities of medical journal editors. A scientific journal is defined by the articles it publishes, as well as by those it declines. The consideration of manuscripts should be rigorous, dispassionate, and timely. Editors should approach each new submission with interest, an open mind, recognition of the privilege of assessing the work of others, and the duty to be thorough and fair. This chapter provides information and insights for authors to understand how journal editors assess manuscripts and key principles of editorial decision-making. (For additional information, see Section 5.11, Editorial Responsibilities, Roles, Procedures, and Policies, in the *AMA Manual of Style*.[1])

Downloaded from academic.oup.com/book/58841 by guest on 17 October 2026

Criteria for Evaluating Manuscripts

Although journals vary in the terms used to describe the major criteria for evaluating manuscripts, the categories of originality, scientific accuracy, presentation, and interest to readers are common criteria. Journals seek to publish studies that are original and scientifically accurate and that are likely to be interesting to the clinical or scientific community. Thus, a general medical journal is unlikely to publish a study that would only be relevant to a limited number of clinicians and readers in one medical specialty, even if the report is original and accurate. Editors often ask the question, would I want to read this article in this journal?

Presentation is important. Although editing can improve writing, the chances a manuscript will be accepted will be reduced when the initial submission is difficult for editors or peer reviewers to understand. Clinical journals also usually assess the likely influence of studies; that is, are clinicians likely to do something differently based on the results, such as starting or stopping a specific medication? Although many types of studies are important, a study that is likely to change how patients are cared for may receive priority over studies that merely provide a description of a practice, such as the percentage of patients who have a disease or are prescribed a medication.

Authors increase the chances that a manuscript will eventually be accepted when they write in clear prose, avoid the use of nonstandard abbreviations and jargon, and follow the specifications in the journal's instructions for authors. Journals are unlikely to grant exceptions to their requirements for manuscript presentation and format. Among other considerations, an exception for one set of authors would set a precedent and create expectations for other authors.

For research manuscripts, editors are usually more interested in a clear and full presentation of the Methods and Results sections than a lengthy Introduction or Discussion section. In general, the majority of words in the text should be reserved for the Methods and Results sections; it is essential that editors and reviewers are able to understand and follow these sections. In general, medical journals advise that the description of methods and results should not be combined into a single section. The Discussion section works best when it focuses on the findings and implications of the study, states the main limitations, and avoids priority claims and speculative comments that do not follow from the data. Conclusions should also follow from the data and should not include broad recommendations that the study findings do not directly support.

Editorial assessment considers originality, scientific accuracy, presentation, interest to readers, and likely influence. The assessment also considers the editorial priorities of the journal. For example, some journals may have an editorial priority for certain types of studies, such as clinical trials; for certain subject areas, such as clinical decision-making or health policy; or for studies that are likely to directly influence patient care. It is important for authors to

Downloaded from academic.oup.com/book/58841 by guest on 17 October 2026

review the journal to which they are considering submitting a manuscript to better understand the journal style and editorial priorities. Additional factors in editorial decision-making include whether the journal has published or is considering other manuscripts on similar topics.

The Life Cycle of a Manuscript

A manuscript has a life cycle at a journal, starting with submission and ending with either rejection or eventual acceptance. At most journals, after a manuscript has passed initial quality control, it is sent to the editor in chief or another senior editor for triage. At triage, some manuscripts will be declined, and others will be assigned to a reviewing editor. The reviewing editor, who is usually the second editor to read the manuscript, will also consider whether the manuscript should be declined, discussed with other editors, or receive external peer review. At some journals, more than one editor will evaluate most manuscripts before they are declined. Having a second assessment increases the likelihood that an initial decision to reject a manuscript has been carefully considered.

Journals vary widely in the number of manuscripts received and published. For journals that are highly selective (ie, that receive many more submitted articles than they are able to publish), such as *JAMA* or *JAMA Internal Medicine*, the editors have a good sense at initial consideration of whether a manuscript has a sufficient chance of ultimately being accepted and whether external peer review would be worthwhile.

Peer review is exceptionally valuable to both editors and authors. Peer reviewers can be thought of as (usually unpaid) advisors to editors, and editors ultimately make the decisions. Oftentimes, manuscripts are not externally reviewed to avoid undue burden on peer reviewers and to provide prompt decisions to the authors of manuscripts that are not going to be accepted.

When evaluating the comments from the peer reviewers, editors are interested not only in the recommendations regarding suitability of the manuscript for publication, but more important, in the specific comments and critiques about the study and its novelty. The editors consider whether the authors could address the issues or whether the issues represent major problems that are not addressable, such as with validity or accuracy (ie, a "fatal flaw" in the study).

In contrast to a manuscript rejected without review, the time to a first decision for a manuscript rejected after peer review is considerably longer. For many journals, including *JAMA* and the JAMA Network journals, the time from receipt of a research manuscript to rejection without external review is generally less than 5 days; with external review, the time for decision-making is increased, often requiring several weeks or 1 to 2 months. (See also Chapter 30, Communicating and Interacting With Journal Editors.)

Downloaded from academic.oup.com/book/58841 by guest on 17 October 2026

For manuscripts that are selected to undergo peer review, editors typically seek evaluation of the manuscript by 2 or 3 peer reviewers, depending on the journal and the nature of the study. In some instances, more reviewers may be required for their expertise in the content, research methods, or statistics and may offer different perspectives. For example, an endocrinologist and a nephrologist might evaluate a clinical trial of a drug to prevent kidney disease in patients with diabetes, or a cardiologist, a pulmonologist, and a reviewer with expertise in research with large databases might evaluate a study using a database to examine the association between syncope and pulmonary embolism. For a manuscript on a controversial topic, reviewers may be chosen from several sides of the debate. (See also Chapter 28, Peer Review in Scholarly Publication.)

Journals often have statistical consultants (dedicated statistical editors or peer reviewers), who may informally or formally review manuscripts with statistical content. To make efficient use of the statistical consultant's time, statistical review may occur after the content reviews are obtained and may be reserved for manuscripts with the greatest likelihood of being developed for publication.

Following review, manuscripts are typically discussed among the senior editors, with the reviewing editor (ie, the editor who is managing the manuscript) leading the discussion by summarizing the manuscript and the reviewers' comments. Depending on the journal and the circumstances, a decision may be made by consensus among the editors, by the editor in chief, by another senior editor, or by the reviewing editor. In certain situations, such as when the reviewing editor and the reviewers do not view the study favorably, the manuscript may be declined without general discussion. In other situations, the editors may defer a decision and obtain further reviews or additional information about the study from the authors. The manuscript would then be reevaluated and discussed further among the editors before a decision is made.

First Editorial Decisions About Manuscripts

For authors, the first editorial decision may be less important than the hoped-for news that a manuscript has been accepted for publication. For editors, however, the first editorial decision is perhaps the most consequential as it defines the group of manuscripts that will receive additional editorial resources and be developed for publication. Although not all manuscripts with a favorable first editorial decision will eventually be accepted, at the majority of journals most (or many) will be.

The usual editorial decisions are revise and reconsider, provisional acceptance, and rejection. As manuscripts are typically not accepted for publication without at least 1 revision, a revise and reconsider decision may be more

Downloaded from academic.oup.com/book/58841 by guest on 17 October 2026

common than a provisional acceptance for some journals. A second or third revision may be needed depending on the strength of the initial submission, the comments and concerns of the peer reviewers and editors, and if additional or new analyses are requested.

Revise and Reconsider Decisions

A revise and reconsider decision is just that, an invitation for the authors to revise a manuscript in accordance with the comments of the editors and reviewers and a willingness by the journal to provide further consideration to the revision, without a commitment to accept the manuscript. Authors should not overinterpret the decision as a preliminary acceptance nor be discouraged because of the cautionary tone of a letter and the many issues and points that they may be asked to cover in a revised manuscript. A revise and reconsider letter is a good letter to receive.

Revise and reconsider letters are some of the most important letters that reviewing editors write. As editors expect authors to fully revise and improve manuscripts, the decision letter should provide a roadmap for the authors to follow.

Working from a standardized template, editors often add language specific to the manuscript, for example, by prioritizing the comments of the reviewers and, if necessary, reconciling comments that reflect inconsistent recommendations from reviewers. The editor usually looks carefully at the entire manuscript. Specific suggestions are often provided about how to better explain the methods, improve the tables and figures, and reduce the length to avoid repetition, as well as for instances in which information in a supplement should be moved to the text, or vice versa. With sufficient time and effort to prepare a comprehensive revise and reconsider letter, the reviewing editor can often minimize the number of subsequent revisions that may be needed.

By the time a journal sends a revise and reconsider decision, the editors have invested substantial time and resources in a manuscript. Thus, journals will often provide authors with a date by which they expect the revision to be returned. Authors should return a revision in a timely fashion and communicate with the reviewing editor or the editorial office if more time is required. If authors are not planning to revise a manuscript, they should inform the journal before the revision is due. Authors' chances of a prompt favorable decision may be increased if they return a revision response letter with itemized and detailed replies to each of the comments of the editors and peer reviewers. Editors may also request a copy of the revised manuscript in "tracked changes" mode that shows all additions and deletions. (See also Chapter 30, Communicating and Interacting With Journal Editors, and Chapter 31, Responding to Journal Decision Letters and Reviewers' Comments.)

Downloaded from academic.oup.com/book/58841 by guest on 17 October 2026

When authors submit a revised manuscript, the reviewing editor will carefully evaluate the revision and consider the responses to the editors' and reviewers' comments. If the revision does not seem sufficiently improved or is not responsive to the concerns, the revised manuscript may receive further external peer review, discussion among the editors, or both. A revised manuscript that falls short of the editors' expectations may be declined or the authors may receive a second revise and reconsider letter and the process will be repeated.

Provisional Acceptance

A provisional acceptance is usually reserved for research manuscripts that have been revised at least once but have remaining issues that require another revision. This type of decision may also be used for suitable manuscripts that are missing some components (correct versions of figures, completed authorship forms, etc). Authors should not misinterpret a provisional acceptance as an acceptance. The decision letter will state that acceptance is contingent on satisfactory revision of the manuscript and satisfactory completion of the specific issues to be addressed. Although it is unusual for a journal to reject a provisionally accepted manuscript, a manuscript that fails to address a specific requirement may be declined.

Rejection Decisions

Many journals that receive a large volume of manuscripts use standardized letters for declining manuscripts. These letters might merely indicate that the manuscript has been declined, or they might suggest that it may be more appropriate for a different journal. When manuscripts have been reviewed, the authors also are sent the comments of the reviewers, and possibly comments from the editors. Reviewers' comments are not necessarily always sent verbatim, as comments that the editors consider inappropriate may be removed. Comments from the editors may be incorporated into the decision letter or sent in a form more similar to the reviewer comments.

Authors should understand that a rejection decision is a decision to decline a manuscript. Unless stated otherwise, a rejection letter is not an invitation to respond to the reviewers' comments and any editorial comments (because the authors believe they can do so) and resubmit the manuscript to the same journal for further consideration. Comments are meant to help the authors revise the manuscript for another journal.

Some journals, like the JAMA Network journals, have a process to refer rejected manuscripts to other journals within the same publishing group or consortium in a specific field to improve efficiency and reduce time to eventual

Downloaded from academic.oup.com/book/58841 by guest on 17 October 2026

publication. Authors may be asked if they wish to participate in such cascading options when they submit their manuscript to the initial journal, and if they choose to do so, the manuscript and any peer reviews can be automatically transferred to the next journal for additional consideration.

In certain instances, editors may open the door in a rejection letter to a new submission, such as a manuscript that includes additional data or analyses, that considers a longer or more recent time period than the original submission, or that is on the same general topic but has a different focus. Terms that editors may use to describe such letters include "reject and tell them why" and "willing reject." The letter usually is clear that if authors choose to submit a new manuscript, it will not be evaluated as a revision, but rather would be considered as a new submission, with no advance guarantee that the new manuscript would undergo peer review and no guarantee that the new manuscript will be accepted for publication.

Conclusion

This chapter provides authors with an overview of how journal editors assess manuscripts and key principles of responsible editorial decision-making. Journals should assess manuscripts on their merits and without prior commitment. Even when an editor has expressed interest in inviting authors to submit a manuscript for consideration, such as based on an inquiry or abstract, there is no substitute for carefully evaluating the entire manuscript after it is submitted, obtaining external peer review when warranted, and discussing the manuscript among the editors.

Manuscript assessment and editorial decision-making, done well, are some of the most rewarding aspects of the privilege to serve as a journal editor. A robust process leads to a better journal.

Reference

1. Christiansen S, Iverson C, Flanagin A, et al. *AMA Manual of Style: A Guide for Authors and Editors*. 11th ed. Oxford University Press; 2020. https://www.amamanualofstyle.com/

Downloaded from academic.oup.com/book/58841 by guest on 17 October 2026

CHAPTER 28

Peer Review in Scholarly Publication

Annette Flanagin, RN, MA

Downloaded from academic.oup.com/book/58841 by guest on 17 October 2026

KEY POINTS

- Peer review—whether it occurs before or after publication—"is an essential and integral part of consensus building and is inherent and necessary to the growth of scientific knowledge."[1]
- Peer review is used by editors to assess and improve the quality of manuscripts submitted to journals; peer reviewers are advisors, with editors making the final decisions at most journals.
- There are 3 primary types of peer review: double-anonymous, single-anonymous, and open review.
- With all types of peer review, including open review, some form of confidentiality is required.
- Journals have various means of providing feedback to and acknowledging and crediting peer reviewers.

Peer review is the process used by scholarly journals to evaluate the quality of submitted manuscripts. Chubin and Hacket described peer review as an "organized method for evaluating scientific work which is used by scientists to certify the correctness of procedures, establish the plausibility of results, and allocate scarce resources (such as journal space, research funds, recognition, and special honor)." [2(p2)] The focus of this chapter is journal peer review.

Purposes and Roles of Peer Review

As Rennie has noted, "the system whereby scientific manuscripts are reviewed by outside experts—editorial peer review—is generally regarded as an essential step prior to biomedical publication."[3(p3)] He acknowledged that while peer review is "arduous, expensive, often slow and subject to all sorts of bias," as a quality assurance mechanism, peer review, with evolving forms of transparency, may democratize the scientific publication process and is considered better

than the alternatives.[3(p3)] The purposes of peer review used by journals include the following:

- To assess the quality of reports of research and other types of manuscripts
- To evaluate the scientific and technical soundness of the report
- To help detect biases and flaws in methods, analysis, interpretation, and presentation
- To assess originality, importance, and suitability for publication in general or for a specific journal or audience
- To help authors improve the quality of the reporting, readability, and usefulness of their reports
- To help editors make decisions to reject, invite revision, or accept submitted manuscripts

There are several roles involved in peer review. Editors are the key decision makers or gatekeepers to what is published in their journals. Peer review helps support editorial decisions to accept or reject manuscripts for publication. Peer reviewers are advisors with expertise, but they are not the decision makers; they help evaluate the merits of reports of research and other manuscripts. The peer review process permits reviewers to be part of the academic community, to contribute to the progress of science, and to learn from the reviewing experience. Authors are recipients of peer review that can help them improve reports of their work. Readers benefit from a peer-reviewed journal's imprimatur and the vetting and sorting of information, and they may contribute to postpublication peer review by submitting formal letters to the editor or posting online comments or social media posts about published articles. (See also Chapter 29, Reviewing Manuscripts for Peer-Reviewed Journals.)

Brief History of Peer Review

The first scientific journal, *Philosophical Transactions*, was founded in 1665. In 1752, the Royal Society of London assumed fiscal responsibility for *Philosophical Transactions* and established a Committee on Papers to review all articles to be published in the journal and is often credited with having established peer review. However, as Kronick has noted, "Peer review can be said to have existed ever since people began to identify and communicate what they thought was new knowledge … because peer review (whether it occurs before or after publication) is an essential and integral part of consensus building and is inherent and necessary to the growth of scientific knowledge."[1] This likely occurred before 1752. For example,

Downloaded from academic.oup.com/book/58841 by guest on 17 October 2026

in 1731, the Royal Society of Edinburgh communicated its editorial policy for *Medical Essays and Observations*: "Memoirs sent by correspondence are distributed according to the subject matter to those members who are most versed in these matters. The report of their identity is not known to the author. Nothing is printed in this review which is not stamped with the mark of utility."[1]

Despite the historical origins, the modern evolution of peer review was haphazard.[3,4] According to Burnham, biomedical journals first appeared in the 19th century as personal or society organs, following the model of general journalism, and few used any system of peer review with regularity.[4] During this time, journal peer review developed independently of grant peer review. Journal editors viewed themselves primarily as educators, and the practice of peer review as it is used today was not generally used until after World War II, and even then was resisted by some prominent journal editors.[4] More formal institutionalization of journal peer review followed increases in the numbers of submitted articles, specialization, and demands for more expert authority and objectivity. What contributed to the institutionalization of traditional peer review in the 20th century is likely stimulating its further evolution and calls for improvement in the 21st century, such as increases in the numbers of submitted and published articles, greater specialization of many disciplines, demands for more expert authority and objectivity, increasing complexity of scientific methods and statistics, and the need to address weaknesses and biases in the reporting of research, particularly as more discussion occurs in social media. In addition, new developments are changing and challenging the traditional peer review process, such as technologic advances, open access, demands for more transparency and reproducibility of research, big data and artificial intelligence, new models and approaches for publication and dissemination of scholarly content, and new threats, including fake peer review and predatory journals (in which authors are charged fees to publish in deceptive journals of dubious reputation and without real peer review, editorial, or publishing services).[5-7]

Limitations and Weaknesses of Peer Review

Traditional peer review has been criticized for being unfair, slow, expensive, inefficient, secret, and biased, as well as for stifling innovation, not preventing error or fraud, causing unnecessary delay in publication, and for not addressing the mismatch between scientific productivity, number of publications, and number of available qualified reviewers.[3,8] To address these concerns, new models of peer review have been developed and tested.

Downloaded from academic.oup.com/book/58841 by guest on 17 October 2026

Types of Peer Review

There are 3 primary types of peer review: double-anonymous, single-anonymous, and open review. The term *anonymous* is preferred over the previously commonly used term *blind*.

- *Double-anonymous review*: authors' and reviewers' identities are not revealed to each other in an attempt to minimize bias.
- *Single-anonymous review*: authors' identities are revealed to reviewers, but reviewers' identities are not revealed to authors.
- *Open review*: authors' and reviewers' identities are revealed. There are several types of open review, including:
  - *Prepublication open review*: reviewers are identified to the authors and perhaps other reviewers during the review process but are not made public.
  - *Postpublication open review*: reviewers, editors, decisions, and all comments are identified to all and made public at the time of publication.
  - *Perpetual open review*: there is interactive, open collaborative review before and after publication.

In addition, there has been experimentation with some new, although uncommon, models. For example, in results-free review, results of research are not shown to the editors and reviewers until after a decision has been made.[9]

Many studies, including some randomized trials, have evaluated various forms of anonymized vs open review. Most trials have reported no differences in quality of double-anonymized, single-anonymized, or open review.[10,11] But some have found conflicting differences in quality,[12,13] and some studies have identified biases that may be better managed with double-anonymized review.[14,15] Studies have shown that all types of peer review are feasible, but double-anonymous review may not always successfully mask authors' identities from reviewers who know the field well or who can identify the authors from cited references.

Single-anonymous review has been the most common form of peer review used by medical journals. However, many medical journals that use single-anonymous review may also offer peer reviewers an option to sign their reviews and voluntarily reveal their identities to authors.[16] With this option, reviewers who choose to reveal their identities do so in the spirit of transparency and accountability and generally do not experience any major concerns. However, some have expressed concern about potential unintended consequences of signing their reviews, such as an author contacting the reviewer to dispute the review or express disagreement with the comments or possible subtle or overt future

Downloaded from academic.oup.com/book/58841 by guest on 17 October 2026

retaliation toward the reviewer. An increasing number of medical journals are using forms of open and collaborative peer review and are publishing reviewer comments with published articles.[17-19] In some other scientific disciplines, authors are offered the option of single-anonymous or double-anonymous review at the time of manuscript submission.[20]

Peer Review Process

No matter which types of peer review or options are available, authors and reviewers should understand the process used by the journal to which they are submitting manuscripts or for which they are reviewing manuscripts. Information about a journal's peer review process should be available in a journal's instructions for authors and in communications that the journal sends to authors and reviewers. With all types of peer review, including open review, some form of confidentiality is required.[21] For example, in single- and double-anonymized review, peer reviewers should not keep copies of manuscripts they have reviewed. Reviewers should not discuss, disclose, or share any information in the manuscript with others without permission of the journal. Moreover, peer reviewers should not contact authors directly to discuss their review without explicit permission of the editor or unless collaborative review involving authors is used. In all forms of peer review, reviewers should recuse themselves or decline invitations to review a manuscript in which they have a conflict of interest (financial or personal) that would hinder their ability to provide an objective review, and reviewers should never use the content of a confidential manuscript they have reviewed for their own personal or professional gain.[21]

A reviewer may wish to invite a colleague to help with the review (perhaps to consult on a specialized or technical aspect of the manuscript or as part of a teaching or mentoring relationship). Some journals prohibit such consultation, and other journals require that permission from the editor be obtained in advance. Reviewers who are uncertain about a journal's policy on including others in the review should contact the editorial office. For example, *JAMA* informs reviewers that they may enlist the aid of colleagues to assist with the review so long as confidentiality is maintained and all other review policies (such as those pertaining to conflicts of interest) are followed. *JAMA* reviewers are required to inform editors if such consultation has occurred.[21] Many journals share copies of reviewers' comments with the other reviewers of that manuscript as a form of constructive feedback and education, either confidentially following an editorial decision or in a collaborative manner during the editorial process.

The number of peer reviewers invited to review a manuscript varies by discipline, journal, and complexity of the manuscript but typically includes

Downloaded from academic.oup.com/book/58841 by guest on 17 October 2026

2 to 3 reviewers. For research manuscripts, in addition to reviewers with expertise in the subject matter of the manuscript, a reviewer with expertise in research design and statistics also may be invited to review. However, a journal does not have an obligation to send every submitted manuscript out for external peer review, especially if the manuscript is not a good fit for the journal or is unlikely to meet the journal's standards for acceptance. Thus, many journals will reject a manuscript without peer review to avoid unnecessary reviewer fatigue and lengthy times between manuscript submission and an unfavorable decision. At *JAMA* and across the JAMA Network of journals, approximately 70% of manuscripts of original research are rejected without external peer review. If a manuscript was peer reviewed, those comments should be sent to the authors. For journals that are part of a publishing group and have a cascading peer review system among journals in that group, authors may be able to choose to have their manuscripts, with or without any reviewer comments, transferred to other specific journals.[21]

Table 28-1 provides an overview of models of peer review from traditional and conservative to newer and liberal models and includes types of peer review, modes of reviewer assignment, acceptance criteria, transparency, and cascading and reuse of peer reviews.

Table 28-1. Peer Review Models, Processes, and Tasks

Process or task	Traditional and conservative models	Moderate models	New and liberal models
Type of review	Double-anonymous	Single-anonymous	Open and collaborative
Reviewer assignment	By editor, with or without author suggestions	Automated from defined database or recommended with search and matching algorithms	Postpublication and open to all
Acceptance criteria and quality control	Quality, importance, originality, contribution, priority, fit, and presentation	Technical quality only	Cursory check
Transparency of peer review	None	General information about journal acceptance rates and turnaround times; publication of lists of peer reviewers	Specific information on reviewers, history, and comments available during peer review and published with articles
Cascading and reuse of reviews	None	Shared within a group of journals or publisher	Preobtained reviews submitted with manuscripts and published with articles

Based on Bjork BC.[23]

Downloaded from academic.oup.com/book/58841 by guest on 17 October 2026

Acknowledgment and Credit for Peer Review

Journals have various models of acknowledging and crediting peer reviewers. Many journals publish the names of peer reviewers who reviewed for the journal during the previous year, or other specific period, to thank them publicly. Journals may offer peer reviewers other rewards or forms of recognition for their effort and time: some journals pay reviewers a small stipend; others offer free online access to the journal, provide continuing education credit or top-performing reviewer awards, or send formal letters that can be shared with employers, supervisors, or others. With postpublication open review, reviews are posted with publication and may be given separate digital object identifiers and may be formally cited by reviewers and others. Services and platforms also are available to permit reviewers to claim public credit for reviews with the use of identifiers assigned to their specific reviews in a public manner or in a confidential manner that associates reviewers with reviews performed for specific journals.[21]

With the rapid rise in artificial intelligence (AI) tools, large language models (LLMs), and generative chatbots, journals have developed policies to guide peer reviewers on use of AI during the reviewer process.[22] Peer review confidentiality policies may prohibit the entering of any part of the manuscript or reviewer comments into an AI model, LLM, or chatbot. Reviewers should exercise caution if using such tools and follow a journal's guidance to reviewers to use or not use these tools, disclose the details of any such use, and to take responsibility for the integrity of their reviewer comments.

Conclusions

Despite some criticisms and challenges, peer review continues to serve the important goal of helping editors and authors evaluate scholarly work and improve the quality of reporting. Newer forms of peer review have been tried, but the basic principles of critical peer review are well established.

References

1. Kronick DA. Peer review in 18th-century scientific journalism. *JAMA*. 1990;263(10):1321-1322. doi:10.1001/jama.1990.03440100021002
2. Chubin DE, Hacket EJ. *Peerless Science*. SUNY Press; 1990.
3. Rennie D. Editorial peer review: its development and rationale. In: Godlee F, Jefferson T, eds. *Peer Review in Health Sciences*. 2nd ed. BMJ Books; 2003.
4. Burnham JC. The evolution of editorial peer review. *JAMA*. 1990;263(10):1323-1329. doi:10.1001/jama.1990.03440100023003

Downloaded from academic.oup.com/book/58841 by guest on 17 October 2026

5. Bohannon J. Who's afraid of peer review? *Science*. 2013;342(6154):60-65. doi:10.1126/science.2013.342.6154.342_60
6. Qi X, Deng H, Guo X. Characteristics of retractions related to faked peer reviews: an overview. *Postgrad Med J*. 2017;93(1102):499-503. doi:10.1136/postgradmedj-2016-133969
7. Cobey KD, Lalu MM, Skidmore B, Ahmadzai N, Grudniewicz A, Moher D. What is a predatory journal? a scoping review. *F1000Res*. 2018;7:1001. doi:10.12688/f1000research.15256.1
8. Rennie D. Guarding the guardians: a conference on editorial peer review. *JAMA*. 1986;256(17):2391-2392. doi:10.1001/jama.1986.03380170107031
9. Results-free review: a new model of peer review. *BMC Psychology*. Accessed October 19, 2023. https://www.biomedcentral.com/collections/RFPR
10. Justice AC, Cho MK, Winker MA, Berlin JA, Rennie D; PEER Investigators. Does masking author identity improve peer review quality? a randomized controlled trial. *JAMA*. 1998;280(3):240-242. doi:10.1001/jama.280.3.240
11. van Rooyen S, Godlee F, Evans S, Smith R, Black N. Effect of blinding and unmasking on the quality of peer review: a randomized trial. *JAMA*. 1998;280(3):234-237. doi:10.1001/jama.280.3.234
12. McNutt RA, Evans AT, Fletcher RH, Fletcher SW. The effects of blinding on the quality of peer review: a randomized trial. *JAMA*. 1990;263(10):1371-1376. doi:10.1001/jama.1990.03440100079012
13. Walsh E, Rooney M, Appleby L, Wilkinson G. Open peer review: a randomised controlled trial. *Br J Psychiatry*. 2000;176:47-51. doi:10.1192/bjp.176.1.47
14. Budden AE, Tregenza T, Aarssen LW, Koricheva J, Leimu R, Lortie CJ. Double-blind review favours increased representation of female authors. *Trends Ecol Evol*. 2008;23(1):4-6. doi:10.1016/j.tree.2007.07.008
15. Lerback J, Hanson B. Journals invite too few women to referee. *Nature*. 2017;541(7638):455-457. doi:10.1038/541455a
16. Editorial and peer review: instructions for authors. JAMA Network. Updated July 14, 2023. Accessed October 19, 2023. https://jamanetwork.com/journals/jama/pages/instructions-for-authors#SecEditorialandPeerReview
17. Resources for reviewers. *BMJ*. Accessed October 19, 2023. https://www.bmj.com/about-bmj/resources-reviewers
18. Eisen M. Peer review: new initiatives to enhance the value of eLife's process. *eLife*. November 7, 2019. Accessed October 19, 2023. https://elifesciences.org/inside-elife/e9091cea/peer-review-new-initiatives-to-enhance-the-value-of-elife-s-process
19. Mehmani B. Publishing peer review reports alongside articles with separate DOIs: a pilot study of 5 journals in different scientific disciplines. Eighth International Congress on Peer Review and Scientific Publication. September 12, 2017. Accessed October 19, 2023. https://peerreviewcongress.org/abstract/publishing-peer-review-reports-alongside-articles-with-separate-dois-a-pilot-study-of-5-journals-in-different-scientific-disciplines/
20. McGillivray B, De Ranieri E. Uptake and outcome of manuscripts in Nature journals by review model and author characteristics. *Res Integr Peer Rev*. 2018;3(5):5. doi:10.1186/s41073-018-0049-z

Downloaded from academic.oup.com/book/58841 by guest on 17 October 2026

21. Flanagin A. Confidentiality in peer review. In: Christiansen S, Iverson C, Flanagin A, et al, eds. *AMA Manual of Style: A Guide for Authors and Editors*. 11th ed. Oxford University Press; 2020. https://www.amamanualofstyle.com
22. Flanagin A, Kendall-Taylor J, Bibbins-Domingo K. Guidance for authors, peer reviewers, and editors on use of AI, language models, and chatbots. *JAMA*. 2023;330(8):702-703. doi:10.1001/jama.2023.12500
23. Bjork BC, Hedlund T. Emerging new methods of peer review in scholarly journals. *Learn Publ*. 2015;28(2):85-91. doi:10.1087/20150202

Downloaded from academic.oup.com/book/58841 by guest on 17 October 2026

CHAPTER 29

Reviewing Manuscripts for Peer-Reviewed Journals

Frederick P. Rivara, MD, MPH

Downloaded from academic.oup.com/book/58841 by guest on 17 October 2026

KEY POINTS

- Reviewers should approach a manuscript as if it were written by a colleague and provide the authors suggestions that may improve the research design, analysis, or presentation or writing.
- The manuscript must be treated with the confidentiality that the authors have entrusted in the journal and the editors have entrusted in reviewers.
- Editors prefer that reviewers not make statements about rejection or acceptance in their comments to authors because the final decision is not the prerogative of reviewers.
- The review should provide objective, constructive, scholarly comments about the substantive aspects of the manuscript and should be carefully prepared and well written.
- Editors rely on the opinions of peer reviewers regarding whether a study is an important contribution to the literature. If a reviewer thinks the manuscript is important, controversial, or for some other reason deserves an editorial, it is helpful to let the editor know.

Peer review is a critical element in the editorial process of scientific journals. The goals of peer review are to provide expert advice to the authors regarding their work, to provide an assessment of the scientific validity of the data and methods, and to provide information to the editors for use in their decision about the suitability of the manuscript for publication.

The quality of journals depends, to a large degree, on the quality of the peer review process. Nearly all scientific journals rely on a volunteer pool of talented individuals who devote time (often from demanding schedules) to review manuscripts. The journal could not be published without their help, and editors are extremely grateful for their efforts. However, reviewers are rarely given any advice, by their senior colleagues or anyone else, on how best to do

reviews. The purpose of this chapter is to provide advice and suggestions for peer reviewers so that their time can be best spent in producing a review that will be helpful to authors and editors. (See also Chapter 28, Peer Review in Scholarly Publication.)

General Approach

In approaching a review, the peer reviewer should keep in mind the golden rule, "Do to others as you would have them do to you," or perhaps, "Review the manuscripts of others as you would have them review your manuscripts." Approach a manuscript as if it were written by a colleague or trainee and try to give the authors suggestions that will help improve their research design, their analysis, or their writing. Even if a reviewer thinks the manuscript should be rejected, the suggestions provided may improve the next effort by these authors. Reviewers should keep in mind how painful it may be for authors when their work is rejected. Reviewers should ensure that comments are professional and have a scholarly tone and should avoid including any comments that could be perceived as condescending, mean spirited, or personally directed toward an author. If a reviewer thinks the manuscript is of poor quality or is not publishable, the reviewer should clearly communicate that recommendation to the journal editor but should be polite in comments to the authors. This is true even for journals with open peer review, in which all comments are seen by the authors, reviewers, and editors.

In addition, peer reviewers should not mislead authors. Editors prefer that reviewers not make statements about rejection or acceptance in their comments to authors because the final decision is not the prerogative of reviewers. The reviewers are valuable consultants, but the editors are the decision makers. However, reviewers should not hesitate to point out to authors problems with the methods of the study or with the writing of the manuscript. If a reviewer thinks something is incorrect or poorly done in a manuscript, they should say so and suggest to authors how they can fix the problem.

A little humility on the part of the reviewer may be helpful. The reviewer should consider the possibility that what the authors have done or said is correct, even if it seems doubtful at first reading. If the manuscript is unclear, the reviewer should explain to the authors that readers will not be able to understand their meaning; only the most defensive author would not appreciate that if a thoughtful reviewer could not understand a sentence, it will not be clear to many readers.

The more specific the reviewer's advice, the more it may be helpful for the authors. If, for example, the authors have not adequately discussed the relevant literature, reviewers can try to provide specific citations; just saying "the paper by Smith" is not helpful. If the authors need to use a different statistical test, the

Downloaded from academic.oup.com/book/58841 by guest on 17 October 2026

reviewer should refer them to a resource (article or textbook) that will provide the details they need.

How long should a review be? It is rare that a single sentence or paragraph is sufficient. Authors may derive brief excitement from a 1-sentence review that says the manuscript should be accepted without any changes. But nearly every manuscript can be improved, and a very short review suggests that little review was actually done. Similarly, a 1-sentence condemnation of the manuscript offers little help to the authors. The length of the review will depend on the individual manuscript and often is related to the quality and complexity of the manuscript. One or 2 pages of comments may suffice for many reviews, whereas 10 pages of comments may be justified for other reviews. However, the content of the review, with inclusion of objective, evidence-based, critical substantive comments, is more important than the length of the review.

Reviewers should not rewrite the manuscript, but it is certainly permissible to comment on grammar and writing style. The majority of journals have manuscript editors who work to substantially improve the quality of the writing. Many reviewers, however, have excellent editing skills. Furthermore, if a reviewer finds that a sentence, phrase, or paragraph seems unclear or awkward, that sentence probably will seem unclear or awkward to other readers. If reviewers would like to offer comments that will improve the writing, the editors certainly appreciate this. It is not necessary to point out to the authors of international submissions that English may not be their first language. They (and the editors) know this. If the manuscript has scientific merit and is accepted, the journal manuscript editors will work to make it more readable.

In all cases, reviewers should treat the manuscript with the confidentiality that the authors have entrusted in the journal and the editors have entrusted in reviewers. The manuscript should not be copied and retained after the review is completed, and the manuscript should not be discussed with, disclosed to, or shared with any third parties without permission of the journal editors. This includes not uploading the manuscript for review to a large language model using artificial intelligence, since this also violates the confidential nature of the authors' work. Asking a colleague to help with the review because of their special expertise is usually acceptable; however, any additional invited reviewers should follow the same confidentiality requirements and their work should be acknowledged in the information sent back to the editors.

Parts of a Review

GENERAL COMMENTS

When writing a review, first start with general comments about the manuscript before going on to specific parts of the manuscript. Is the manuscript concise

Downloaded from academic.oup.com/book/58841 by guest on 17 October 2026

or could it be shortened to make it more readable? Do some parts need to be expanded to make it clearer? How does it contribute to the existing literature?

Every study has flaws. The question is how much the flaws might bias the results and whether any can be fixed. Are there irreparable flaws that affect the validity of the work to such a degree that the results are invalid? If so, the reviewer should let the editor know and point out the concerns to the authors.

TITLE AND ABSTRACT

Does the title accurately describe the study, or is it misleading or incomplete? Will the title be found by search engines looking for articles on the study's content? Is the abstract informative enough that it can stand alone as a summary of the study? Are the main numerical results of the study in the results section of the abstract? Is all the material in the abstract presented in the manuscript? Are the numbers given in the abstract consistent with those reported in the manuscript? Do the conclusions in the abstract flow from the results in the abstract, and are the conclusions in the abstract appropriate?

INTRODUCTION

Do the authors succinctly establish the rationale for the study? Do they clearly state the study question?

METHODS

The reviewer should pay close attention to the Methods section and understand what the authors did. Does the study clearly describe and follow a known study design? Did the authors follow the principles of this design? If a reviewer has specific references on methodology or design that the authors should include, it is tremendously helpful for the reviewer to provide that information. For clinical trials, the reviewer should check to see if the outcomes reported in the manuscript are the same as those prespecified in the trial registration and study protocol.

Editors are very conscious of the ethics of research as well as potential conflicts of interest. All research reports that involve data from human research participants require a specific statement that an appropriate institutional review board or ethics committee reviewed the study. The peer reviewer should check that such a statement is included in the Methods section, and that the authors have clearly stated procedures for obtaining informed consent from research participants. For industry-sponsored studies, the reviewer may evaluate whether the role of industry personnel is clearly indicated, either in the Methods section or in the acknowledgments.

Many journals have a statistical consultant as part of the editorial staff.

Downloaded from academic.oup.com/book/58841 by guest on 17 October 2026

That consultant, or a peer reviewer with biostatistical training, usually is asked to review the methodologic and analytic aspects of manuscripts reporting research. Peer reviewers should comment on the methods and analysis used and let the editor know of any specific concerns. Many reviewers are likely to have more expertise than many readers. If a reviewer is unclear about the study design or the analysis, then it will likely also be unclear for other readers. Sometimes a reasonable approach is to just indicate to authors that what they report in the manuscript is unclear and ask them to try to explain their method in a different way. At times, it may be reasonable for reviewers to suggest additional analyses, such as sensitivity analyses to explore or provide insights for some observations, or to check for the robustness of some results. The reviewers usually should not suggest that those analyses (which by definition are post hoc) should supersede the prespecified primary or secondary analyses in the manuscript. Also, while reviewers may be tempted to suggest that a study should have been designed differently, the reviewer should realize that the study as designed in the manuscript under review is the methodology that should be evaluated.

RESULTS

Are the results presented clearly? Do they repeat information that is in the tables and figures, and if so, is this excessively repetitious? Did the authors account for all participants in a study? Are the tables and figures understandable and well labeled? Do they display the data in the clearest way possible? Are the numbers consistent in the abstract, results, tables, and figures? It is often useful to add up the columns in a few tables to make sure they are correct.

DISCUSSION

Did the authors relate their study to prior work in the literature? Is it clear how this study supports, or disagrees with, prior work, and why? Did the authors acknowledge the limitations of their study and discuss how these limitations might affect the results and their interpretation? Are the conclusions justified by their data?

REFERENCES

Are the references appropriate for the statements they are meant to support? Are they up-to-date, or is more recent information available?

SUPPLEMENTS

Supplements and related materials (eg, video) have become a more prominent part of manuscripts and should be evaluated by peer reviewers. For some

Downloaded from academic.oup.com/book/58841 by guest on 17 October 2026

manuscripts, review of supplemental materials will be essential, such as with study protocols and statistical analysis plans. For other supplemental material, such as tables or figures, reviewers can comment on these materials and indicate if any should be moved to the main text or if any are unnecessary. Journals have varying policies regarding review of supplemental material.

Suggestions for Presenting Specific Comments

For each comment to the authors, the reviewer should clearly indicate the precise location in the manuscript to which the comment pertains. This approach will ensure that the editors and authors can match the comment with the content in the manuscript that needs to be addressed. The reviewer should preface each comment with the precise section and page, paragraph, and/or line number (if included) in the manuscript.

For example, "Page 6, para 2, line 7: The authors should explain which variables were included in their models and provide justification for selecting these variables."

Also, it may be helpful for reviewers to provide specific suggestions to authors for important aspects of the manuscript, rather than to simply identify a problem. For instance, a reviewer comment that simply identifies a problem, such as "The title of the manuscript is noninformative and could be improved," is less helpful than a comment that provides a recommendation for improvement, such as "The title of the manuscript could be more informative. A suggested title is as follows: … " (and the reviewer could provide an alternate title for the authors and editors to consider).

Comments to the Editors

The editors are responsible for making the decision about the outcome of a manuscript, but they usually request and value the reviewers' suggestions, such as whether the manuscript should be (1) accepted in its present form; (2) accepted after modest revisions; (3) reconsidered after revision, often involving major changes; or (4) rejected at this stage. The recommendation from the reviewer should be based on a number of considerations. Are the data and methods such that the results might be credible? Even if the results of the study seem surprising or counterintuitive, reviewers should generally judge the quality of a study by the quality of its data and methods, not by the findings or final results. Results, which may confirm or refute prior results or beliefs, cannot generally be used to measure the quality of research. Reviewers might consider whether their recommendation would change if the results were the opposite

Downloaded from academic.oup.com/book/58841 by guest on 17 October 2026

of what was reported. If so, the reviewer might reconsider their thoughts about the manuscript and the recommendation regarding suitability for publication.

Important considerations for the reviewer in the evaluation of the manuscript also include the following: How new and important is the information in the manuscript? How much does the reported information add to the field? Even if one or a few articles have reported the same finding, confirmation of that finding in a new location or population or by a new method might be a useful addition to knowledge. Reviewers are chosen to review the manuscript because of their particular expertise. Editors rely on peer reviewers to tell them whether a study is an important contribution to the literature. When a reviewer thinks that the manuscript under review is important, controversial, or for some other reason may deserve an editorial, it is helpful for the reviewer to let the editor know. In addition, the reviewer should indicate to the author if they are interested in and willing to prepare an editorial for the journal or may suggest a colleague who would be qualified to write an editorial.

Timeliness of Reviews

All journals try to process manuscripts as rapidly as possible. Many authors know which journals have relatively rapid turnaround for editorial evaluation and decision-making and which have prolonged turnaround times that may require many months. A substantial proportion of the processing time for manuscripts is related to the peer review process, including the editor identifying qualified reviewers, the editor or journal office contacting the reviewers, the reviewers responding to the invitation with their agreement to perform the review, and the reviewers completing and submitting their reviews. Delays can occur at any step in the process. For example, a problematic situation may occur when a reviewer who had agreed to review the manuscript in a timely fashion (typically, journals request reviews to be completed in 2 to 3 weeks) delays returning the review for a month or longer, and then when contacted about the review, declines to complete the review. This may result in substantial delays in a decision to the authors. If a reviewer who has agreed to review a manuscript finds that it is not possible to complete the review in the agreed upon timeline, such as because of time commitments or other reasons, the reviewer should contact the editorial office promptly.

When a reviewer accepts the invitation from a journal to review a manuscript, a 3-step process may help. First, read the manuscript soon after it is received. Second, return to the manuscript in a day or so, read it carefully, and write the review. Third, carefully review, read, and edit the review, perhaps after letting a day or two go by. Most authors give a lot of care to their own manuscripts; after all, when they are published, their name is there for all to see. But reviews are generally anonymous and may carry little reward, which may tempt

Downloaded from academic.oup.com/book/58841 by guest on 17 October 2026

reviewers into being less careful with their reviews. The reviewer should edit the comments in the review carefully for clarity, tone, grammar, and other issues, such as removing language that could be perceived to be unnecessarily harsh or unprofessional. High-quality reviews should not only include thoughtful, substantive comments about the content of a manuscript, but also should be presented in a well-written and well-organized fashion.

Conflicts of Interest for Reviewers

Reviewers who are invited to review manuscripts should carefully consider whether they may have a conflict of interest in performing the review. Many journals include a place in the reviewer form in which reviewers are expected to report their conflicts of interest.

In all cases, the reviewers should notify the editor of any potential conflicts of interest at the time they receive the invitation to review the manuscript. For instance, reviewers who have a financial conflict of interest, such as owning equity interest in a company that makes a drug tested in the study the manuscript is reporting, should communicate that information to the editor before agreeing to review the manuscript. This does not necessarily preclude an individual from reviewing the manuscript, but it allows the editor to weigh this information when considering whether the reviewer should proceed with performing the review and in evaluating the content of the review.

Reviewers also may have professional or personal relationships that should be considered in deciding whether to review a manuscript. In general, a reviewer should not review a manuscript from a colleague at the same institution or a manuscript from an author with whom the reviewer has collaborated or has coauthored other manuscripts. Reviewers generally should decline to review manuscripts from individuals with whom they have these or other types of personal or professional relationships, and they should notify the journal office of the reasons for declining to accept the invitation to review. Since journals may have different policies about who can and cannot review manuscripts, if reviewers have any questions about whether their interests (financial or otherwise) or relationships represent a conflict of interest that may disqualify them from reviewing a manuscript, they should contact the editorial office and explain the nature of their concerns. (See also Section 5.5.6, Requirements for Peer Reviewers, in the *AMA Manual of Style*.[1])

Benefits of Reviewing

Being a good reviewer is, like writing and editing, a skill that improves over time. Reviewing has many benefits:

Downloaded from academic.oup.com/book/58841 by guest on 17 October 2026

1. Improving a manuscript is a service that many authors appreciate. All authors can recall thoughtful and helpful reviews that were received regarding their own work and are grateful to those who took the time to enhance their work.
2. Improving the quality of published articles performs a service to readers and to the clinical and scientific communities.
3. Good reviews may attract investigators doing quality research to return to the journal, improving the quality of the journal.
4. Reviewing enhances the reviewers' skills as investigators and authors, and it may help improve the design of the reviewers' future studies and the quality of their own writing.
5. Providing a high-quality review may lead to an invitation to write an Editorial for that or future manuscripts.

Conclusion

The ultimate goal of biomedical publishing is to provide information that will serve to prevent illness, improve care, and promote health. Thoughtful peer review is a critical part of this process.

ACKNOWLEDGMENT

This chapter is an updated version of the following previously published article: Cummings P, Rivara FP. Reviewing manuscripts for *Archives of Pediatrics & Adolescent Medicine*. *Arch Pediatr Adolesc Med.* 2002;156(1):11-13. doi.org/10.1001/archpedi.156.1.11

Reference

1. Flanagin A. Requirements for peer reviewers. In: Christiansen S, Iverson C, Flanagin A, et al, eds. *AMA Manual of Style: A Guide for Authors and Editors.* 11th ed. Oxford University Press; 2020. Accessed September 22, 2003. https://academic.oup.com/amamanualofstyle/book/27941/chapter/207564250#414753124

Downloaded from academic.oup.com/book/58841 by guest on 17 October 2026

CHAPTER 30

Communicating and Interacting With Journal Editors

Mary M. McDermott, MD

Downloaded from academic.oup.com/book/58841 by guest on 17 October 2026

KEY POINTS

- Authors should be judicious about editorial communications and remain mindful of appropriate author/editor boundaries.
- Authors should obtain a basic understanding of the journal content and style prior to contacting editors.
- Manuscript cover letters should be concise and include required elements as indicated in the journal's instructions for authors.
- After manuscript submission, authors may consider contacting editorial staff to inquire about the disposition of the manuscript at 10 to 12 weeks after the manuscript was submitted or checking the submission site for an update on status.
- Author response letters accompanying revised manuscripts should thoroughly address each editorial and peer review comment, including indicating line numbers in the revised manuscript where revisions can be located.
- Developing relationships with editors, such as with frequent high-quality manuscript submissions, peer review, or during author outreach events, can be mutually beneficial for editors and authors.

Communications between authors and editors are an essential component of the manuscript submission and publication process. These communications can clarify journal expectations and editorial priorities and provide important information for a transparent and thorough manuscript evaluation by the editor. Communicating with journals takes several forms. For example, the cover letter is one method of author-editor communication. Another example is the letter responding to editor and reviewer comments when a revised manuscript is invited. Direct emails are another form of communication. This chapter discusses optimal methods, content, and context for author communications with journal editors and provides practical suggestions for authors regarding

Table 30-1. Summary of Author-Editor Communications

Type of communication	Appropriate content	Additional considerations
Manuscript cover letter	• Include author contact information and any conflicts of interest and notify the editor of any related manuscripts that are published or in development. • Follow the journal's author instructions regarding what to include in the cover letter. • Conflicts of interest should be included in the cover letter.	• The cover letter should be brief, since editors are not likely to read a lengthy letter.
Presubmission inquiry	• Typically only a subset of manuscript types require a presubmission inquiry. • Follow the journal's instructions for authors regarding the appropriate content.	• An editorial request to submit the manuscript does not guarantee publication. • If the editor declines to review the manuscript, this decision should be respected.
Response letter to a request for revision	• Each editor and peer reviewer comment should be itemized and responded to thoroughly. • Editorial comments typically have priority over peer reviewer comments.	• Authors should be sure to indicate line numbers or manuscript sections for where revisions can be located in the revised manuscript. • Authors should refrain from simply stating "done" in response to editor and peer reviewer comments.
After acceptance	• Edited manuscripts and proofs should be reviewed promptly for accuracy. • Any errors discovered after acceptance or publication should be reported to the editor promptly.	• Major rewriting or changes in authors or author order are not appropriate at this stage.

interactions with editors. This chapter includes discussion of presubmission inquiries to a journal, preparing an effective cover letter to accompany a submitted manuscript, communications during the manuscript submission process, and communicating directly with editors after manuscript submission (see **Table 30-1**). (Preparing a response to reviewer and editor comments as part of submitting a manuscript revision and appealing editorial decisions are reviewed in Chapter 31, Responding to Journal Decision Letters and Reviewers' Comments.)

General Recommendations About Communication With Journal Editors

Different journals have different preferences for communication with authors. Some editors or journals may welcome and encourage direct communication

Downloaded from academic.oup.com/book/58841 by guest on 17 October 2026

from authors, whereas others may prefer more formal communication, such as through the manuscript submission process. Although it may be initially unclear to authors which approach is preferred, authors should be selective with these communications and follow guidelines in the journal's instructions for authors or on the journal website for contacting the journal or communicating with editors.

Authors may be inclined to email journal editors directly to inquire about editorial policies or editorial interest in a specific original research topic or manuscript; these communications are often inefficient for editors and can be deleterious when they result in redundancies or unnecessary infringement on the editor's time. Some journals prefer that authors email the editorial manager, who may serve as an intermediary between the author and the editor. Emailing the editorial manager can clarify whether the journal prefers for authors to directly contact the editor. Authors should be judicious with communications to the editor and should remain mindful of appropriate author/editor boundaries during manuscript review. In general, authors should avoid emailing editors to inquire about the editor's interest in a particular manuscript, unless a specific presubmission inquiry is required. Authors of original research manuscripts who are uncertain about whether their manuscript is appropriate for a particular journal usually can discern this information by reading the instructions for authors and by reading several issues of the journal to understand the type of research typically published by the journal. Reading the journal provides important information about editorial priorities, journal style, and standards for study types, quality, and data presentation. Therefore, becoming familiar with these aspects of the journal is an integral part of the decision to submit a manuscript to a specific journal.

For questions about manuscript submission requirements, authors should read the instructions for authors thoroughly before contacting journal editors and should not directly contact editors with questions that are addressed in the instructions for authors. Information about a manuscript that may be helpful to an editor but that is not included in the manuscript content, such as an upcoming presentation of the manuscript data at a major scientific meeting or the existence of related manuscripts by the author, can be communicated in the manuscript cover letter. Communications should always be professional, respectful, reasonably succinct, and informative.

Presubmission Inquiries

For some journals, certain manuscript types, such as review or opinion articles or special communications, may require a presubmission inquiry. Categories of manuscripts requiring a presubmission inquiry are typically indicated in

Downloaded from academic.oup.com/book/58841 by guest on 17 October 2026

the instructions for authors. Original research manuscripts typically do not require a presubmission inquiry and in general authors should refrain from emailing journal editors to inquire about editorial interest in original research manuscripts, unless there is a need for expedited consideration (for example, for a study that will be presented in a late-breaking clinical trial session at a major meeting or a study of substantial and immediate public health importance). Even when a presubmission inquiry is required, authors should read the journal sufficiently to ensure a basic understanding of the journal content and style.

Some journals have formal mechanisms for presubmission inquiries and may have a specific link on the journal website for submitting these inquiries along with the abstract from the proposed manuscript. For other journals, presubmission inquiries to editors are sent by email, either to a designated email address listed in the instructions for authors or perhaps to a specific editor (such as the editor for a section of the journal). These communications should be succinct and follow the guidelines for presubmission inquiries that are described in the instructions for authors, including only essential information as delineated in the instructions for authors. While a brief statement about the author's experience or expertise relevant to the topic of the presubmission inquiry may be helpful to the editor, editors are unlikely to thoroughly read a lengthy presubmission inquiry. Similarly, authors may consider including information about why their proposed submission is important and how it meets the journal's specific editorial priorities, but this information should be succinct. Overall, a brief presubmission inquiry that simply includes the elements required as indicated in the author instructions is likely to be most effective and helpful to the editor. Authors should also include information about conflicts of interest related to their presubmission inquiry. Presubmission inquiries should be sent by the author rather than through an intermediary acting on behalf of the author, such as a secretary or writing assistant.

Responses from editors to presubmission inquiries typically consist of 2 general categories. First, the editor may indicate interest in having the author submit the full manuscript for evaluation. Authors should realize that this type of response only indicates interest from the editor in evaluating the full manuscript and does not imply any guarantee or promise that the manuscript will be sent for evaluation to external peer reviewers and should definitely not be interpreted as indication that the proposed manuscript will be accepted for publication. Second, in response to a presubmission inquiry, the editor may indicate that there is not an interest in having the author submit the full manuscript for evaluation and consideration. Authors who receive this type of response should accept the decision and submit the manuscript to another journal, without challenging or debating the editor about this decision.

Downloaded from academic.oup.com/book/58841 by guest on 17 October 2026

Manuscript Cover Letters

Manuscript cover letters are an important source of communication with journal editors. Manuscript cover letters may be used to underscore the relevance of a manuscript for a journal, suggest potential reviewers, and communicate special circumstances. Authors should confirm the name of the editor of the journal before submitting the cover letter, especially if they are submitting a manuscript to a second journal after a previous rejection. Similar to presubmission inquiries, succinct cover letters are most effective. Therefore, if authors choose to summarize the content or the importance of their submitted manuscript, this should be done in 2 to 3 sentences. In summarizing the work, authors might indicate how their manuscript advances the field, describe the novel aspects of the manuscript, or otherwise explain briefly why the work is important.

A cover letter may also suggest potential peer reviewers, but the editor may or may not decide to use the authors' suggested reviewers. Authors should only suggest that the editor avoid certain reviewers if the authors believe that these reviewers would not conduct a fair review of the manuscript or if the potential reviewers have documented conflicts of interest. In these instances, authors should indicate the specific reason(s) that they believe the reviewers could not provide a fair and balanced evaluation of the manuscript. Note that many manuscript submissions systems have sections for designation of suggested reviewers or those to avoid. Cover letters can also notify the editor of upcoming presentations of the work at scientific meetings. This information can be useful when the presentation is covered by the media while the manuscript is under review or if publication simultaneous to the oral presentation might be possible.

Cover letters can also address concerns that editors may have on review of the manuscript, such as related manuscripts by the author that are published or in preparation, posting of the manuscript on a preprint server, or late registration of a randomized trial. For example, the author could use the cover letter to briefly explain why a clinical trial was registered late or how the manuscript differs in a significant way from a related and previously published article or a related manuscript under consideration by another journal. In the latter instance, the related article or manuscript should also be uploaded on the journal website so that the editor can evaluate any potential overlap.

A cover letter can also address any anticipated editorial concerns, such as a delay between completion of a study and manuscript submission or justification for why the manuscript may include, for example, more figures and tables than allowed by the journal. In the latter instance, authors may use a cover letter to indicate concessions they are willing to make if requested by the editor, such as moving some tables and figures to online only. If the author has engaged in presubmission communications with an editor, that information should be described in the cover letter. In particular, if an editor encouraged submission of

Downloaded from academic.oup.com/book/58841 by guest on 17 October 2026

the manuscript, it is important for the author to mention that interaction with the editor in the cover letter. As with presubmission inquiries, the cover letter should be succinct. The cover letter should typically be 1 page or less. The cover letter also should include the full contact information for the corresponding author. If the corresponding author anticipates being unavailable during the time the manuscript will be under evaluation at the journal, an alternate author should be identified who will serve as corresponding author during that time.

Manuscript Submission

In addition to a cover letter and the manuscript files, authors should consider uploading additional relevant files that may be important to facilitate a thorough and fair evaluation of the manuscript. For example, randomized clinical trials should include the trial protocol and statistical analysis plan as additional supplemental files. The protocol and statistical analysis plan help the editors and reviewers evaluate whether the authors adhered to their original protocol and statistical analysis plan. For original research manuscripts, authors should be certain to include related manuscripts from the same study that are either published or have been submitted to another journal for peer review. When the authors have a related manuscript previously published or under review, it is essential and expected for editors to be aware of the related manuscripts so that the editors can make an independent determination about overlap between the manuscripts that may preclude a separate publication. For this reason, the related manuscripts should be uploaded as additional documents during the manuscript submission process. If there may be overlap, it is much better for the authors and the editors to learn of the potential overlap as soon as possible to avoid later conflicts and misunderstandings.

Most journals do not require that authors provide reviewer comments when the manuscript was previously submitted elsewhere and rejected. However, authors should consider whether it may be beneficial to include comments from prior peer reviewers along with information about how the authors responded to the peer reviewer comments. When the authors have made substantial changes to the manuscript in response to reviews by another journal, it may serve the authors' interests to show prior reviews and the authors' responses to the reviews as part of additional attachments with the manuscript.

Editor Communications After Manuscript Submission

After manuscript submission, authors should generally avoid contacting the editor until results of the review return. However, if the author obtains new

Downloaded from academic.oup.com/book/58841 by guest on 17 October 2026

information that may be particularly important or relevant to the manuscript review, that information should be communicated to the editor. For example, if a study summarized in an original research manuscript is accepted for presentation at a major academic meeting for which simultaneous publication may be possible, this information may be helpful for the journal editor. Alternatively, if an error is identified in analyses submitted to the journal, particularly if the error affects the manuscript conclusions, this information should be communicated promptly to the journal editor.

Most journals complete initial manuscript assessment within 2 weeks, making an initial determination of whether the manuscript will be rejected without review or sent for external peer review within this time. For manuscripts that are rejected without external peer review, depending on the journal, authors ordinarily can expect to receive the decision to decline the manuscript within 2 to 3 weeks after initial submission. However, for some journals, this initial decision may occur within several days. Editorial review typically requires more time for manuscripts that are sent for external peer review. While most journals ask peer reviewers to complete their review within 2 to 3 weeks, there may be delays, such as difficulty finding reviewers who agree to review the manuscript or when reviewers exceed the requested time for the review. At *JAMA*, for all manuscripts (original research, reviews, opinion pieces) submitted in 2023, the median time from receipt of a manuscript to rejection without review was 3 days, and the median time required for peer review was 12 days.[1] However, not all journals have the resources, support staff, or reviewer pool to achieve similar peer review times for editorial decisions. In addition, when discussion of the manuscript at an editorial meeting is required after peer reviews are completed, this can lengthen the time for editorial review. Therefore, in general, it may be reasonable for authors to contact an editor if they have not received a decision about the submitted manuscript after about 10 to 12 weeks. Many journals also post manuscript information on submission sites, which authors can check for updates on the status of their manuscripts.

Responding to Editor and Reviewer Discussions for Manuscript Revisions

When a revised manuscript is invited, authors should prepare a response letter listing each of the editors' and reviewers' comments verbatim and provide a complete response to each comment. Preparing an excellent response letter is complex, and inexperienced authors should ask for help from more senior colleagues. Across the JAMA Network journals, the acceptance rate of manuscripts for which a revision has been requested is greater than 75%, and the editorial decision depends on the quality of the revised manuscript and the

Downloaded from academic.oup.com/book/58841 by guest on 17 October 2026

thoroughness and responsiveness of the authors to comments from editors and reviewers, as detailed in the authors' response letter.

Itemized and detailed responses to each comment demonstrate that the author carefully considered each comment. A thorough response is typically more favorably received and appreciated by journal editors. Authors should avoid simply stating "done" in response to individual comments from editors and authors. Instead, authors should systematically state their response to the comment and should always indicate where the editor can find any edits or additions made in the revised manuscript in response to the comment. Authors should also indicate, verbatim, the specific change(s) made in the revised manuscript in response to the editor or reviewer comment. Providing this information, including the line numbers or manuscript sections where responses can be found, facilitates the review process for the editor and peer reviewer and is typically appreciated by the editor and peer reviewer.

Even when authors disagree with suggestions made by the editor or reviewer, authors should carefully and respectfully respond to each comment. Thorough justifications and explanations for comments that do not result in manuscript changes are important. It may be appropriate to perform additional data analyses to respond to some comments more fully, particularly when the additional data analyses help justify the author's response. In these instances, it may be helpful to include results of the new data analyses in the author response letter to help support the author's response, even when the author decides not to include the new data analyses in the revised manuscript. When additional data analyses, tables, or figures are included in the response letter with a manuscript revision, the author can offer to include these elements in the revised manuscript at the editor's request. Authors should always be respectful in their responses, even when they may disagree strongly with comments made by the editor, the reviewers, or both.

In general, authors should avoid direct email to the editor during the manuscript revision process. However, there are exceptions. For example, if it is not possible for the author to meet the journal's deadline for submission of the revised manuscript, the author should notify the editorial office to request a deadline extension. In these instances, the author should be as accommodating as possible in suggesting an alternative deadline. In addition, when a comment made by a peer reviewer contradicts a comment from the editor, or when 2 peer reviewers make conflicting statements that require an author response, it may be appropriate to contact the editor for clarification.

However, 2 points should be considered before contacting the editor. First, it is generally safe to assume that when comments made by an editor and a reviewer are contradictory, it is best to follow the editor's recommendation. Second, when 2 peer reviewers make contradictory comments, and the editor does not provide direction, the author may select which of the contradictory

Downloaded from academic.oup.com/book/58841 by guest on 17 October 2026

comments they prefer to respond to and indicate that the alternative comment could not be simultaneously addressed. Another approach would be for the author to contact the editor who invited the revised manuscript and request that the editor reconcile the differences in the reviewers' contradictory comments. (Additional information and details about responding to reviewer and editorial comments and preparing a manuscript revision are included in Chapter 31, Responding to Journal Decision Letters and Reviewers' Comments.)

Postacceptance Communications With Journal Editors

Once a manuscript has been accepted for publication, communications typically consist of editing-related and production-related issues prior to publication. Edited manuscripts and/or proofs should be reviewed and returned promptly, within the journal's requested timeframe. If an author anticipates that they will not be available during the time when edited manuscripts and/or proofs will be received, the author should notify the journal and provide contact information for an alternative author for review and approval. Edited manuscripts and proofs should be reviewed carefully to address any queries and for any text or data errors so that they can be corrected prior to publication. Major text rewriting is not appropriate at this stage of publication. Manuscript text, data in tables and figures, author affiliations, and conflicts of interest should be reviewed carefully for accuracy. Adding data or adding authors or changing author order is not appropriate during the final editing and production process.

After manuscript acceptance, authors should keep the fact that the manuscript was accepted for publication confidential until it is published. Authors are advised to not share information about the acceptance by the journal with others (except coauthors) and to not post such information on social media until after publication. If the author will be presenting the manuscript at a conference prior to publication, authors should contact the journal to clarify issues related to publication date, media inquiries, news coverage, and the journal embargo. (See also Chapter 41, Interacting With the News Media.) Errors identified after the manuscript is published should be reported promptly to the editor.

Additional Considerations

In general, journals welcome the opportunity to develop relationships with authors, particularly when their work is of interest to the journal. This may occur when authors establish a track record of high-quality research publications in an individual journal and serve that journal in other ways, such as by writing editorials and serving as peer reviewers. In addition, some journals may host

Downloaded from academic.oup.com/book/58841 by guest on 17 October 2026

"author outreach" events at major medical or scientific meetings or other venues. Editors may contact individual investigators and authors for a meeting, often in part because of an author's previous publications in the journal or interest by the journal in receiving future submissions from the investigator or author. Authors should view these interactions as opportunities to establish a relationship with the editor, a relationship that may be mutually beneficial for future manuscript submissions and publications. Attending an author outreach event provides an opportunity for authors to interact informally with editors and is a good time to ask informally about journal content or a potential manuscript submission. Journal editors desire to maintain positive professional relationships with authors.

Conclusions

Communication between authors and editors is an integral component of manuscript review and publication. Most author and journal communications, summarized in **Table 30-1**, consist of manuscript cover letters, manuscript revision response letters, presubmission inquiries, postacceptance activities, and author outreach activities to communicate with journal editors. Authors should consult the journal instructions for authors and be familiar with the journal content and style when communicating with editors. Both authors and editors benefit from a positive professional relationship.

Reference

1. Bibbins-Domingo K, Flanagin A, Christiansen S, Park H, Curfman G. 2023 Year in review and what's ahead at *JAMA*. *JAMA*. 2024; 331(14):1181-1184. doi:10.1001/jama.2024.3643

Downloaded from academic.oup.com/book/58841 by guest on 17 October 2026

CHAPTER 31

Responding to Journal Decision Letters and Reviewers' Comments

Frederick P. Rivara, MD, MPH

Downloaded from academic.oup.com/book/58841 by guest on 17 October 2026

KEY POINTS

- In responding to reviewers' comments when the editor invites a revision, all comments should be addressed with either changes or a thoughtful explanation of why changes were not made in response to a particular point.
- Appealing an editor's decision to reject a manuscript is rarely successful and should only be done if, for instance, the authors are able to add new data that address an important study limitation or can provide evidence that there were substantive errors in the review.
- If a manuscript is rejected with review at a journal, it should be revised to incorporate the useful comments of the reviewers before submission to another journal.
- Correspondence between authors and editors should be respectful and professional.

Authors will generally receive 1 of 4 decisions from the editor of a journal about a submitted manuscript: reject (with or without peer review); revise and resubmit for further consideration; accept if revised; and accept as is. However, few authors receive any training in how to respond to decision letters about their submitted manuscripts and the accompanying comments of editors and reviewers. This chapter provides suggestions for how to respond to these decisions and undertake the important task of writing a response letter to the journal editor.

Dealing With Rejection Decisions

Receiving a letter of rejection from a journal regarding a submitted manuscript is often unpleasant and certainly unwanted. Because most journals decline a

much greater proportion of submitted manuscripts than they accept, it is inevitable that authors will receive letters informing them that their manuscript has been declined by a journal. Most successful researchers have learned to develop a thick skin regarding rejection and not to take the decision personally. Experienced authors will learn what they can from having the manuscript rejected, will modify the manuscript based on information they may receive from the journal, and will proceed to submit the manuscript to another journal.

REJECTION WITHOUT REVIEW

Most journals will not routinely obtain external peer review for all or even the majority of submitted manuscripts, and editors will make decisions to decline some manuscripts based on review by 1 or more editors. For these manuscripts, authors may receive the editorial decision promptly, usually communicated with a standardized letter that has little or no specific information about or reason for the decision to decline the manuscript.

Receiving a letter of rejection (without peer review of the manuscript) may not necessarily reflect poorly on the submitted manuscript. It may mean that the editors decided that the manuscript simply was not appropriate for the journal or could not be assigned a high enough priority for publication in the journal given other submissions or previous publications. Editors strive to publish articles that make important new contributions and achieve a balance in the journal across many different topics. In some instances, authors may experience unfortunate timing, such as if the journal had just published or accepted a study very similar to the manuscript the authors submitted. There are numerous other reasons that editors may decline manuscripts, including, but not limited to, (1) the topic of the manuscript does not fit with the content and mission of a journal (eg, if a journal does not publish case reports or preclinical laboratory studies); (2) the data are too old to be useful or relevant; (3) the findings are not novel or important; (4) there are important methodologic issues, such as with poorly designed studies or incorrect analyses; and (5) the manuscript has an incorrect format for the journal (eg, excessively long manuscripts).

REJECTION WITH REVIEW

For manuscripts that are rejected from a journal following peer review, most journals will include the comments from the reviewers along with the decision letter. Authors should carefully read and consider all comments and suggestions they receive. In most cases, the authors will benefit from this consultation about their manuscript, and the comments may be helpful to improve the manuscript. Authors should consider revising the manuscript to incorporate helpful comments from the reviewers, and if the authors still believe the work merits publication, submit the manuscript to another journal. Many journals

Downloaded from academic.oup.com/book/58841 by guest on 17 October 2026

encourage authors to submit copies of previously obtained reviews along with comments on how the reviews were addressed in a cover letter. Submission of a revised manuscript to a second journal should be done quickly; delay wastes time, and some manuscripts may become less relevant as the data lose timeliness. For instance, an editor reviewing a research manuscript may be less enthusiastic if the data were collected many years earlier. Authors presumably conducted the study because it was considered to have potential value. Getting a manuscript published requires fortitude; some manuscripts may be rejected by several journals before they are finally accepted for publication. Another reason it is important to revise an article before submitting it to another journal is that the second journal may choose the same reviewer (a common occurrence, especially in a narrow area of research). If the reviewer informs the editor that they reviewed the manuscript for another journal, but the authors ignored the reviewer's suggestions and made no changes to the manuscript, that editor may be more inclined to also reject the manuscript.

APPEALING REJECTION DECISIONS

Some authors who receive notification that their manuscript has been rejected may be inclined to appeal the editor's decision. In general, urging the editors of most journals to reconsider a decision is usually a low-yield strategy. Authors who demand or insist on reconsideration of a rejected manuscript, especially if done in a confrontational or argumentative manner, usually will be unsuccessful. Likewise, resubmitting a revised manuscript that was rejected by the editor and without the editor's approval is very unlikely to be successful. Authors also may mistakenly be under the impression that the editorial decision was based solely on the comments of the peer reviewers and may incorrectly assume that if they revise the manuscript and address the reviewers' comments they received in the rejection letter, the journal will automatically reconsider the revised manuscript. Reviewer comments are only one aspect of the editorial decision process, and the editors, not the reviewers, are responsible for making the editorial decision. (Additional information about the editorial process is in Chapter 27, Manuscript Assessment and Editorial Decision-Making.)

However, there may be occasional manuscripts for which an author's appeal of an editorial decision may be entertained by the journal editor. For instance, authors may be able to add new data that address an important study limitation (eg, the submitted manuscript was conducted at a single site, but the authors are able to include data from other sites, or the submitted manuscript only reported baseline cross-sectional data from a study, but the authors are able to add longitudinal data). Another possible situation that may justify authors' appeal of a decision is when there is evidence that the editors' comments about the manuscript or the reviewers' comments have had major errors. This does not mean a simple difference of opinion about the manuscript's

Downloaded from academic.oup.com/book/58841 by guest on 17 October 2026

importance or novelty, but rather should involve substantive errors related to study methodology or data interpretation, and authors must support their concerns about these errors with evidence and data.

For manuscripts for which authors wish to appeal decisions, authors could consider writing a detailed letter to the editor requesting reconsideration, explaining the reasons for the appeal, and indicating how they would revise the manuscript, in the event the editor expresses a willingness to reconsider the manuscript. The appeal of the editorial decision should be clearly supported by evidence, rather than opinion, and the approach should be professional, respectful, polite, nonargumentative, and unemotional. Editors are not likely to respond well to appeals of decisions and requests for reconsideration if the authors are argumentative, irate, arrogant, or condescending. Badgering another person, even if being done by the world's most famous researcher, is unlikely to yield a positive outcome. (See also Section 5.11.1.2.1, Appeals, in the *AMA Manual of Style.*[1])

Responding When Revisions Are Requested

The most common route to publication of a submitted manuscript is for the authors to receive a letter from the editor indicating that the current version of the manuscript is not acceptable for publication but that offers the opportunity for the authors to revise the manuscript in response to comments from the editors and reviewers, and to submit a revised version of the manuscript for reconsideration. A letter like this is an important step; it gets the author's foot in the door and, for most journals, substantially increases the chances (but does not guarantee) that the manuscript will eventually be accepted for publication. Authors need a strategy for revising the manuscript and responding to the comments so that the revised manuscript can gain full acceptance.

First, authors should carefully read all comments from the reviewers and the editor. Some of these comments may be critical, and others may seem incorrect or superficial. Authors should allow some time to react, and perhaps grumble. A second, more dispassionate reading is likely to improve the revision. Authors should then set about developing a plan for revising the manuscript to address the substantive comments of the editors and reviewers, and for crafting a response letter that is polite, thoughtful, clear, and detailed.

Second, and perhaps most important, authors should develop a strategy to respond promptly. If months elapse before the revision is submitted, other competing manuscripts submitted in the interim may take higher priority. Authors should review the comments from the journal and should formulate a timeline for submitting the revised manuscript. In most cases, authors should try to submit the revised manuscript within 1 to 3 weeks. However, if more time is necessary, such as may occur if the journal requires the authors to update the data

Downloaded from academic.oup.com/book/58841 by guest on 17 October 2026

in the original manuscript or to conduct additional analyses, more time may be requested to complete these tasks and submit the revised manuscript.

Third, in revising the manuscript, authors should be polite and professional. Some authors may be tempted to suggest that the reviewer was completely off base or unfamiliar with the study content, but this is not likely to get a revised manuscript accepted or to create the impression that the authors are thoughtful scientists. Authors should avoid a defensive or confrontational tone; the revision process is not a political debate. The goal for authors is to glean helpful information from the comments, adopt any useful suggestions to improve the manuscript, and calmly explain a clear point of view for points with which they disagree.

Fourth, authors should devote time to carefully preparing their response. The response document is a powerful tool for authors and can be very effective in demonstrating to the editors that the authors have prepared a thoughtful, scholarly, and complete response to the comments from the editors and reviewers. There is no limit on the length of the response to the editors' and reviewers' comments. If it takes many pages to address each point and explain all the changes, editors are willing to read a long response document. Authors should go through the reviewers' comments in an orderly, outlined manner.

There are several approaches for responding to comments, but one of the most effective approaches is the following, which includes 3 parts for each comment: (1) Copy and paste each comment (verbatim, not paraphrased) from the editor or reviewers into the response document, and identify that comment, perhaps as "Reviewer 1, comment 1." (2) Provide a direct response to that comment, along with a detailed explanation and agreement or disagreement with incorporating the suggestion, with the response identified as "Author response" and perhaps included in a different font. (3) Clearly indicate how the manuscript has been revised. For each comment, copy and paste into the response document any substantive changes made to the manuscript, and clearly indicate the location of this change in the revised manuscript (eg, page 6, paragraph 4, lines 3-9). Although this response document may be long, this approach makes it easier for editors to evaluate the responses and the accompanying manuscript revision by putting everything they need into one orderly document.

For example, the journal editor invites a revision and sends comments from both the editor and reviewers A and B. In the manuscript, the authors wrote, "Study participants ranged in age from 0 to 10 years; 27% were 0 to 2 years, and 41% were 2 to 6 years."

Reviewer A commented, "The description of the age distribution of study participants was unclear. Were 2-year-olds in the first group or the second group? And the 2 groups add up to only 68%." It may seem obvious that the authors meant that 68% of the study participants were in the 2 youngest age

Downloaded from academic.oup.com/book/58841 by guest on 17 October 2026

categories and that 32% were in the oldest group. However, the reviewer was correct in noting the vagueness of the age boundaries.

The response letter might include something like the following:

> **Reviewer A comment:** "The description of the age distribution of study participants was unclear. Were 2-year-olds in the first group or the second group? And the 2 groups add up to only 68%."
> **Author response:** *The reviewer was concerned about the lack of clarity on our description of the age distribution of study participants in the first paragraph of the Results section.*
> *The reviewer is correct, and we appreciate the chance to clarify this point.*
> **Manuscript revision:** The manuscript has been revised as follows: "Twenty-seven percent of study participants were younger than 2 years, 41% were 2 to 5 years, and 32% were 6 to 10 years." (Page 4, para 2, lines 5-7 in the revised manuscript.)

By numbering the responses and first giving the reviewer's comment and then giving the authors' answer and response, authors make it easier for the editors and reviewers to follow the details of the response. By restating what appears to be the concern of the reviewer, authors are forced to think carefully about what the reviewer wrote. This can sometimes be illuminating, both for the authors and for the editors. By including the actual manuscript changes in the response document, the editor can follow what the authors have done without searching for the changes in the revised manuscript. Notice that the previous response is polite and expresses gratitude. If reviewers offer authors ways to improve the manuscript, the authors should incorporate the suggestions, unless the suggestion changes the meaning substantially or introduces incorrect information. Even though the hypothetical manuscript's original wording is nearly as clear as the revision, the response conveys the sense that the authors are willing to adopt reasonable suggestions.

Most journals ask authors to identify changes with a tracked-changes format in a second copy of the revised manuscript. This can easily be done using word-processing software. However, this procedure often creates a long manuscript that is difficult to read and fails to clearly juxtapose the reviewers' comments with the authors' changes. Itemizing and detailing the revision comments in a formal response letter makes the editor's evaluation of the revised manuscript easier.

Fifth, authors do not have to revise the manuscript to address every comment by the editors or reviewers, but they still must address all the comments in the response letter and should modify the manuscript where it is appropriate to do so. If the authors decide not to comply with a suggestion, the editor will want a valid reason and clear explanation. Responding at length to the reviewer and editor about their concerns without making changes in the manuscript may be appropriate for some comments, but authors who fail to adopt

Downloaded from academic.oup.com/book/58841 by guest on 17 October 2026

a reasonable suggestion just because they may prefer something a certain way may not result in a favorable editorial decision. For example, if an editor indicates that Figure 2 should be eliminated and the related information summarized in the text, authors usually should follow this suggestion. In instances in which authors disagree with suggestions from the editors or reviewers, it is helpful to politely address the disagreement, using phrases such as the following: "We agree with the reviewer that … but …"; "The reviewer is correct to point out … but …"; "Although we agree with the reviewer that …"; "We too were disappointed by the low response rate, and …"; "We support the reviewer's assertion that … although …"; and "With all due respect to the reviewer, we believe that this point is not correct."

When authors are confident that their analytic method or choice of wording is better than or more accurate than that suggested by the reviewer, they should provide a logical and concise explanation for consideration by the editor. Ultimately, it is the authors' names that will be published on the article. If a subsequent Letter to the Editor criticizes something in the study, it will not be an acceptable defense to say that what was in the article was based only on the suggestion of a peer reviewer. In the end, authors will have to take responsibility for their work.

In these cases of disagreement, the authors should provide a clear explanation, supported by evidence and references whenever possible, and these supporting materials (eg, references) should be listed in the response document. Also, for situations in which there is disagreement, the authors should express a willingness to negotiate: "Although we prefer not to adopt this suggestion for revision, we would be willing to reconsider other approaches, if the editors prefer."

In addition, peer reviewers do not always agree with each other with their comments and recommendations; in these cases, authors must make a choice. Authors should decide which suggestion seems more valid and appropriate, provide a response based on that decision, and revise the manuscript accordingly, but indicate in the response document that the reviewers provided conflicting advice and that they hope they made the best choice. If authors are truly puzzled or uncertain about what to do with apparently conflicting comments from reviewers, the authors should contact the editor for clarification.

Ultimately, the authors' goal with the revised manuscript and formal response letter should be to leave no unaddressed issues or unresolved questions that require further resolution. If authors fail to address comments from the editors and reviewers in a complete, convincing, cooperative, and satisfactory manner, it is unlikely that the revised manuscript will be accepted for publication.

However, authors should also recognize that even a carefully crafted response letter and extensively revised manuscript may not lead to acceptance of the manuscript. Although the journal is giving authors the opportunity to have

Downloaded from academic.oup.com/book/58841 by guest on 17 October 2026

a revised manuscript reconsidered, the editors are under no obligation to publish the revised manuscript. Other issues or concerns may emerge during the revision process that highlight flaws in the manuscript or that lower the publication priority for the manuscript. If the ultimate decision is rejection, authors should be encouraged that the journal was interested enough to review 2 versions of the manuscript and should realize that the revised version will usually be an improvement and can quickly be submitted elsewhere. (See also Chapter 30, Communicating and Interacting With Journal Editors.)

REDUCING MANUSCRIPT LENGTH

Most journals state the typical length for manuscripts in their instructions for authors. As part of the revision process, the editor may request that the authors condense the overall length of the manuscript to be more consistent with other types of articles published in the journal. Such requests may accompany an invitation to submit a major revision or appear in a letter of provisional acceptance that asks for minor changes including a reduction in manuscript length. Authors should make every effort to follow this advice; the editor is trying to balance priorities and has determined that the key information and message in the manuscript can be conveyed with a shorter length. To achieve final acceptance, authors will have to reduce the length of the manuscript. With careful reading, authors usually can find entire sentences or even whole paragraphs that can be removed. In many cases, a more concise report will more clearly and efficiently convey the key message of the manuscript. Authors also may request that the editors provide some suggestions for areas of the manuscript that should be preferentially condensed. Responses by the authors that they cannot reduce the length of a 5000-word manuscript are not likely to result in favorable editorial decisions.

However, there may be a conflict between reviewer suggestions and the editor's request to trim the manuscript. For example, if the editor requests deleting 1000 words of text but the reviewer asks for a new analysis or discussion that might add 500 words, the authors should still provide a detailed response to the reviewer's suggestion in the response letter but point out in their response to the editor that it would not be possible to incorporate that suggestion in the text and still condense the manuscript. Authors should avoid using saving space or length limitations in the manuscript as a reason for not addressing a comment from the reviewers or editors. Again, in this case, the authors should contact the editor to request clarification of the preferred option.

Downloaded from academic.oup.com/book/58841 by guest on 17 October 2026

Accept If Revised (Provisional Acceptance)

Authors may receive letters from the journal editor indicating that the manuscript will be provisionally accepted, provided the authors satisfactorily complete minor revisions. This would be an unusual occurrence before a research manuscript has undergone revision, but for a manuscript that is provisionally accepted, authors should quickly make the suggested changes and return the revised manuscript promptly, and hopefully the manuscript will be accepted. Also, if other items are requested by the editors, such as completion of authorship forms or conflict of interest disclosures or properly formatted figures, authors should provide that information promptly.

Conclusion

Receiving decisions from the editor of a journal about a submitted manuscript is an integral aspect of the manuscript submission process. Responding to decision letters and the accompanying comments of editors and reviewers in an effective, efficient, and convincing way is a critically important step toward achieving publication.

ACKNOWLEDGMENT

This chapter is an updated version of the following previously published article: Cummings P, Rivara FP. Responding to reviewers' comments on submitted articles. *Arch Pediatr Adolesc Med.* 2002;156(2):105-107. doi:10.1001/archpedi.156.2.105

Reference

1. Christiansen S, Iverson C, Flanagin A, et al. *AMA Manual of Style: A Guide for Authors and Editors*. 11th ed. Oxford University Press; 2020. Accessed April 11, 2024. http://www.amamanualofstyle.com

Downloaded from academic.oup.com/book/58841 by guest on 17 October 2026

CHAPTER 32

Pet Peeves of Editors

Jody W. Zylke, MD

Downloaded from academic.oup.com/book/58841 by guest on 17 October 2026

KEY POINTS

- Pet peeves involving language, such as too many abbreviations, are minor annoyances.
- Some pet peeves stem from failure to follow the journal's instructions for authors and may reflect poorly on the author.
- Pet peeves involving incomplete or unclear reporting of methods and results or interpretation of data may limit the ability of editors or reviewers to assess the validity or relevance of the study and require substantial revision before formal assessment can occur.
- Authors who ask for or demand exceptions or preferential treatment may cause editors to be concerned or irritated, and these requests are unlikely to be successful.
- Although most pet peeves will not result in manuscript rejection, avoiding them can only work in an author's favor.

Everyone has pet peeves—those minor annoyances that an individual finds particularly irritating or vexing. One person's pet peeve may cause them to become quite upset, yet might not bother another person. Many pet peeves involve language (eg, "Whatever!" and "Really?") or are related to other people's behavior (being chronically late or constantly interrupting others). Being human, editors have pet peeves too.

Not surprisingly, some of editors' pet peeves involve language. Although they likely vary from journal to journal and even editor to editor, language-related pet peeves make manuscripts less clear or more difficult to read. For example, in medical writing, the term *provider* is commonly used, but it is unclear whether this term refers to a physician, a nurse, a hospital, or a health care system. *Impact* appears in almost every submission. Not only is this term overused, but it is often used incorrectly, both as a verb and a noun[1] and with various other hackneyed uses, such as *impactful*. The meaning of the pronoun *we* in a sentence may be ambiguous, such as in "We should all follow this advice," which could refer to patients, physicians, society, or the authors. Thus, this

"royal we" should be replaced with more specific language indicating to whom this term refers. Likewise, other terms such as *stakeholders* can be vague and imprecise and should be replaced with the groups or individuals such terms are intended to represent. (See also Chapter 9, Tone, Terminology, and Technical Aspects of Scientific Writing.)

Abbreviations are a major potential source of annoyance. Some abbreviations are commonly used in one specialty or discipline but not in others. Other abbreviations are invented for a particular manuscript. Others may be used to save space. For example, does CHD mean coronary heart disease or congenital heart disease? What is gained by abbreviating a single word such as schizophrenia as SZP? Although a neonatologist might understand this sentence, "VLBW infants are at risk of ROP, BPD, NEC, and EOS," few clinicians in other disciplines would, and the string of letters is fatiguing to read and decipher. Editors recommend using abbreviations sparingly and limiting them to well-accepted abridgments.

Language imprecision or too many abbreviations are minor annoyances, but other pet peeves are more serious. For example, authors sometimes do not revise a submission cover letter after a manuscript has been rejected at another journal. For example, a cover letter accompanying a submission to *The Lancet* that is addressed to the editor of *JAMA* or that mentions near the end of the letter how much the authors are looking forward to having the work published in another journal is likely to irritate editors. Likewise, misspelling of the journal editor's name or addressing the editor as "Dear Sir" when the journal editor is a woman also is problematic. Not revising a manuscript in response to comments received from peer review if the manuscript was first submitted to a different journal is a mistake, as it is possible that the new journal will use the same peer reviewers, who may recommend rejection simply because the authors were nonresponsive to their initial comments. Whether such errors reflect arrogance, laziness, carelessness, or lack of respect for the editors or prior peer reviewers, these errors do not reflect well on the authors. (See also Chapter 31, Responding to Journal Decision Letters and Reviewers' Comments.)

Substantive problems related to journal submission requirements and manuscript preparation are common. Editors may become annoyed when authors have not read the instructions for authors prior to submission of a manuscript or examined similar articles published in that journal. For example, like many journals, *JAMA* uses a specific type of structured abstract, but manuscripts are regularly submitted with the wrong abstract format. Some journals have clear administrative requirements specified in the instructions for authors. For instance, *JAMA* requires statements about the author's access to data, as well as information about who funded the study and the role of the funders. Authors of clinical trials are expected to provide a copy of the protocol and statistical analysis plan, which are key to assessment of the reporting of the trial. Many journals require or encourage preregistration of clinical

Downloaded from academic.oup.com/book/58841 by guest on 17 October 2026

trials, systematic reviews, and other types of studies. Another requirement is for authors to clearly indicate if the submitted manuscript has been posted as a preprint or whether the information reported in the submitted manuscript overlaps with or is closely related to other reports that have been published, are in preparation, or are under consideration by other journals, and authors are expected to provide confidential copies of those related manuscripts. When authors do not provide this information or fail to provide these related manuscripts, but their existence becomes known later, such as during peer review or after publication, editors may become concerned about duplicate or overlapping publication and may lose trust in the authors. These types of omissions involving submitted manuscripts may lead editors to question whether the authors really want their article published in that specific journal.

Another pet peeve of editors is when authors do not report the methods and results of their studies adequately, thereby limiting the ability of editors or reviewers to assess the validity or relevance of the study. For example, a manuscript may not define key terms in the Methods section. The threshold for statistical significance or a minimal clinically important difference may not be specified, hindering interpretation of statistical significance or clinical importance. In shorter reports such as Research Letters, the entire Results section of some submissions has consisted of "See the table." Authors frequently report only relative risks without any indication of absolute values—although a reduction in risk by 50% sounds important, if the absolute reduction is from 2% to 1%, the reported 50% relative benefit may be misleading. Authors may use metrics that are not easily interpretable, such as z scores or β coefficients, or report effect sizes without measures of error or variance. For clinical trials, authors may not report results as specified in the protocol—ie, the primary outcome in the protocol should be the primary outcome in the manuscript.

Even if the methods and results are presented adequately in the text, authors should avoid only presenting results qualitatively in the abstract without the actual data—ie, a "dataless" abstract. Since many readers often only read the abstract, it is important that key outcomes with quantitative results be included in the abstract. (See also Chapter 11, Writing an Informative Abstract.)

Interpretation of a study is also an issue for editors. For instance, some authors may inappropriately use causal language (ie, asserting a claim of cause and effect rather than association) in the conclusion of observational studies in which the study design and methods can only estimate associations and do not include assumptions required to support a causal interpretation and for which a conclusion would not be justified. Authors may overinterpret results based on statistically significant but not clinically important findings, which may be a particular problem in studies using large databases. Authors may inappropriately imply that findings that do not meet the predefined threshold for statistical significance are important, using terms like *trends* or *borderline significance*. Authors of clinical trials may dismiss a negative primary outcome and

Downloaded from academic.oup.com/book/58841 by guest on 17 October 2026

focus their reporting and conclusion on significant secondary or exploratory outcomes. When it comes to interpretation of their research findings, authors could learn a valuable lesson from the understated yet objective nature of the conclusion of perhaps the most famous scientific article of the 20th century, which ushered in the modern era of science: "It has not escaped our notice that the specific pairing we have postulated immediately suggests a possible copying mechanism for the genetic material."[2]

Editors may also be irritated if authors neglect to cite key references that were reported in the journal of submission or cite their own work almost exclusively, both of which may suggest the authors have not performed a thorough literature search. These omissions suggest to editors that authors do not read the journal to which they are submitting, or that the authors believe that they are the exclusive experts in a specific field of research.

Editors also may become perturbed when authors expect or at times demand preferential treatment or expect the journal to make exceptions from standard policies for their work. Certainly, some studies report results that have immediate clinical or public health importance, and for those studies journals often offer rapid review and publication. However, very few studies reach this level of importance and urgency. Rushing a manuscript through review and revision to publication burdens reviewers and staff and is not undertaken lightly.[3] Despite this, some authors request expedited review for an observational study with a retrospective analysis of data collected 5 years before. Or, some authors ask for expedited publication to coincide with a meeting but submit the study only a few weeks before the meeting presentation. Authors should notify editors as early as possible if their manuscript has been accepted for presentation at a major meeting, and especially if they have a major study that has been accepted to be presented as a late-breaking trial. In addition, authors often seek exceptions to journal requirements and reporting standards, such as the format or length of the title and subtitle, the number of authors allowed, the word length of the manuscript, or the number of tables and figures that can be included. Editors have reasons for requirements and if exceptions are made, future authors will want an exception too. If an opinion article, like a Viewpoint (with a limit of 1200 words of text and 3 authors) or a Research Letter (with a limit of 600 words), cannot be written by the required number of authors or within the designated length, then that category of article may not be the best fit for that particular work.

Using too many abbreviations or formatting a submission with the incorrect abstract are unlikely to result in rejection of a manuscript, although these issues may raise questions and are likely to require revision. More substantive issues, such as failing to describe methods or present absolute results, glossing over insignificant primary outcome findings, or highlighting trends, may require extensive revision and possibly reframing of the data presentation or even interpretation of the study conclusion. Neglecting to provide copies of required

Downloaded from academic.oup.com/book/58841 by guest on 17 October 2026

information, such as study protocols or closely related manuscripts, may delay evaluation of the manuscript or reduce editors' confidence in the authors. Nevertheless, authors likely want to avoid irritating editors and so should avoid these pet peeves, both minor and major, if possible. Really!

References

1. Fontanarosa PB. Editorial matters: guidelines for writing effective editorials. *JAMA*. 2014;311(21):2179-2180. doi:10.1001/jama.2014.6535
2. Watson JD, Crick FH. Molecular structure of nucleic acids: a structure for deoxyribose nucleic acid. *Nature*. 1953;171(4356):737-738. doi:10.1038/171737a0
3. Bauchner H. The rush to publication: an editorial and scientific mistake. *JAMA*. 2017;318(12):1109-1110. doi:10.1001/jama.2017.11816

Downloaded from academic.oup.com/book/58841 by guest on 17 October 2026

Downloaded from academic.oup.com/book/58841 by guest on 17 October 2026

PART 6

Authorship and Ethical Issues

Downloaded from academic.oup.com/book/58841 by guest on 17 October 2026

Downloaded from academic.oup.com/book/58841 by guest on 17 October 2026

CHAPTER 33

Authorship Criteria and Ethical Aspects

Phil B. Fontanarosa, MD, MBA, Howard Bauchner, MD, and Annette Flanagin, RN, MA

Downloaded from academic.oup.com/book/58841 by guest on 17 October 2026

KEY POINTS

- Each individual named as an author of a manuscript is accountable for the validity, veracity, and integrity of the information reported.
- Before embarking on preparing a manuscript, all individuals who are being considered for inclusion as authors should prospectively agree on the roles and responsibilities each person will have in writing the manuscript and making other contributions to the manuscript, including the position in the author byline.
- Each individual designated as an author must meet all criteria for authorship (such as the ICMJE criteria), and all individuals who meet all the criteria should be identified as authors.
- The corresponding author is responsible for all communications with the journal and for ensuring that all coauthors are aware of and in agreement with the content of these communications.

Authors of all scientific publications, ranging from opinion articles involving a limited number of individuals to team science reports or research involving hundreds of investigators and multiple research consortia, must adhere to the same principles and standards to ensure the necessary accountability and responsibility for the work being reported. Each individual named as an author is accountable for the validity, veracity, and integrity of the information reported in the manuscript.

Author Roles and Agreement

Before embarking on preparing a manuscript, all individuals who are being considered for inclusion as authors should agree on the roles and responsibilities each person will have in writing the manuscript and making other

contributions to the manuscript. The degree of involvement and the responsibilities for justifying authorship may be related to the responsibilities that individuals had fulfilled when conducting a research study or performing a review. The prospective discussion about authorship also should include consideration of expected contributions of each author, the order of authorship, and who will serve as corresponding author when the manuscript is submitted to a journal. (See also the section "Corresponding Author" for more details on the role of the corresponding author, and the section "Changes in Authorship" in this chapter.)

In addition, prior to embarking on manuscript preparation, authors should agree on the overall message of the article, the conclusions, and in the case of research, the presentation of statistical analyses and interpretation of the study findings. Disagreements and major differences of opinion among authors should be discussed and resolved before submission of a manuscript to a journal.

Authorship Criteria

Even though there may be different views regarding the designation of authorship, many biomedical journals subscribe to and follow the authorship criteria established by the International Committee of Medical Journal Editors (ICMJE).[1] Most journals, including *JAMA* and the JAMA Network journals, require that each individual named as an author on any article must complete and submit an individual authorship form that provides formal attestation that they have met these criteria.

According to current ICMJE recommendations,[1] authorship should be "based on the following 4 criteria:

1. Substantial contributions to the conception or design of the work; or the acquisition, analysis, or interpretation of data for the work; and
2. Drafting of the work or reviewing it critically for important intellectual content; and
3. Final approval of the version to be published; and
4. Agreement to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved."

The fourth criterion was added to ensure that if issues arise following publication of the manuscript—for example, in data analysis—all authors are responsible in assisting in attempts to resolve the concern.

The ICMJE guidelines also indicate that "In addition to being accountable for the parts of the work he or she has done, an author should be able to identify which co-authors are responsible for specific other parts of the work. In addition, authors should have confidence in the integrity of the contributions of

Downloaded from academic.oup.com/book/58841 by guest on 17 October 2026

their co-authors." The guidelines also recommend that "All those designated as authors should meet all four criteria for authorship, and all who meet the four criteria should be identified as authors. Those who do not meet all four criteria should be acknowledged. These authorship criteria are intended to reserve the status of authorship for those who deserve credit and can take responsibility for the work. The criteria are not intended for use as a means to disqualify colleagues from authorship who otherwise meet authorship criteria by denying them the opportunity to meet criterion #s 2 or 3. Therefore, all individuals who meet the first criterion should have the opportunity to participate in the review, drafting, and final approval of the manuscript."[1]

Honorary and Ghost Authors

Authorship requires meaningful substantive contributions to the study or work and to the manuscript. Simply contributing data to a study or serving as a supervisor or representative of an institution or research group does not alone fulfill criteria for authorship. Prespecified agreements that guarantee authorship to individuals for agreeing to be part of an investigation, often by contributing data, are not appropriate if each individual does not also fulfill the authorship criteria. Authorship must not be bestowed in an "honorary" fashion (ie, honorary or guest authors), whereby individuals who do not meet authorship criteria are granted authorship for other reasons.[2-5]

At times, the converse may occur, when some individuals who do meet criteria for authorship are not named (ie, ghost authors),[2-5] which has occurred, for instance, in some articles that have employed writing agencies or others to conduct studies or prepare manuscripts. However, this practice of failing to identify individuals who participated in preparing a manuscript is ethically problematic and not acceptable, and these individuals should be identified for their contributions to the work.

Individuals who do not meet authorship criteria but who have made important substantive contributions to the work should be acknowledged for their contributions and, if appropriate (ie, they meet authorship criteria), may be listed as nonauthor collaborators. Otherwise, they should be listed in the Acknowledgment section, with complete names and indications of their contributions.[6] (See also Section 5.2, Acknowledgments, in the *AMA Manual of Style*.[6])

Designation of Authorship and Author Contributions

Authors have several options for designating authorship in manuscripts and scientific publications.

Downloaded from academic.oup.com/book/58841 by guest on 17 October 2026

The author byline, which lists those designated as authors, is typically listed after the title in the manuscript. All individuals named in the byline must meet authorship criteria and are designated as authors. Others who contributed substantially but do not meet criteria for authorship can be designated as nonauthor collaborators with their contributions and affiliations indicated in the Acknowledgment section of the article. Authors are advised to check the specific journal's instructions for authors for guidance on what is required for indicating authorship in submitted manuscripts (eg, each author's complete name, academic degrees, affiliations, contributions, and conflicts of interest disclosures). (See, for example, the Authorship Responsibility section of the JAMA Network's Instructions for Authors.[7])

To help allocate credit and accountability for contributions to a scientific article, many journals collect self-reported information from all authors regarding their specific contributions to the report according to the ICMJE authorship criteria (such as study conception and design, data collection, and analysis) and to the manuscript (such as writing and reviewing), and some journals publish these as Author Contributions in the Article Information section or Acknowledgment section at the end of the article. For example, *JAMA* and the JAMA Network journals collect information on specific contributions of authors via an electronic authorship form completed by each author.[7] The contributions listed in the journal's authorship form may help researchers decide among themselves who qualifies for authorship and who should be listed as a nonauthor collaborator. It is the responsibility of each author to report this information accurately and honestly and to attest to the veracity of this information, and it is the responsibility of the corresponding author to review and approve this information in the final version of the article. This has become increasingly important as issues of reproducibility and transparency have emerged.

Many journals follow the Contributor Roles Taxonomy (CRediT), which follows a rationale for identifying specific contributions similar to that of the ICMJE but with additional specific contributions and provides "a classification of the diverse roles performed in the work leading to a published research output in the sciences."[8] The taxonomy includes 14 roles: conceptualization; data curation; formal analysis; funding acquisition; investigation; methodology; project administration; resources; software; supervision; validation; visualization; writing, original draft; and writing, review, and editing. This taxonomy is intended to identify the contributions of all who contribute to research that is published, including authors and nonauthor collaborators.

In addition, PubMed/MEDLINE citations include the names of authors listed in the byline of the article. These MEDLINE records also include the names of nonauthors who are designated as collaborators and listed elsewhere in the article (typically for articles with group author names).[9] MEDLINE lists the names of authors and nonauthor collaborators in the same order as they

Downloaded from academic.oup.com/book/58841 by guest on 17 October 2026

appear in the published article, but it does not include footnotes or indications of shared contributions.

Recently, use of artificial intelligence, machine learning, large language models, and other technologies to assist with writing and editing has become more common and has prompted concerns about responsible and transparent use of such tools. Many journals have determined that such nonhuman tools cannot be named as authors and require authors to report use of these tools for writing and editing assistance in the Acknowledgment section, as they would with any such human assistance.[10]

(For additional guidance on options for authorship for large teams of investigators and authors, see Chapter 34, Group Authorship and Team Science.)

Designation of Shared Author Responsibilities

Another trend in scientific publishing has been the designation of shared responsibilities for key contributions to the manuscript. Most commonly, this designation involves shared credit as first authors (often recognized as the principal investigator) or last authors (traditionally perceived as the senior author). In addition to reporting the specific contributions of these authors (along with the contributions of all authors), articles in some journals allow designation of "co-first" or "co-last" authors. Requests for more than 2 co-first authors or co-last authors may be considered by some journals but may require detailed justification.[2] There is some concern that the proliferation of shared responsibility (or designation) as first or last author makes it difficult to assess individual contribution to articles. For example, consider a manuscript with a total of 8 authors, in which 5 individuals request to be designated equally as first author, and 2 request to be designated equally as last author; it would appear that only 1 author would be listed in the middle. Journals may consider these types of requests to not be justified or practical, and requests such as these may diminish what it means to be a first or last author.

Thus, the number of individuals claiming a shared position in the byline should be limited to a number that reflects the total number of authors. A designation of equal contribution or shared authorship position can be reported in the Author Contributions section in the Acknowledgment at the end of the article, as follows: "Dr A and Dr B contributed equally as co-first authors."

Some journals permit authors to indicate such information with footnotes following the author's name in the byline. Other shared responsibilities, such as equal contributions to the data analyses, usually are not specifically designated, but all individuals who contributed to data analysis and other important activities can be designated in the Author Contributions section of the Acknowledgment section.

Downloaded from academic.oup.com/book/58841 by guest on 17 October 2026

Corresponding Author

The corresponding author is responsible for fulfilling the important duties for that role, such as serving as the primary point of contact with the journal for responding to and resolving all questions and issues regarding the submitted manuscript and published article. The corresponding author is responsible for all communications with the journal and is responsible for ensuring that all coauthors are aware of and in agreement with the content of these communications.[2]

Thus, having a single person acting for and representing the authors on a manuscript is important for facilitating communication and for resolving issues that arise during the time a manuscript is under consideration. In addition, postpublication issues often arise that require coordinated attention, such as responding to letters to the editor or online comments, news media inquiries, or correction of errors. At times, more serious concerns may arise, such as allegations of fabrication or falsification, undeclared conflicts of interest, or pervasive data errors, that require investigation and resolution.

Accordingly, authors of articles published in most journals will designate a single corresponding author. Requests for having up to 2 individuals listed as corresponding authors on a published article may be considered and may require justification.[2] In such cases, some journals may require that 1 author is designated as the primary point of contact responsible for all communication with the journal about the manuscript and article, and this person will be listed first in the Corresponding Author section of the published article.

Changes in Authorship

Once a manuscript is submitted to a journal for evaluation and consideration for possible publication, any changes in authorship (such as adding or removing authors or changing the order of authors in the byline) may raise concerns and must be convincingly explained to the journal editors and approved by all coauthors. For example, for some journals, such as *JAMA* and the JAMA Network journals,[2,7] the addition or removal of an author's name from the author byline in a manuscript under consideration but before acceptance requires a detailed explanation from the corresponding author providing the reason for the change in authorship with indication that all authors, including any being added or removed, agree with this change. This explanation can be sent as a letter signed by all authors or as an email with all authors copied (including any being added or removed). These same requirements are necessary for any changes in the order of authorship listing in the author byline. Requests for changes in authorship or in order of authorship after publication are rarely

Downloaded from academic.oup.com/book/58841 by guest on 17 October 2026

justified and would require all the above information, and if justified, the letter of explanation would be published along with a formal Correction notice.

Many journals now also accept changes to author names after publication. For example, *JAMA* and the JAMA Network journals have the following policy:

> "Authors who request confidential name changes after publication because of changes in identity, marital status, religion, or other reasons may have their names changed in articles without indication of the reason for the change and without a formal correction notice. If an author prefers this change to be public, a formal Correction notice can be issued, with or without the reason per author preference. The journal will not request the approval of coauthors, but the requesting author may wish to notify coauthors if this change will affect subsequent citations to the article. The requester may be asked to notify the corresponding author about this change to the published article; alternatively, the journal may inform the corresponding author of this change (without explaining the reason for the change)."[7]

Resolving Disagreements Among Authors After Manuscript Submission

Ensuring agreement among all authors for the content of a manuscript is the responsibility of the authors. Journals and journal editors are not in the position to evaluate, adjudicate, or resolve disagreements or disputes among authors and will require the authors and perhaps their institutions to resolve all disagreements. At times disagreements among authors may arise following submission of the manuscript, such as during the revision process. If substantial disagreement among authors involving a manuscript under consideration occurs, some journals will suspend evaluation of the manuscript until those disagreements are resolved satisfactorily among all authors and the journal receives documentation from all authors that demonstrates a satisfactory and appropriate resolution.

Conclusion

Authorship in biomedical publication offers many rewards but also responsibilities before, during, and after publication. These include collaboration with coauthors, meeting authorship criteria, transparency of contributions, being accountable for the work, and assurances of a work's validity, veracity, and integrity.

Downloaded from academic.oup.com/book/58841 by guest on 17 October 2026

ACKNOWLEDGMENT

This chapter is an updated version of the following previously published article: Fontanarosa P, Bauchner H, Flanagin A. Authorship and team science. *JAMA*. 2017;318(24):2433-2437. doi:10.1001/jama.2017.19341

References

1. Recommendations for the conduct, reporting, editing, and publication of scholarly work in medical journals. International Committee of Medical Journal Editors. Updated January 2024. Accessed April 11, 2024. https://www.icmje.org/recommendations
2. Flanagin A. Authorship responsibility. In: Christiansen S, Iverson C, Flanagin A, et al, eds. *AMA Manual of Style: A Guide for Authors and Editors*. 11th ed. Oxford University Press; 2020. Accessed April 11, 2024. https://academic.oup.com/amamanualofstyle/book/27941/chapter/207564250#39577873
3. Rennie D, Flanagin A. Authorship! Authorship! Guests, ghosts, grafters, and the two-sided coin. *JAMA*. 1994;271(6):469-471. doi:10.1001/jama.1994.03510300075043
4. Wislar JS, Flanagin A, Fontanarosa PB, Deangelis CD. Honorary and ghost authorship in high impact biomedical journals: a cross sectional survey. *BMJ*. 2011;343:d6128. doi:10.1136/bmj.d6128
5. Greenland P, Fontanarosa PB. Ending honorary authorship. *Science*. 2012;337(6098):1019. doi:10.1126/science.1224988
6. Flanagin A. Acknowledgments. In: Christiansen S, Iverson C, Flanagin A, et al, eds. *AMA Manual of Style: A Guide for Authors and Editors*. 11th ed. Oxford University Press; 2020. Accessed April 11, 2024. https://academic.oup.com/amamanualofstyle/book/27941/chapter/207564250#39577887
7. Authorship responsibility. Instructions for Authors. JAMA Network. Updated April 4, 2024. Accessed April 11, 2024. https://jamanetwork.com/journals/jamanetworkopen/pages/instructions-for-authors#
8. Contributor Roles Taxonomy. CRediT. Accessed October 20, 2023. https://credit.niso.org
9. Authorship in MEDLINE. US National Library of Medicine. Updated March 30, 2023. Accessed October 20, 2023. https://www.nlm.nih.gov/bsd/policy/authorship.html
10. Flanagin A, Bibbins-Domingo K, Berkwits M, Christiansen SL. Nonhuman "authors" and implications for the integrity of scientific publication and medical knowledge. *JAMA*. 2023;329(8):637-639. doi:10.1001/jama.2023.1344

Downloaded from academic.oup.com/book/58841 by guest on 17 October 2026

CHAPTER 34

Group Authorship and Team Science

Phil B. Fontanarosa, MD, MBA, Howard Bauchner, MD, and Annette Flanagin, RN, MA

Downloaded from academic.oup.com/book/58841 by guest on 17 October 2026

KEY POINTS

- Authors of team science research reports involving multiple investigators and research consortia must adhere to the same principles and standards of authorship to ensure the necessary accountability and responsibility for the work being reported.
- As the numbers of individuals involved in team science investigations continue to increase, it is essential to ensure that each individual author is accountable for the validity, veracity, and integrity of the scientific investigation.
- Regardless of nomenclature used, it is important that readers be able to identify the authors of a research report and distinguish them from nonauthor collaborators or other contributors.
- Individuals who do not meet authorship criteria but who have made important substantive contributions to the work should be acknowledged for their contributions and can be listed as nonauthor collaborators.
- Reports based on team science research have several options for designating authorship, based on whether the author byline of the report includes the names of individual authors, the names of research groups, or the names of both.

The complexity, scope, and scale of scientific research have expanded substantially. During the past several decades, there has been an increasing number of large, international, multicenter clinical trials; multidisciplinary investigations involving interventional studies or observational research; and studies that combine large data sets ("big data") from multiple cohorts or research consortia and use sophisticated analytic methods. This trend toward increasingly collaborative research involving multiple investigators and research groups has been referred to as group science, ensemble science, or more commonly, *team*

science. How authors and nonauthor collaborators are identified in publications to ensure appropriate credit and recognition of team science is evolving, can be challenging, and is of great importance to the scientific community and individual investigators.

Team science has real and potential advantages, including the ability to bring expertise and experience from numerous investigators or disciplines to address an important research topic from multiple perspectives and the ability to collect or combine data from various sites or cohorts to generate large data sets to address scientific questions efficiently and effectively. Team science is likely to further increase with the growth of research networks and consortia and the continued emergence of big data and data sharing.

Team science also creates potential challenges, including identifying the optimal group of investigators to address the study questions of interest; rigorously addressing issues of heterogeneity in attempts to combine data or data sets; ensuring engagement, appropriate participation, and supervision of all members of the scientific team; reaching agreement and consensus regarding presentation and interpretation of study findings; and appropriately recognizing the contributions of individual members of the research team in scientific publication.

Team Science and Authorship

Team science in scientific research has been accompanied by corresponding trends in the numbers of authors included in scientific publications. For instance, for scientific articles indexed in PubMed/MEDLINE from 1975 to 2023, the mean number of individuals listed as authors increased from 1.9 to 6.38 per article, and the mean proportion of scientific articles with a "collective name" (such as group or corporate authorship) increased from 1.01 to 1.10.[1] In addition, some reports involving major research discoveries have listed hundreds to thousands of individuals as authors. For example, in the 2 articles that reported the sequencing of the human genome in 2001, 1 report included more than 270 individuals named as authors,[2] and the other report listed a research consortium that included more than 20 centers and more than 240 individual authors and collaborators.[3] Numerous other articles in biomedical journals have involved team science investigations, some with hundreds of individuals named as authors.

Authors of all scientific publications, including team science research reports involving multiple investigators and research consortia, must adhere to the same principles and standards of authorship to ensure the necessary accountability and responsibility for the work being reported. Even though there may be different opinions and perceptions regarding the designation of authorship of these reports, many biomedical journals subscribe to and follow

Downloaded from academic.oup.com/book/58841 by guest on 17 October 2026

the authorship criteria established by the International Committee of Medical Journal Editors (ICMJE).[4] For example, all JAMA Network journals require that every individual named as an author on any article must complete and submit an individual authorship form that provides formal attestation that they have met these criteria.[5,6] (The ICMJE authorship criteria are included in Chapter 33, Authorship Criteria and Ethical Aspects.)

According to the ICMJE criteria, authorship requires meaningful substantive contributions to the study or work and to the manuscript. Simply collecting or contributing data to a study or serving as a representative of a research consortium does not alone fulfill criteria for authorship. Prespecified agreements that guarantee authorship to individuals or research groups in return for agreeing to be part of an investigation, often by contributing data, are not appropriate if each individual does not also fulfill the authorship criteria. Authorship must not be bestowed in an honorary fashion. (See also Chapter 33, Authorship Criteria and Ethical Aspects.)

As the number of individuals involved in team science investigations continues to increase, it is essential to ensure that each individual author is accountable for the validity, veracity, and integrity of the scientific investigation. Individuals who do not meet authorship criteria but who have made important substantive contributions to the work should be acknowledged for their contributions and can be listed as collaborators.

Authorship Terminology

The following list of common terms and definitions also may be helpful in assessing and applying norms of credit for authors and nonauthor collaborators in team science.[5]

Contributor: Anyone, such as an author, a collaborator, or other, who has assisted or contributed in a meaningful way to the work.

Author: A type of contributor who has participated sufficiently in the work to take public responsibility for the content, either all of the work or an important part of it, and meets defined criteria for authorship. Identification of authorship in a manuscript and published article can appear in 2 places. The names of authors are listed in the article byline (ie, byline author designation), or the names of authors are not listed in the article byline but are listed elsewhere and they are identified as authors, typically in an Acknowledgment or Article Information section (ie, nonbyline author designation).

Group author: A group of individuals, usually involving multicenter study investigators, members of working groups, or official or self-appointed expert boards, panels, or committees, who wish to display a group name to indicate authorship. The group author may represent the entire research group or may

Downloaded from academic.oup.com/book/58841 by guest on 17 October 2026

be a subgroup of individuals (such as a Writing Committee) from the larger research group. (See examples below.)

Collaborator: Another type of contributor who is a nonauthor member of a formal group and who contributes significantly to the work but does not qualify for authorship. In these cases, a group name may be listed in the byline.

Other contributors: Anyone else who contributed in some meaningful way who is not an author or a nonauthor collaborator. These individuals can be listed under Additional Contributions in an Acknowledgment or Article Information section.

Author, Author Group, and Research Group Designations

Manuscripts reporting results of investigations based on team science typically involve large numbers of authors and nonauthor collaborators, often include multiple research consortia, and frequently have a designated group name representing the scientific team.

Reports of research based on team science research have several options for designating authorship, based on whether the author byline of the report includes the names of individual authors, the names of research groups, or the names of both.

The following guidelines used by *JAMA* and the JAMA Network journals are recommended[6]:

1. All individuals named in the byline of reports of team science must meet authorship criteria and are designated as authors; all authors are required to complete authorship and disclosure forms and should indicate their specific contributions to the work and their affiliations and disclose potential conflicts of interest. Others who contributed substantially can be designated as nonauthor collaborators with their contributions and affiliations indicated in the Acknowledgment section of the article.
2. There is no limit on the number of authors for a report of research (provided the authorship criteria are met).
3. A long list of authors (eg, more than 50) may not fit in the space available for the author byline on the title page of the print version or PDF version of an article, which typically includes the title and abstract. In these cases, other options may need to be considered, such as publishing a group name only in the byline and listing the individual author members of the group in the Acknowledgment section along with their affiliations, contributions, and conflict of interest disclosures. With this approach, all authors are listed in the order they appear in the

Downloaded from academic.oup.com/book/58841 by guest on 17 October 2026

group in the Acknowledgment section and in PubMed and the group name is also listed in PubMed.

4. The author byline may include the name of a research group or consortium in several ways, such as in combination with named authors or alone in the byline as described in the examples below. In each case, all author members of a group must meet the criteria for authorship and must be identified as authors (either in the byline or in the Acknowledgment section). Other nonauthor members of the group who contributed substantially should be listed separately as collaborators in the Acknowledgment section or in a supplement. If properly identified, all author members of the group and the group name as well as the nonauthor collaborators will be listed in PubMed.
5. More than 1 research group or consortium may be listed in the byline, provided there is justification and the above guidelines are followed.

In each of these cases, it is important to separately identify authors and nonauthor collaborators of a group or consortia. Some journals, such as *JAMA* and the JAMA Network journals, will publish the names of authors along with their affiliations, specific contributions, and conflict of interest disclosures in the Acknowledgment section of the article. Following the author information, the names and affiliations of nonauthor collaborators are listed. PubMed has separate fields to list authors, group names, and collaborators.

The byline of the article may include several possible authorship designations; the following are among the most commonly used.

INDIVIDUAL AUTHORS, NO GROUP NAME

Individuals who meet authorship criteria are listed in the author byline of the article, without the name of any research group. The name of a research group or research consortia involved with the study and the collaborator members of those groups could be listed in the Acknowledgment section at the end of the article. In PubMed, the individuals listed in the byline are designated as authors:

Byline: Authors A, B, C …

INDIVIDUAL AUTHORS **FOR** A RESEARCH GROUP (ALL MEMBERS OF THE GROUP ARE NOT AUTHORS)

Individuals who meet authorship criteria are listed in the author byline of the article, followed by the name of the research group. The nonbyline members of the research group are not authors, but they may be formally listed as collaborators. The named authors are listed first, followed by an indication that they are serving as authors on behalf of or representing the research group, designated as "for the Research Group." The name of the research group and

Downloaded from academic.oup.com/book/58841 by guest on 17 October 2026

the members of that group are listed in the Acknowledgment section at the end of the article. In PubMed, the individuals listed in the byline are designated as authors, and the nonauthor members of the research group may be designated as collaborators:

Byline: Authors A, B, C … for the Research Group

INDIVIDUAL AUTHORS **AND** A RESEARCH GROUP (ALL MEMBERS OF THE GROUP ARE AUTHORS)

Individuals who meet authorship criteria are listed in the author byline of the article, followed by the name of the research group. All members of the research group are authors as designated by "and the Research Group" in the byline. The name of the research group and the nonbyline author members of that group are listed in the Acknowledgment section at the end of the article. The individuals named in the byline and the individual members of the research group are listed as authors along with the group name in PubMed:

Byline: Authors A, B, C … and the Research Group

RESEARCH GROUP (ALL MEMBERS OF THE RESEARCH GROUP ARE AUTHORS), NO INDIVIDUAL AUTHORS NAMED IN THE BYLINE

The byline only includes the name of the research group, without including the names of individual authors. All author members of the research group are listed as authors in the Acknowledgment section at the end of the article. Any nonauthor members of the group who contributed substantially may be listed as collaborators in the Acknowledgment section. The PubMed record lists the individual author members of the research group and the group name followed by any nonauthor collaborators:

Byline: The Research Group

SUBGROUP OF AUTHORS **AND** A RESEARCH GROUP (ALL MEMBERS OF THE SUBGROUP AND RESEARCH GROUP ARE AUTHORS), NO INDIVIDUAL AUTHORS NAMED IN THE BYLINE

The byline includes the name of a subgroup of authors who are members of the research group, such as a Writing Committee, and the name of the research group, without including the names of individuals in the subgroup or the research group. All members of the subgroup and all members of the research group are authors. The author members of that subgroup and the larger group are listed in the Acknowledgment section at the end of the article. As in the previous example, the PubMed record lists the individual author

Downloaded from academic.oup.com/book/58841 by guest on 17 October 2026

members of the research group and the group name followed by any nonauthor collaborators:

Byline: The Writing Committee and the Research Group

SUBGROUP OF AUTHORS WRITING **FOR** A RESEARCH GROUP (ALL INDIVIDUALS IN THE SUBGROUP ARE AUTHORS; OTHER MEMBERS OF THE RESEARCH GROUP ARE NOT AUTHORS), NO INDIVIDUAL AUTHORS NAMED IN THE BYLINE

The byline includes the name of a subgroup of authors who are members of the research group, such as a Writing Committee, and the name of the research group, without including the names of individuals in the author group or the research group. All members of the subgroup of authors (ie, the Writing Committee) are authors, and other members of the research group are not authors. The author members of that subgroup and the members of the research group who are not authors are listed in the Acknowledgment section at the end of the article. As in the previous example, the PubMed record lists the individual author members of the writing subgroup and the group name followed by any nonauthor collaborators:

Byline: The Writing Committee for the Research Group

Other Authorship Considerations

Information regarding other considerations involving authorship of reports of team science investigations, such as designation of authorship and author contributions, designation of shared author responsibilities, and the role of the corresponding author, are included in Chapter 33, Authorship Criteria and Ethical Aspects.

Conclusion

A wide array of authorship possibilities has emerged over the past few decades, reflecting team science and concern about appropriate credit for those who have conducted or contributed to a research investigation. Team science has a critically important role in advancing biomedical research discovery, reflecting tremendous scientific progress in many fields and advances in study design and analytic techniques. Team science not only requires rigorous attention to research methodology and scientific reporting, but also requires careful attention to authorship criteria, credit, and responsibility to ensure that the efforts

Downloaded from academic.oup.com/book/58841 by guest on 17 October 2026

of those who qualify for authorship are recognized, that the contributions of those who do not qualify as authors are appropriately reported, and that the integrity of authorship in team science is maintained, and its meaning and value are not diminished.

ACKNOWLEDGMENT

This chapter is an updated version of the following previously published article: Fontanarosa P, Bauchner H, Flanagin A. Authorship and team science. *JAMA*. 2017;318(24):2433-2437. doi:10.1001/jama.2017.19341

References

1. Number of authors per MEDLINE/PubMed citation. US National Library of Medicine. Updated May 27, 2023. Accessed April 11, 2024. https://www.nlm.nih.gov/bsd/authors1.html
2. Venter JC, Adams MD, Myers EW, et al. The sequence of the human genome. *Science*. 2001;291(5507):1304-1351. doi:10.1126/science.1058040
3. International Human Genome Sequencing Consortium. Initial sequencing and analysis of the human genome. *Nature*. 2001;409(6822):860-921. doi:10.1038/35057062
4. Recommendations for the conduct, reporting, editing, and publication of scholarly work in medical journals. International Committee of Medical Journal Editors. Updated January 2024. Accessed October April 11, 2024. https://www.icmje.org/recommendations
5. Flanagin A. Authorship responsibility. In: Christiansen S, Iverson C, Flanagin A, et al, eds. *AMA Manual of Style: A Guide for Authors and Editors*. 11th ed. Oxford University Press; 2020. Accessed April 11, 2024. https://academic.oup.com/amamanualofstyle/book/27941/chapter/207564250#395778731
6. Authorship responsibility. Instructions for Authors. JAMA Network. Updated April 4, 2024. Accessed April 11, 2024. https://jamanetwork.com/journals/jamanetworkopen/pages/instructions-for-authors#

Downloaded from academic.oup.com/book/58841 by guest on 17 October 2026

CHAPTER 35

Ethical Issues in Biomedical Publication

Phil B. Fontanarosa, MD, MBA, Howard Bauchner, MD, and Annette Flanagin, RN, MA

Downloaded from academic.oup.com/book/58841 by guest on 17 October 2026

KEY POINTS

- Biomedical researchers must adhere to the highest ethical standards for research integrity as they pursue an unbiased search for scientific truth and new knowledge.
- Authors must adhere to sound ethical standards when they report the results of their studies and communicate them to the scientific and clinical communities and, ultimately, to the public.
- Research misconduct involves fabrication, falsification, or plagiarism in proposing, performing, or reviewing research, or in reporting research results, and when misconduct is found to have occurred in published articles, the remedy is retraction.
- Authors must avoid inappropriate reporting that involves duplicate submission, duplicate publication, and misrepresentation, and they must provide statements that reflect appropriate ethical oversight and protection of confidentiality of patients and others who participate in research.
- Journals generally follow consistent recommendations (eg, those of the International Committee of Medical Journal Editors and the Committee on Publication Ethics) regarding issues related to ethical concerns involving submitted manuscripts or published articles.

Biomedical research and scientific publication are predicated on the ethical principles of honesty, integrity, and trust. These ethical standards are essential because of the serious implications and potential consequences involving medical research. Clinicians and other health care professionals use information from medical research reports to influence how they make decisions in providing care for patients. If these reports are invalid or biased, use of the findings in clinical care could result in harm to patients and waste resources, and dissemination of the findings could contribute to scientific misinformation, which

is an increasing worldwide challenge. In addition, publication of reports with serious ethical problems jeopardizes and compromises the integrity of the scientific record. Other investigators who use the findings from unethical reports to form the basis of future research or incorporate the findings from unethical reports in meta-analyses or reviews could inadvertently produce faulty research hypotheses or data syntheses or inadvertently promulgate misleading and false information.

This chapter discusses several ethical issues that researchers and authors should understand, including research misconduct, issues related to research oversight in scientific reporting and manuscript preparation and submission, and the duties of authors who discover important mistakes in their work after publication. The responsibilities of journal editors in responding to these ethical issues also are reviewed. (Additional detail regarding these issues is available in Chapter 5.0, Ethical and Legal Issues, in the *AMA Manual of Style*.[1])

Research Misconduct

According to the US Department of Health and Human Services, "Research misconduct means fabrication, falsification, or plagiarism in proposing, performing, or reviewing research, or in reporting research results."[2] According to the US Office of Research Integrity, "When FFP [fabrication, falsification, plagiarism] occurs in federally funded research (including in proposals for research grants), it is a federal crime that can be punished severely with fines, loss of funding eligibility, and even imprisonment."[3]

Data fabrication is defined as "making up data or results and recording or reporting them."[2] This is perhaps the most egregious form of research misconduct and may have far-reaching implications.

Data falsification is defined as "manipulating research materials, equipment, or processes, or changing or omitting data or results such that the research is not accurately represented in the research record."[2] This is another form of serious research misconduct.

Plagiarism is defined as "the appropriation of another person's ideas, processes, results, or words without giving appropriate credit."[2] Plagiarism may be the most common type of research misconduct, and it may occur intentionally or at times may be inadvertent. (See also Chapter 36, Plagiarism.)

Publication of scientific reports that are based on fabricated or falsified data compromises the integrity of the research process, distorts the research record, and may result in harm to patients or public health and safety.[1,3] Concerns about possible research misconduct may be raised by peer reviewers during their evaluation of a manuscript, by scientists or other readers after publication of an article, or at times by individuals who are familiar with specific aspects of the research or analysis. Concerns about an inability to replicate

Downloaded from academic.oup.com/book/58841 by guest on 17 October 2026

published findings or analyses have resulted in investigations that led to admissions or discovery of data fabrication and falsification or an inability to verify reported data and findings. High-profile retractions of multiple published articles by offending scientists have ranged from reports that purportedly demonstrated the ability to clone new lines of human stem cells[4]; described discovery of genetic "fingerprints" to guide cancer therapy[5]; suggested that damaged heart muscle could be regenerated with stem cells[6]; and established relationships between external cues and eating behaviors in children and adults.[7] In some cases, reports based on fabricated or falsified data resulted in lasting, harmful effects, such as the lingering misperception that certain vaccines administered to children may have been related to autism, despite retraction of the fraudulent article on which this claim was based.[1,3,8] (See also Section 5.4, Scientific Misconduct, in the *AMA Manual of Style*.[1])

Issues With Research Oversight

Other types of ethical issues may occur during research investigations, such as mistreatment or deception of research participants or misuse of patient data. Accordingly, biomedical journals require that submitted manuscripts that involve human research participants or use of their identifiable data and reports that involve animal research include specific statements about research oversight, including ethical approval of studies and provisions for informed consent and confidentiality for study participants. (See also Section 5.8, Protecting Research Participants' and Patients' Rights in Scientific Publication, in the *AMA Manual of Style*.[1])

ETHICAL APPROVAL

For original research reports involving human participants, authors must provide a statement that the study was reviewed and approved by an academic or research institutional committee responsible for research oversight, such as an institutional review board (IRB) or ethics committee at an academic medical center or an independent IRB (eg, a commercial IRB credentialed by the Association for the Accreditation of Human Research Protection Programs, some of which are registered by the US Food and Drug Administration and the US Office for Human Research Protections).

Any exemption or waiver of the requirement for IRB or ethics committee review and approval must be documented clearly in the manuscript, and the decision for such waivers must be made by the IRB or ethics committee policies and procedures and not the investigators. Certain types of studies, such as those based exclusively on review of deidentified medical records or those conducted as part of quality improvement evaluations or initiatives, may be

Downloaded from academic.oup.com/book/58841 by guest on 17 October 2026

eligible for consideration for expedited review or may be granted a waiver or exemption from formal review; however, that decision must be made by an IRB or ethics committee or directed by institutional policy or national regulation, not by an investigator. Other types of studies that may be exempt from formal review, according to the US Code of Federal Regulations (known as the *Common Rule*), include research that presents no more than minimal risk of harm to participants and may include, for example, research conducted in established or commonly accepted educational settings that specifically involves normal educational practices; studies that only include interactions involving educational tests (eg, cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior; and benign behavioral interventions that are brief in duration, harmless, painless, not physically invasive, and not likely to have a significant adverse lasting effect on the study participants and that the investigator has no reason to think the participants will find offensive or embarrassing.[9] The types of studies that may be exempt will vary from country to country. However, in all cases, any determination regarding the need for ethical review and oversight must be made by or in conjunction with an IRB or ethics committee or follow research ethics policies of authors' institutions or national regulations and must not be made unilaterally by the investigators.[1,9]

INFORMED CONSENT

For all manuscripts that report research investigations involving identifiable human participants, authors also must include a clear statement that all participants in these studies provided informed consent and must indicate how that consent was obtained and provided. If an IRB or ethics committee waived the requirement for informed consent, that determination should be clearly indicated. However, as with determining the need for ethical review of a study, the determination regarding any variation from the requirement for prospectively obtaining informed consent from research participants (such as waiving the need for consent or use of deferred consent) must be made by the IRB or ethics committee or institutional policy or national regulation and must not be made unilaterally by the investigators.[1,9]

CONFIDENTIALITY

A related issue involves the importance of protecting patient confidentiality and privacy in reports submitted to and published in biomedical journals. For example, case reports with descriptions of a single patient or small numbers of patients or study participants, or articles that include images of patients, raise the possibility that the individuals included in these reports may be identifiable. For all articles in which there is any possibility that a person included in

Downloaded from academic.oup.com/book/58841 by guest on 17 October 2026

the report may be identified, even if only to themselves, the authors must obtain consent from those individuals to publish that information.[1,10] Authors should always opt for obtaining consent for publication of identifiable patients and study participants rather than deciding that such consent is not needed. Lack of consent risks the possibility of inappropriately reporting unauthorized information about an individual and violating their right to privacy. For example, *JAMA* and the JAMA Network journals require authors of all manuscripts that include potentially identifying information to provide written consent from the patient (or participant) that authorizes publication of this material. These and other journals have a specific document that can be completed by the patient (or participant), and as part of this consent process, authors are required to provide the manuscript that includes the identifying material to the person whose information is being reported.[1,10]

Issues Related to Scientific Reporting

When reporting information in biomedical journals, authors have a simple duty and responsibility—to report the truth. Accordingly, manuscripts submitted to and published in biomedical journals must follow ethical standards for complete, transparent, and honest reporting, and authors should be aware of several important ethical issues to ensure they uphold their duty and responsibility for truthful reporting.

Duplicate submission involves submission of the same manuscript or a very similar manuscript to more than one journal simultaneously or after the manuscript has been submitted to and is under consideration at a journal. Authors of biomedical reports should submit their manuscript to only one journal at a time. Duplicate submission is inappropriate and not permitted in biomedical publication.[1]

Duplicate publication (or redundant publication) involves publication of the same article or a very similar article in more than one journal. To gain multiple publications, some authors may inappropriately submit manuscripts to one journal that contain materials that were partially, largely, or completely duplicative of material already published in or under consideration by other journals. Duplicate publication is inappropriate, as articles published in biomedical journals should represent unique, nonoverlapping, or nonredundant contributions. With thousands of biomedical journals available, detecting duplicate publication may be a challenge. However, increasing numbers of journals are using software programs that will detect similar content and plagiarism prior to publication, including duplicate publication of an author's own content as well as plagiarism of another's content. For instance, authors should inform the editors if the Methods section of a manuscript is similar to or identical to that used in other reports from the same authors.

Downloaded from academic.oup.com/book/58841 by guest on 17 October 2026

Following the COVID-19 pandemic and the widespread use of preprints in biomedicine, posting of a manuscript on a preprint server does not preclude consideration of that manuscript by biomedical journals. However, authors should disclose the posting of preprints of studies that are the same or closely related to manuscripts submitted to journals to the editors at the time of submission and note if there are any major differences between the preprint and the submitted manuscript.[11,12] (See also Chapter 40, Preprints, Preprint Servers, and Biomedical Publication.)

Incremental publication (also referred to as segmented publication or "salami" publication) involves reporting small amounts of incremental findings that are derived from the same study population or sample in 2 or more simultaneous or subsequent publications. These reports characteristically involve the same or similar authors, study hypotheses, methods, and data sets and include a sufficient amount of minimal incremental new information, which has been referred to as the "least publishable unit." For example, authors of a longitudinal study might report results from 2-year follow-up in one article, then submit another manuscript that reports results from the 3-year follow-up of the same study and patient population to another journal. Although these reports do not necessarily represent ethical violations, questions may be raised if authors do not explicitly indicate the context for the subsequent report by clearly citing the previous report, indicating the study results that already have been reported, and clearly describing the new information the subsequent report provides.

To help avoid ethical concerns being raised about duplicate submission, duplicate publication, or incremental publication, authors should specifically indicate, at the time of manuscript submission, as requested by most journals, the relationship between the submitted manuscript and all other reports from the same study (or from the same or similar review articles or from the same or similar opinion articles). Authors should transparently provide this information, and they should clearly indicate the new information that the manuscript being submitted provides compared with the other reports, cite the other reports, and provide copies of closely related published articles, confidential copies of related manuscripts in preparation or submitted to other journals, and links to or copies of manuscripts posted on preprint servers. (See also Section 5.3, Duplicate Publication and Submission, in the *AMA Manual of Style*.[1])

Misrepresentation in manuscripts submitted to biomedical journals may be another manifestation of important ethical problems. While this issue usually does not involve data fabrication or falsification, there may be more subtle manifestations of misrepresentation, either in research reports or in opinion articles, that include incomplete or selective reporting and biased interpretation or promotion of ideas, products, or services without objective supporting evidence.[13] These issues can be best addressed with complete and transparent reporting of study methods and protocols and financial interests of authors and study sponsors.

Downloaded from academic.oup.com/book/58841 by guest on 17 October 2026

For example, authors of manuscripts that report the results of clinical trials that evaluate an intervention are expected to present the study findings with fidelity to and consistency with the prespecified trial protocol and statistical analysis plan.[14] For some studies, such as those in which the primary outcome fails to demonstrate an effect of the intervention (such as with null or neutral findings, ie, non–statistically significant results), the authors may deemphasize these primary findings and overemphasize selective secondary outcomes with positive results or may introduce and emphasize post hoc findings that appear favorable for the intervention. Misrepresentation and biased reporting and interpretation also may occur with incomplete reporting, such as failure to report prespecified outcomes from a clinical trial in which the intervention demonstrates harmful outcomes or failure to report adverse effects completely.

Another factor that may contribute to misrepresentation and biased interpretation in manuscripts submitted to biomedical journals is the financial and other interests of authors or study sponsors/funders. Implicit in the unstated research agreement between biomedical researchers and patients or other participants in clinical research is the expectation and requirement that researchers will report findings honestly and objectively, and in doing so, the efforts and contributions of participants in research studies will advance science and benefit other patients when the results of the studies are applied. When the interests of researchers or sponsors interfere with objectivity and complete transparency in the conduct and reporting of research findings, the research agreement is violated and trust in the research enterprise may be jeopardized. All authors, regardless of their interests related to the study findings, must ensure that the information reported in their manuscripts is presented objectively and in an unbiased fashion. Authors with conflicts of interest are expected to report those completely, as failure to do so may be perceived by some as a form of research misconduct.[15] (See also Chapter 37, Conflict of Interest and Biomedical Publication.)

In addition, for some investigations, research funders (including industry, foundations, and governmental agencies) may have direct involvement with the study, including data collection and management and manuscript preparation. Authors working with study sponsors and funders should ensure that the information in the manuscript is presented objectively and without misrepresentation or biased interpretation, such as inappropriately exaggerating the benefits of the sponsor's product or inappropriately espousing ideology favored by the sponsoring organization.

Some research sponsors/funders may contractually have control over the final content and interpretation reported in the manuscript and the decision about whether and where to submit a manuscript, including requirements for publication in certain types of journals (eg, high impact factor, open access) or having veto rights that could prevent the authors from submitting the manuscript for publication. Authors should be aware of these issues and carefully

Downloaded from academic.oup.com/book/58841 by guest on 17 October 2026

consider the potential ethical implications when accepting funding or entering contracts to collaborate with research sponsors in conducting clinical investigations.

Investigations of Allegations of Scientific Misconduct and Other Ethical Concerns

Concerns about or allegations of scientific misconduct or other ethical issues brought to the editors of journals are challenging and time-consuming for the authors, editors, and institutions.[16] Many journals generally follow consistent recommendations, such as from the International Committee of Medical Journal Editors (ICMJE)[17] or Committee on Publication Ethics (COPE),[18] regarding evaluation of issues related to assessment of ethical concerns involving submitted manuscripts or published articles.

The first step involves determining the validity of the allegation and an assessment of whether the allegation is consistent with the definition of research misconduct. In some cases, when authors are accused of misconduct, the criticism represents a different interpretation of the data or disagreement with the statistical approach used, rather than scientific misconduct. This initial step also involves determining whether the individuals alleging misconduct have conflicts of interest associated with the allegation. In some cases, interest in and scrutiny of an article may be related to conflict of interest or strongly held beliefs, and these factors may contribute to bringing an allegation about authors of an article. This does not mean that potential conflicts of interest on the part of the persons bringing the allegations preclude the possibility of scientific misconduct on the part of the authors, but such a consideration is part of the overall assessment process.

If scientific misconduct or other substantial research irregularities are considered a possibility, the journal editor may share the allegations with the corresponding author, who, on behalf of all coauthors, is requested to provide a detailed response. Depending on the nature of the allegation, it can take some time for some authors to address the concerns, but authors should respond immediately to acknowledge receipt of the concerns and indicate their intention for a formal response. After the author's response is received and evaluated by the journal editors, additional review from and involvement of experts (such as statistical reviewers) may be obtained. In the majority of cases, the authors' responses and additional information provided regarding the concerns raised are sufficient to make a determination of whether the allegations raised are likely to represent misconduct. For cases in which it is unlikely that misconduct has occurred, clarifications, additional analyses, or both, published as a Letter to the Editor and often including a correction notice and correction to the published article, generally are sufficient.

Downloaded from academic.oup.com/book/58841 by guest on 17 October 2026

However, if the authors' responses to the allegations raised are unsatisfactory or unconvincing, or if there is any doubt as to whether scientific misconduct has occurred, additional information and investigation are usually necessary. The journal editors would then contact the related research institution and request a formal evaluation or further investigation. At that time, and depending on the nature of the allegations, the journal may publish a notice of Expression of Concern about the published report in question, indicating that issues of validity or other concerns have arisen and are under investigation.

Involvement of authors' institutions is done with great care for several reasons. In these cases, institutions are responsible for ensuring appropriate due process and confidentiality based on their policies and procedures. However, just as journals receive allegations of scientific misconduct and research irregularities, some without merit, so too do institutions. It simply is not possible for every institution to conduct a detailed investigation of every allegation received; thus, journal editors should ensure that institutions are asked to be involved after a determination has been made that scientific misconduct is a possibility and when authors have not adequately responded to the concerns raised.

The type of investigation an institution conducts depends on the specific allegations and the institutional policies and procedures. In some cases, the investigation has involved reviewing the data, the article and related articles, and the analysis. In other cases, the investigation has involved reanalysis of the study data by the authors, or independent statistical analysis by a third party not involved in the initial study. Other cases have involved investigation of ethical issues related to the research, such as concerns about lack of appropriate ethical review and approval of the study, insufficient informed consent for study participants, and inadequate notification to study participants about information related to risks of an intervention. No single approach is appropriate in all cases, and the specific approach depends on the details of the allegation. In 2017, a group of representatives who deal with scientific misconduct, including university and institutional leaders and research integrity officers, federal officials, researchers, journal editors, journalists, and attorneys representing respondents, whistleblowers, and institutions, examined best and failed practices related to institutional investigation of scientific misconduct.[19] The group developed a checklist that could be used by institutions to follow reasonable standards to investigate an allegation of scientific misconduct and to provide an appropriate and complete report following the investigation.

Typically, editors will request that institutions provide periodic updates on the status of an investigation, and once the investigation is completed, institutions are expected to provide the editors with a detailed report of their findings. Recently, there have been calls for better communication and coordination between institutions (namely institutional research integrity officers) and journal

Downloaded from academic.oup.com/book/58841 by guest on 17 October 2026

editors to address allegations of scientific misconduct involving published research.[20]

When authors are found to have participated in research misconduct or other serious irregularities involving articles that have been published in scientific journals, editors have a responsibility to ensure the accuracy and integrity of the scientific record. For cases in which misconduct has been identified, the institution and the authors may recommend and request retraction of the published article. In cases with documented fabrication, falsification, and often plagiarism, the appropriate remedy is retraction of the published article.

In other cases, based on the report of the investigation from the institution, the journal editors make the determination of what actions are needed, such as whether an article should be retracted, or when a notice of Expression of Concern has been posted, whether it should be subsequently followed by a Notice of Retraction. In each case, the notices are linked to and from the original article, and retracted articles are clearly watermarked as retracted so that readers and researchers are properly alerted to the invalid nature of the original articles.

There has been criticism that the practice of retraction in scientific publication takes too long, and that journals should retract manuscripts for which serious concerns have been raised more quickly. In some cases that may be possible, such as when fabrication or falsification has occurred and the author, an institution, or government agency has requested retraction with information supporting this request. However, for many serious allegations of misconduct involving published articles, the process may take months and may involve verification of the allegation, contact with the corresponding author(s) and coauthors, discussion with the institution(s) involved, potential reanalysis of data, review by the journal and possibly independent expert reviewers, and careful assessment and decision-making. Most journals assume that investigators have not committed research misconduct, and hence, the investigators are afforded due process, depending on the governing rules of their institution.

Inadvertent Pervasive Error

Another potential ethical issue involves authors' discovery of previously undetected errors that have important implications for the content of their published article. For example, authors of a published article may subsequently discover that an error had occurred in their data set or that a faulty command had been introduced in the statistical code or calculation that had been used for data analysis. These errors may render some, much, or all the data reported in the published article incorrect and may change the study conclusions.

Although these inadvertent, honest errors are not considered research misconduct, failure to report their occurrence and correct the scientific record

Downloaded from academic.oup.com/book/58841 by guest on 17 October 2026

represents a serious ethical failure. Accordingly, when authors discover or are made aware of any errors in their published articles, they have an obligation to immediately notify the journal in which the article was published. The authors should provide a complete explanation, including the nature of the error and exactly how the error occurred and was discovered. The authors also should provide a detailed description and itemization of all errors in the published article and whether and how the corrected data affect the study results, interpretation, and conclusions.

Journal editors evaluate these reports of inadvertent error carefully and make a determination of the necessary corrective action. For instance, in some cases with relatively minor errors, such as when some of the data reported in the study require correction but there are no major changes in the directionality or statistical significance of the findings and no major changes in the conclusions or interpretation, the journal may determine that the study is still valid and the errors in the article could be remedied with a correction of the data in the article. This typically involves updating and republication of the corrected article along with publication of a correction notice and a Letter with an explanation from the authors describing how the error occurred and the implications of the error for the findings in the published article.[21]

However, other actions may be needed if the inadvertent error results in an extensive amount of erroneous information in the published article, including extensive changes in the data as well as changes in the directionality or statistical significance of the findings or major changes in the conclusions or interpretation. In such cases, journal editors will determine whether the corrected results and conclusions are valid and reliable and have merit. The editors also will assess whether, had the corrected results and different conclusions been reported in the original manuscript, the editors would have made the same decision to accept the manuscript for publication. For example, at *JAMA* and the JAMA Network journals, *The Lancet*, and other journals, if the editors decide that the corrected article is valid and the corrected results have merit, the journal may elect to publish a Notice of Retraction and Replacement, whereby the erroneous article is retracted and is replaced by the corrected article.[21,22] This notice is accompanied by posting of the PDF and digital versions of the replacement article along with an online supplement that contains a copy of the original article with the errors highlighted and a copy of the replaced article with the corrections highlighted, and a letter of explanation from the authors describing how the error occurred and the implications of the error for the findings in the published article. If, in contrast, the journal editors determine that the corrected article or the science involved are no longer valid, they may decide to retract the article.[21]

Downloaded from academic.oup.com/book/58841 by guest on 17 October 2026

Conclusion

Biomedical research and scientific publication are predicated on the ethical principles of honesty, integrity, transparency, and trust. Authors and editors work together to ensure that the reporting of research in published articles fulfills these principles.

ACKNOWLEDGMENT

This chapter is an updated version of the following previously published article: Bauchner H, Fontanarosa PB, Flanagin A, Thornton J. Scientific misconduct and medical journals. *JAMA*.2018;320(19):1985-1987. doi:10.1001/jama.2018.14350

References

1. Flanagin A. Ethical and legal considerations. In: Christiansen S, Iverson C, Flanagin A, et al, eds. *AMA Manual of Style: A Guide for Authors and Editors*. 11th ed. Oxford University Press; 2020. Accessed April 11, 2024. https://academic.oup.com/amamanualofstyle/book/27941/chapter/207564250
2. Definition of research misconduct. Office of Research Integrity. US Department of Health and Human Services. Accessed October 21, 2023. https://ori.hhs.gov/definition-misconduct
3. RCR casebook: research misconduct. Office of Research Integrity. US Department of Health and Human Services. Accessed October 21, 2023. https://ori.hhs.gov/rcr-casebook-research-misconduct
4. Kennedy D. Editorial retraction. *Science*. 2006;311(5759):335. doi:10.1126/science.1124926
5. Acharya CR, Hsu DS, Anders CK, et al. Gene expression signatures, clinicopathological features, and individualized therapy in breast cancer. *JAMA*. 2008;299(13):1574-1587. Retracted in: *JAMA*. 2012;307(5):453. doi:10.1001/jama.2012.2
6. Oransky I. Anversa cardiac stem cell lab earns 13 retractions. Retraction Watch. December 13, 2018. Accessed October 21, 2023. https://retractionwatch.com/2018/12/13/anversa-cardiac-stem-cell-lab-earns-13-retractions/
7. Bauchner H. Notice of retraction: Wansink B, Cheney MM. Super bowls: serving bowl size and food consumption. *JAMA*. 2005;293(14):1727-1728. *JAMA*. 2018;320(16):1648. doi:10.1001/jama.2018.14249
8. Boseley S. Lancet retracts 'utterly false' MMR paper. *The Guardian*. February 2, 2010. Accessed October 21, 2023. https://www.theguardian.com/society/2010/feb/02/lancet-retracts-mmr-paper
9. US Department of Health and Human Services. Protection of human subjects: Exempt Research. 45 CFR §46.104. July 19, 2018. Accessed October 21, 2023. https://www.ecfr.gov/on/2018-07-19/title-45/subtitle-A/subchapter-A/part-46#46.104

Downloaded from academic.oup.com/book/58841 by guest on 17 October 2026

10. Flanagin A, Bauchner H, Fontanarosa PB. Patient and study participant rights to privacy in journal publication. *JAMA*. 2020;323(21):2147-2150. doi:10.1001/jama.2020.3590
11. Flanagin A, Fontanarosa PB, Bauchner H. Preprints involving medical research—do the benefits outweigh the challenges? *JAMA*. 2020;324(18):1840-1843. doi:10.1001/jama.2020.20674
12. Bauchner H, Moher D. Ensuring an accurate scientific record in an era of pre-print servers. *Dtsch Arztebl Int*. 2022;119(40):675-678. doi:10.3238/arztebl.m2022.0293
13. Bauchner H, Rivara FP. The scientific communication ecosystem: the responsibility of investigators. *Lancet*. 2022;400(10360):1289-1290. doi:10.1016/S0140–6736(22)01898–0
14. Bauchner H, Golub RM, Fontanarosa PB. Reporting and interpretation of randomized clinical trials. *JAMA*. 2019;322(8):732-735. doi:10.1001/jama.2019.12056
15. Botkin JR. Should failure to disclose significant financial conflicts of interest be considered research misconduct? *JAMA*. 2018;320(22):2307-2308. doi:10.1001/jama.2018.17525
16. Bauchner H, Fontanarosa PB, Flanagin A, Thornton J. Scientific misconduct and medical journals. *JAMA*. 2018;320(19):1985-1987. doi:10.1001/jama.2018.14350
17. International Committee of Medical Journal Editors. Updated January 2024. Accessed April 11, 2024. https://www.icmje.org/
18. COPE: Committee on Publication Ethics. Accessed April 11, 2024. https://publicationethics.org/
19. Gunsalus CK, Marcus AR, Oransky I. Institutional research misconduct reports need more credibility. *JAMA*. 2018;319(13):1315-1316. doi:10.1001/jama.2018.0358
20. Garfinkel S, Alam S, Baskin P, et al. Enhancing partnerships of institutions and journals to address concerns about research misconduct: recommendations from a working group of institutional research integrity officers and journal editors and publishers. *JAMA Netw Open*. 2023;6(6):e2320796. doi:10.1001/jamanetworkopen.2023.20796
21. Christiansen L, Flanagin A. Correcting the medical literature: "to err is human, to correct divine." *JAMA*. 2017;318(9):804-805. doi:10.1001/jama.2017.11833
22. Heckers S, Bauchner H, Flanagin A. Retracting, replacing, and correcting the literature for pervasive error in which the results change but the underlying science is still reliable. *JAMA Psychiatry*. 2015;72(12):1170-1171. doi:10.1001/jamapsychiatry.2015.2278

Downloaded from academic.oup.com/book/58841 by guest on 17 October 2026

CHAPTER 36

Plagiarism

Melina R. Kibbe, MD

Downloaded from academic.oup.com/book/58841 by guest on 17 October 2026

KEY POINTS

- Plagiarism may be the most common form of research misconduct in academia and occurs throughout all aspects of the written word, from essays to published articles to grant applications, among others.
- Plagiarism is avoidable by understanding the types of plagiarism and how they manifest.
- Authors should read and thoroughly understand all source material before starting to write and must appropriately cite all references, whether words are used and quoted verbatim or concepts and ideas are discussed.
- The ramifications of plagiarism can be severe and can adversely affect an academic career.
- Understanding plagiarism, duplicate submission, and their related issues is paramount for anyone in an academic field, including authors writing and preparing manuscripts for submission to journals.

The US Public Health Service includes plagiarism as 1 of the 3 major forms of misconduct in the Policies on Research Misconduct, along with falsification and fabrication.[1,2] While the true prevalence of plagiarism in medical publications is difficult to determine, the introduction and use of plagiarism detection software has made detection more straightforward. When plagiarism occurs, the ramifications can be devastating and could have serious implications for a person's professional career. Thus, learning how to avoid plagiarism is incredibly important for anyone in a research career. This chapter will address the definitions of plagiarism and self-plagiarism, the occurrence of plagiarism, different types of plagiarism, methods to detect plagiarism, ramifications of plagiarism, and best practices to avoid plagiarism.

Definition

Plagiarism is commonly defined as the use of another person's words, ideas, figures, or other content and passing them off as one's own. Several formal definitions exist. The World Association of Medical Editors (WAME) delineates plagiarism as "the use of others' published and unpublished ideas or words (or other intellectual property) without attribution or permission, and presenting them as new and original rather than derived from an existing source."[3] WAME states that plagiarism is a form of scientific misconduct and should be managed accordingly. The US Office of Research Integrity (ORI) considers plagiarism to include "both the theft or misappropriation of intellectual property and the substantial unattributed textual copying of another's work."[4] Further, the ORI states that "the theft or misappropriation of intellectual property includes the unauthorized use of ideas or unique methods obtained by a privileged communication, such as a grant or manuscript review." In addition, the American Association of University Professors defines plagiarism as "taking over the ideas, methods, or written words of another, without acknowledgment and with the intention that they be taken as the work of the deceiver."[5]

Self-plagiarism is a concept that is more challenging for authors to comprehend. It is commonly understood as the reuse of one's own words, ideas, or concepts without appropriate attribution to the original source. WAME defines self-plagiarism as "the practice of an author using portions of their previous writings on the same topic in another of their publications, without specifically citing it formally in quotes."[3] The ORI describes self-plagiarism as occurring when authors "reuse their own previously disseminated content and pass it off as a 'new' product without letting the reader know that this material has appeared previously."[6] While self-plagiarism is not included as research misconduct in the US Public Health Service Policies on Research Misconduct (42 CFR §93),[2] it may pose a legal challenge with respect to copyright infringement. If the author's original content was published and the copyright is owned by a different individual, publisher, foundation, or society, then reuse of the words, content, or images can represent a copyright infringement. The *AMA Manual of Style* recommends that the term *self-plagiarism* be "avoided to describe duplication by the same author(s) given that plagiarism is a form of theft and authors cannot steal from themselves" and that "because this practice does not include misappropriation or theft of another's work, it is better described as a form of duplicate publication or duplicate submission." (See also Section 5.4.2, Misappropriation: Plagiarism and Breaches of Confidentiality, in the *AMA Manual of Style*.)[7]

Downloaded from academic.oup.com/book/58841 by guest on 17 October 2026

Scope of Plagiarism in Academic Publication

The true rate of occurrence of plagiarism in scientific publishing is unknown. However, the advent of plagiarism detection software and survey methodologies has provided some insights into the practice. In a study of the prevalence of plagiarism among medical students who were asked to write an essay on 1 of 4 source articles,[8] Bilić-Zulle et al used plagiarism detection software on the essays and counted the number of paragraphs with 6 or more words and calculated a plagiarism rate (ie, the "ratio of the absolute number of matching words and the total number of words in the essay"). Bilić-Zulle et al found the average percent of plagiarized text among the essays was 19%. Among the 198 medical students, only 17 (9%) students were found to have not plagiarized any text from the source articles, and 68 (34%) students were found to have plagiarized less than 10% of the source text. Another survey by Kukolja et al involving 761 medical students from 4 medical schools to determine the attitudes toward academic misconduct through an anonymous questionnaire[9] found that of the 477 students who answered the survey question, 68% self-reported "turning in work obtained in large part from the internet." Surprisingly, 17% of these students perceived this practice as "not cheating" and 42% perceived this as only "trivial cheating."

With respect to journal submissions and publications, McFarlin et al reported on a study of all manuscript submissions to the *International Journal of Exercise Science*. The authors found a 46% prevalence of plagiarism among all submitted manuscripts from December 2009 until July 2010, with 30% representing self-plagiarism of content from an author's previous publication and 16% representing plagiarism.[10] They found that the most common sites of plagiarized material were in the Introduction and Methods sections. In support of these data, a study by Grieneisen and Zheng examined the justifications provided for retracting articles between 1928 and 2011. Of 3631 notices that stated a justification for the retracted article, 796 (22%) were for plagiarism.[11]

Plagiarism is not limited to published articles. With respect to grant applications, Allison Lerner, the inspector general of the National Science Foundation, reported to a congressional panel in 2013 that the number of significant scientific misconduct allegations had more than tripled in the previous decade.[12] Specifically demonstrating the problem of plagiarism, Lerner reported that more than 80% of the 120 reports of misconduct were related to plagiarism. In 2019, the Duke University Office of Scientific Integrity and the Advancing Scientific Integrity, Services and Training (ASIST) team held a town hall on plagiarism and intellectual credit.[13] Of the 190 faculty, staff, and trainees that attended the town hall, 43% responded to witnessing or suspecting plagiarism in their own careers.

Thus, the scope of plagiarism as a form of scientific misconduct is not small, but rather it occurs throughout all communities of academia, including

Downloaded from academic.oup.com/book/58841 by guest on 17 October 2026

students, trainees, staff, and faculty. Plagiarism persists throughout a variety of platforms that includes but is not limited to copied material without attribution being included in essays, journal articles, book chapters, grant applications, and online content or websites. To avoid committing plagiarism, it is important to have a good understanding of the types of plagiarism and strategies to prevent the practice.

Types of Plagiarism

Many different types of plagiarism exist. One logical classification system of plagiarism is based on the layers of natural language that involve lexis, syntax, and semantics.[14] The first type of plagiarism using this classification is *character-preserving* plagiarism, in which text is copied and pasted and used without quotation marks and without attribution. This is also known as direct, literal, verbatim, or intentional plagiarism. Any text that is reproduced verbatim should be indicated with quotation marks and be referenced. The second type is *syntax-preserving* plagiarism, in which simple substitution techniques are employed. One of the most common approaches is to use synonym substitutions. The third type is *semantics-preserving* plagiarism, in which general paraphrasing is used (ie, the words and sentences are changed, but the meaning is preserved). This type of plagiarism is also referred to as translational paraphrasing, mosaic plagiarism, or patchwork plagiarism, and it is difficult to identify. The fourth type is *idea-preserving* plagiarism, in which the concepts and ideas of another author are presented as one's own without attribution. This type of plagiarism has also been referred to as template plagiarism or boilerplate plagiarism.

Plagiarism Detection Software

Software is available to detect plagiarism, text similarity, and duplication. There are free internet-based as well as subscription-based systems. Most of these programs function by comparing the text of a single manuscript or article to a large database of electronic sources to determine the degree of similarity. Similarity is established by examining how often a group of consecutive words are duplicated. The number of consecutive words is set by the user of the software; journals frequently use a threshold of 5 to 7 consecutive words. Common subscription-based platforms used by journals and academic institutions include iThenticate and Similarity Check (https://www.ithenticate.com) and Turnitin (https://www.turnitin.com). For example, reports from these programs typically include an evaluation of the number of matching words from sources identified compared with the total number of words in the manuscript,

Downloaded from academic.oup.com/book/58841 by guest on 17 October 2026

which may be reported as a percentage as an overall "similarity index" or "similarity score." The report also may include the number of exact words and the percentage based on the individual primary sources. Higher scores on these programs raise the possibility of having too much material in the manuscript taken from other sources and may suggest that journal editors may need to evaluate the manuscript further for the possibility of plagiarism.

Other programs are available, such as Grammarly (https://www.grammarly.com) and Bartleby Write (https://www.bartleby.com/write), which require a small subscription. Several free internet-based platforms also exist, such as Viper (both a free and a pay-as-you-go system; https://www.scanmyessay.com). Authors should be aware, however, that these free detection systems may use different and limited source databases and different definitions of similarity. Thus, interpret the results of the scan with caution.

Ramifications of Plagiarism

There are many different ethical and legal ramifications of plagiarism. Plagiarism is considered research misconduct[2] and represents unethical behavior and theft of intellectual content. Yet, the ramifications and consequences of plagiarism can vary widely. If plagiarism is detected at the time of journal submission, a manuscript may simply be rejected. Depending on the degree of plagiarism, the journal editors may contact all authors, along with the corresponding author's department head, institutional official in charge of research integrity, or both. The Committee on Publication Ethics, which is a group of mostly editors and publishers committed to maintaining the highest ethical standards of publishing, has a flowchart for managing this precise scenario.[15] If plagiarism is detected after a manuscript has been published, the sanctions may be more severe.[16] This may involve notification of all authors, the authors' department head(s), their institutional representative(s) for research integrity, and other journal editors or publishers of the plagiarized material. The authors may be prohibited from submitting work to the journal for a number of years. In some cases, the article is likely to be officially retracted. If plagiarism is detected within grant applications, the governing official of the granting agency is likely to contact the author's institutional official who oversees research integrity. These scenarios can lead to loss of grant funding, closure of research laboratories, demotion in rank or position, or dismissal from employment and could have significant negative effects on the national and international reputation of the author that may last a lifetime. In cases of severe or egregious plagiarism, the authors may even be prosecuted under criminal law statutes.

Self-plagiarism is not considered research misconduct.[6] However, it may be considered a breach of scholarship and ethical standards and could be

Downloaded from academic.oup.com/book/58841 by guest on 17 October 2026

considered copyright infringement. Thus, authors are advised to report any reuse of their previously published content and to use good scholarship, including citing the previous publication and using quotation marks for content that is republished verbatim. Authors may also need to obtain permission to republish major portions of text, tables, and figures from the owners of previously published content unless it was published under an open access license. Journal editors generally do not ask authors to rewrite or revise their previously reported Methods and Statistical Analysis sections for follow-up studies using the same methods and analyses, but in such cases authors should clearly describe and cite the previously published related studies. There is no consensus on the percent of acceptable similarity of overlapping content with respect to self-plagiarism or any verbatim duplication of text.[17] However, in a meeting of surgery journal editors at the American College of Surgeons, there was consensus that there should not be more than 5% similarity with any single source. Again, authors should be sure to cite and credit all sources and indicate verbatim use of sentences and phrases with quotation marks.

How to Avoid Plagiarism

The best way to avoid plagiarism is to have a very high level of awareness regarding the different types of plagiarism. In addition, a recommended best practice is to read all source material in depth before writing so that the author can gain an in-depth understanding of the material. If the author has gained this level of understanding of the material, they will be able to write using their own words and thoughts. When authors write about topics that they have little knowledge about, the tendency to plagiarize is greater. When using or referring to exact text through copy and paste, quotation marks must be used, and the source must be appropriately cited. Of note, short, direct quotes, with proper attribution, are considered "fair use" and do not typically require permission from the copyright holder. However, extensive quoting of copyrighted material can constitute copyright infringement even if enclosed in quotation marks and appropriately referenced. In this latter situation, permission from the owner of the copyrighted material should be obtained. If an idea, concept, or fact is used from a source, it should be appropriately cited. If an author would like to reproduce (or use a very similar version of) a table or figure from another source, permission from the owner of the content should be obtained and credited. If the source content was published under an open access license, permission is not needed, but credit to the original source should be given. Permission and credit are typically included in the legend or footnotes of the table or figure with wording such as "Permission to reproduce this figure was granted by [name of content owner]," with a cited reference to the source and often with an indication of copyright or open access license.

Downloaded from academic.oup.com/book/58841 by guest on 17 October 2026

(For additional information on reuse of content from other sources, see Section 5.6.7, Copying, Reproducing, Adapting, and Other Uses of Content, in the *AMA Manual of Style*.[17])

Conclusion

The concepts of plagiarism, duplicate submission, and their related issues are important for authors to understand. Plagiarism, which may be the most common form of research misconduct and occurs throughout all aspects of the written word, including essays, grant applications, published articles, and other reports, should be avoided. The consequences of plagiarism can be severe for authors, and understanding the types of plagiarism and the principles of good scholarship can help authors avoid this type of misconduct.

References

1. US Public Health Service. 42 CFR §50. Responsibilities of awardee and applicant institutions for dealing with and reporting possible misconduct in science; final rule. *Fed Regist*. 1989;54(151):32446-32451. Medline:11651184
2. US Department of Health and Human Services. 42 CFR §50 and §93. Public Health Service policies on research misconduct; final rule. *Fed Regist*. 2005;70(94):28370-28400. Accessed October 22, 2023. https://ori.hhs.gov/sites/default/files/42_cfr_parts_50_and_93_2005.pdf
3. World Association of Medical Editors; Publication Ethics Committee. Recommendations on publication ethics policies for medical journals. Accessed October 22, 2023. http://wame.org/recommendations-on-publication-ethics-policies-for-medical-journals#Plagiarism
4. ORI policy on plagiarism. Office of Research Integrity. US Department of Health and Human Services. Accessed October 22, 2023. https://ori.hhs.gov/ori-policy-plagiarism
5. American Association of University Professors. Statement on plagiarism. *Academe*. 1989;75(5):47-48. Accessed October 22, 2023. https://www.jstor.org/stable/40249740
6. Roig M. Avoiding plagiarism, self-plagiarism, and other questionable writing practices: a guide to ethical writing. Office of Research Integrity. Updated 2015. Accessed October 22, 2023. https://ori.hhs.gov/content/avoiding-plagiarism-self-plagiarism-and-other-questionable-writing-practices-guide-ethical-writing
7. Flanagin A. Misappropriation: plagiarism and breaches of confidentiality. In: Christiansen S, Iverson C, Flanagin A, et al, eds. *AMA Manual of Style: A Guide for Authors and Editors*. 11th ed. Oxford University Press; 2020. https://www.amamanualofstyle.com/
8. Bilić-Zulle L, Frković V, Turk T, Azman J, Petrovecki M. Prevalence of plagiarism among medical students. *Croat Med J*. 2005;46(1):126-131. Medline:15726686

Downloaded from academic.oup.com/book/58841 by guest on 17 October 2026

9. Kukolja Taradi S, Taradi M, Knežević T, Đogaš Z. Students come to medical schools prepared to cheat: a multi-campus investigation. *J Med Ethics*. 2010;36(11):666-670. doi:10.1136/jme.2010.035410
10. McFarlin BK, Lyons TS, Navalta JW. Prevalence of plagiarism in manuscript submissions and solutions. *Int J Exerc Sci*. 2010;3(3):68-69. Medline:27182331
11. Grieneisen ML, Zhang M. A comprehensive survey of retracted articles from the scholarly literature. *PLOS One*. 2012;7(10):e44118. doi:10.1371/journal.pone.0044118
12. Mervis J. NSF audit of successful proposals finds numerous cases of alleged plagiarism. *Science*. March 8, 2013. Accessed October 22, 2023. https://www.sciencemag.org/news/2013/03/nsf-audit-successful-proposals-finds-numerous-cases-alleged-plagiarism
13. Chiscop-Head E. How big of a problem is plagiarism in the academic and research community? Duke University School of Medicine blog. February 12, 2019. Accessed October 22, 2023. https://medschool.duke.edu/blog/how-big-problem-plagiarism-academic-research-community
14. Foltýnek T, Meuschke N, Gipp B. Academic plagiarism detection: a systematic literature review. *ACM Comput Surv*. 2019;52(6). doi:10.1145/3345317
15. Plagiarism in a published article. Committee on Publication Ethics. Accessed October 22, 2023. https://publicationethics.org/node/34581
16. Plagiarism in a submitted manuscript. Committee on Publication Ethics. Accessed October 22, 2023. https://publicationethics.org/node/19701
17. Flanagin A. Copying, reproducing, adapting, and other uses of content. In: Christiansen S, Iverson C, Flanagin A, et al, eds. *AMA Manual of Style: A Guide for Authors and Editors*. 11th ed. Oxford University Press; 2020. https://amamanualofstyle.com

Downloaded from academic.oup.com/book/58841 by guest on 17 October 2026

CHAPTER 37

Conflict of Interest and Biomedical Publication

Phil B. Fontanarosa, MD, MBA, Howard Bauchner, MD, and Annette Flanagin, RN, MA

Downloaded from academic.oup.com/book/58841 by guest on 17 October 2026

KEY POINTS

- Conflicts of interest (COIs) are common among authors of articles in biomedical journals and are likely to become more prevalent and more challenging to manage.
- It is critical that authors report COI information accurately, completely, and transparently so editors, reviewers, and readers can evaluate whether the information in the article could be influenced or biased because of authors' COIs.
- Despite increased awareness and attention, problems persist with COI reporting by authors of reports submitted to and published in biomedical journals, including failure to disclose, incomplete or inconsistent disclosures, and misinterpretation of what represents a relevant disclosure.
- Editors have responsibilities to appropriately include information regarding COIs of authors in published articles and to appropriately manage COIs of editorial staff members and peer reviewers to ensure that published information is accurate, that editorial evaluations are objective and unbiased, and that the integrity of the scientific record is maintained.

Conflict of interest (COI) can affect virtually every aspect of medicine and biomedical research. According to one definition, "The potential for conflict of interest and bias exists when professional judgment concerning a primary interest (such as patients' welfare or the validity of research) may be influenced by a secondary interest (such as financial gain). Perceptions of conflict of interest are as important as actual conflicts of interest."[1]

There has been increasing attention to COI in medicine and biomedical research, including reports from authoritative national and international organizations,[1,2] US federally mandated reporting of industry payments to physicians

and teaching hospitals (ie, Open Payments),[3] tracking of payments to physicians from industry by consumer groups (ie, Dollars for Docs),[4] enhanced policies and procedures governing COI at academic medical centers[5] and research institutions,[6] and efforts to harmonize reporting of COI overall and in scientific publications.[1]

Despite this increased awareness and attention, problems persist with COI reporting by authors of reports submitted to and published in biomedical journals. These include, among other issues, failure to disclose financial relationships and other important potential COIs, incomplete or inconsistent disclosures, and misinterpretation of what represents a relevant disclosure. Some of these problems have been manifest in high-profile cases of failure to disclose substantial financial and administrative relationships with biopharmaceutical and device companies and other health care–related companies by leaders at major academic medical centers and at other well-respected organizations.

This chapter discusses important issues involving COI in biomedical publications, including the responsibilities of authors, editorial evaluation of COI related to research reports and opinion articles, approaches to safeguard against COI in the editorial decision process, and recent developments related to COI reporting and management in biomedical journals. (For additional detail on this topic, see Section 5.5, Conflicts of Interest, in the *AMA Manual of Style*.[7])

Responsibilities of Authors

Transparent reporting, objective evaluation, and effective management of COI are essential to ensure the integrity and credibility of published articles and to promote public confidence and trust in the scientific process and the credibility of published articles. Accordingly, authors of manuscripts submitted for consideration for publication (including research reports, reviews, opinion articles, letters to the editor, and online comments) have important responsibilities regarding potential COIs and are expected and required to report detailed information about all financial interests, activities, relationships, and affiliations that may in any way be perceived to be related to the subject matter of their manuscript.

Authors must be forthcoming and consistent in reporting COI information. However, with respect to specific relationships, authors may not perceive or agree that a particular relationship represents an actual or relevant COI. In general, because a potential COI can depend on individual perceptions and beliefs about what may represent a conflict or pose a bias, the approach at many journals (including *JAMA* and the JAMA Network journals) is to encourage authors to provide complete and broad disclosure, thereby allowing readers to

Downloaded from academic.oup.com/book/58841 by guest on 17 October 2026

be aware of authors' potential COIs and enabling readers to decide whether a COI disclosure is important in their interpretation of the article.[7,8]

As indicated in the *JAMA* Instructions for Authors, "Authors are expected to provide detailed information about all relevant financial interests, activities, relationships, and affiliations (other than those affiliations listed in the title page of the manuscript) including, but not limited to, employment, affiliation, funding and grants received or pending, consultancies, honoraria or payment, speakers' bureaus, stock ownership or options, expert testimony, royalties, donation of medical equipment, or patents planned, pending, or issued."[8] This approach is consistent with the approach recommended by the International Committee of Medical Journal Editors (ICMJE) guidelines for definitions and terms of COI disclosures.[1]

The ICMJE has recognized that "disagreement, confusion, and controversy regarding authors' disclosures arise when opinions differ over which relationships and activities to report," that an "author might not report an item that others deem important because of a difference in opinion regarding what is 'relevant,' confusion over definitions, or a simple oversight," and that "authors may be concerned that readers will interpret the listing of any item as a 'potential conflict of interest' as indicative of problematic influence and wrongdoing."[9] The ICMJE encourages disclosures of all related interests and has recommended avoiding use of the term "conflict."[9] Thus, the ICMJE has developed a disclosure form and questions that many journals have adopted.[10] The form advises authors to report all relationships, activities, and interests that are related to the content of the manuscript. This includes reporting "all support for the work reported in this manuscript without time limit" and to reporting on the following related interests for the previous 36 months: grants or contracts from any entity; royalties or licenses; consulting fees; payment or honoraria for lectures, presentations, speakers bureaus, manuscript writing, or educational events; payment for expert testimony; support for attending meetings and travel; patents planned, issued, or pending; participation on a data and safety monitoring board or advisory board; a leadership or fiduciary role on or in any other board, society, committee, or advocacy group, paid or unpaid; stock or stock options; receipt of equipment, materials, drugs, medical writing, gifts, or other services; and other financial or nonfinancial interests.[10]

Although many universities and other institutions and organizations have established policies (such as time intervals) and thresholds (such as specific amounts) for reporting financial interests and other COIs, many journals require authors to provide complete disclosure of all financial relationships and potential financial COIs, regardless of amount or value. For example, authors of a manuscript about hypertension should report all financial relationships they have with all manufacturers and owners of products, devices, tests, and services used in the diagnosis and management of hypertension, not only those relationships with entities whose specific products, devices, tests, and services

Downloaded from academic.oup.com/book/58841 by guest on 17 October 2026

are mentioned in the manuscript. Authors also are expected to report all financial and material support for the research and the work (such as sponsor support and source of funding) clearly and completely (usually at the end of the manuscript).[7,8]

Just as authors are expected to operate under the principles of honesty and integrity in reporting the results of research studies, authors also are expected to operate under these same principles when reporting financial and other COI disclosures. Complete and detailed reporting of potential COIs is essential to maintain confidence and trust in biomedical research and to ensure transparency with respect to understanding possible relationships between authors' potential COIs and the information reported in their articles. In addition to reporting complete and detailed financial COI information, authors are encouraged to report other information that may be relevant to the subject matter of their article. For instance, an author who serves or recently has served as an officer of a medical society or advocacy organization who writes about topics that have relevance for that organization also is expected to include that additional information in their COI disclosures.

If authors are uncertain about what constitutes a relevant financial interest or relationship for an individual author or relevant support for the work being reported, they should err on the side of complete disclosure or contact the editorial office for clarification. To help promote more complete disclosures by authors and more consistent reporting among journals, the Association of American Medical Colleges organized a major initiative intended to achieve harmonization of financial disclosure reporting in biomedical journals.[11] Among the recommendations are that all authors should report all financial interests and relationships they have related to biosciences, regardless of type or subject matter, and should highlight those interests and relationships they determine may be "relevant" to the manuscript under consideration.[11]

In many journals, information about each author's financial interests, activities, relationships, and affiliations and declarations is reported in the published report (or in supplemental information with the article) and thereby disclosed to readers. The COI information often is included at the end of the published article or, as some journals do, by posting the submitted financial disclosure forms online along with the published article. In addition, all financial and material support for the research and the work is reported in the published article along with the specific role of the funding organization or sponsor in each of the following activities: "design and conduct of the study; collection, management, analysis, and interpretation of the data; preparation, review, or approval of the manuscript; and decision to submit the manuscript for publication."[8]

The purpose of requiring detailed reporting of COIs and financial support and making this information available to readers is to enable readers to evaluate the authors' COI disclosures and the financial aspects of the published

Downloaded from academic.oup.com/book/58841 by guest on 17 October 2026

article and to interpret the information in the article with respect to the disclosures.

Evaluation of COIs by Biomedical Journals

As part of the editorial assessment process, editors evaluate the COI disclosure information reported by the authors and the financial support for the study.

COIS AND RESEARCH REPORTS

The potential for COI to result in bias can occur in any manuscript. In addition to requiring detailed reporting about COI from each author and detailed information about research funding and support, at *JAMA* these articles are subject to both external peer review and in-depth internal editorial evaluation. For many reports, including randomized clinical trials and meta-analyses, standards have been established for reporting the results. Although reporting standards do not eliminate COI, they provide a blueprint for what should be expected in a research report.

Several issues regarding COI and research reports require additional attention. Research reports funded by industry are either those in which industry supports the research project but is not involved in the analysis or preparation of the manuscript for publication or those in which industry has key involvement in the study design, collection and analysis of data, and preparation of the manuscript for publication. Because of the inherent COI that industry sponsors have with publishing research reports that are favorable regarding their products, in general it is preferable in studies with industry support for these sponsors to have a limited role that is prospectively defined and detailed.

In addition, some agreements with investigators include statements about the rights of the funder to review a manuscript prior to submission and in some cases may allow the sponsor to prevent or delay submission of the manuscript for consideration for publication or may include provisions for the funder to control the decision regarding to which journal the manuscript can be submitted. Delaying publication of any manuscript at the request of any funder (beyond a reasonable time for its review) is unacceptable, and no investigator or institution should engage in a contractual arrangement in which the funder has the right to approve the final language of the manuscript or veto publication.

In some research studies, investigators at biopharmaceutical and device companies are involved in the design and conduct of the study. Some of these investigators have been concerned when there have been discussions suggesting that they be excluded as authors or that they have been encouraged to add academic authors with the perception that doing so might help the study be more favorably assessed during the journal review process. This is contrary to the

Downloaded from academic.oup.com/book/58841 by guest on 17 October 2026

standards of transparency and fairness. Although the COI for these investigators is apparent (ie, based on their employment by the study sponsor or other factors, such as stock holdings or options), numerous safeguards are in place that should allow the journal to objectively evaluate the study, such as the availability of trial protocols, statistical analytic plans, and trial registration information. Investigators from biopharmaceutical and device companies who meet authorship criteria should be included as authors on the manuscript.

Over the past few years, it has become clear that some governmental agencies and nonprofit research organizations are providing greater oversight for manuscripts that are either prepared by their employees or funded with resources from those entities. In some cases, even though this review process may be part of the legislative mandate of the agencies, this level of oversight of research manuscripts also raises some concerns. Just as industry sponsors should not be able to delay or affect the submission of a manuscript or publication of an article, neither should governmental agencies or other funders. It is not clear how often manuscripts have been delayed or changed because of these reviews. However, all authors should be afforded the protection and academic freedom to publish the results of studies regardless of the interest of the funder, whether a governmental agency, foundation, or for-profit company.

COI AND OPINION ARTICLES

Opinion articles represent a challenge for editors, and some journals indicate that they do not permit authors with any COI to write such articles. Freestanding opinion manuscripts (such as Viewpoints or Perspectives) are submitted independently of a research report and the authors' COI disclosures are considered in the review of the submission. Some journal editors prospectively consider potential COIs of authors when inviting them to prepare opinion articles such as Editorials and Commentaries to comment on and accompany a published research report. Authors are advised to prospectively share their COIs with editors when invited to submit these manuscripts.

For these opinion articles, editorial judgment and discretion are necessary, and issues related to COI and authorship are evaluated on a case-by-case basis. For instance, if authors may directly benefit from publication of an opinion article (eg, if the authors own stock in a company that manufactures the product they are writing about), an editor may decline to publish such an article, especially if the manuscript appears biased or promotional about the product.

Accordingly, all opinion articles should be reviewed for concerns about bias, such as when an author expresses strongly held opinions that do not appear to reflect the data or evidence. This is particularly concerning if an author selectively emphasizes some results of a research report and does not accurately reflect the totality of the evidence in a balanced way. There is subjectivity in the decision regarding who can and who cannot write opinion articles,

Downloaded from academic.oup.com/book/58841 by guest on 17 October 2026

and what represents a disqualifying COI. Many experts have various relationships with industry, such as consulting arrangements, grant support, or serving on data and safety monitoring boards, and automatically disqualifying such experts from expressing their opinion might represent a form of bias. It is the obligation of journal editors to ensure that these articles accurately reflect the evidence.

Allegations of Undisclosed COI

Even though biomedical journals require authors to provide full and complete disclosure of their COIs, a recurring issue involves discrepancies in an author's reporting of specific COIs, such as inconsistent disclosures in related recent publications (eg, in different articles or in different journals) or in different sources (eg, public databases, committee reports). Sometimes these differences are appropriate (such as when different journals have different disclosure policies), but sometimes they are not. Journal readers or other interested individuals (such as investigative journalists) may notify the editors that a particular author has not accurately declared their COIs. These allegations may involve concerns about undeclared, incomplete, or inconsistent reporting of COI information in a published article. If these allegations appear to have merit, authors of the article will be contacted about the concerns, with a request for a complete and detailed explanation.[7]

Three common situations illustrate some concerns involving allegations related to undisclosed COI of authors. For example, the allegation of undeclared COI may be determined to be correct. Such allegations may be based on a search of the literature or internet and a comparison of declarations of COI in previous articles with the current one, a search of databases that report industry payments to physicians, or by documentable previous knowledge of an individual's COI. In these cases, if there is an undeclared COI in a published article, the author may be asked to acknowledge the incomplete or inaccurate disclosure in a letter of explanation that is published along with a correction to the original article that clarifies the disclosure information.

Another example may involve an allegation of an undeclared COI, but the author may disagree that the undisclosed information represents a relevant COI. In these cases, journal editors often must adjudicate the disagreement, which may be complex and may involve substantial time and effort. An example might involve an author who consults with a company that makes various products that are unrelated to the published article. However, presumably unbeknown to that individual, the company also has a wholly owned subsidiary, and the allegation is that given the company's ownership of the subsidiary with a financial interest in the content of the article, the author should have been aware of that issue and declared a COI. Another example might involve an

Downloaded from academic.oup.com/book/58841 by guest on 17 October 2026

author who consults for a nonprofit group and that group receives substantial funding from industry. The allegation may be that although the author received funding from the nonprofit entity, given that the funding was a "pass-through" from a company and is related to the content of the article, that relationship should have been declared. Other examples may be related to differences of opinion about the relevance of COIs, many of which require adjudication by journal editors. In general, if authors declare all potential COIs, not only those they think are relevant to the content of the article, and those COIs are acknowledged in the article, readers can then decide about relevance.

As a third example, an apparent undisclosed COI may occur because of different time windows for reporting COI used by different journals (or by different entities or organizations). For instance, journals that follow the ICMJE policy and many other journals require reporting of all relationships that were present during the 3 years prior to manuscript submission, whereas other journals and entities may have longer or shorter time windows for potential COIs that need to be declared. Different timelines may create the appearance of discrepancies for reported and unreported COI information among various sources.

In most situations similar to those in these examples, the authors' responses to the issues raised and additional explanatory information provided are sufficient to resolve the COI concerns, and usually are rectified with publication of a letter of explanation from the authors and a correction of COI information in the published article or discussion in online comments. However, in egregious cases of failure to disclose important COI information, the journal editors may consider notifying the institution or organization responsible for oversight of the author who has a substantial undeclared or inaccurate COI disclosure in a published article. The editors also may consider, on a case-by-case basis, notifying the funding source or sponsor for the work reported in the article that involved undisclosed COI information. Institutions and funders could then decide whether further action is required.

Evolving Issues and Potential COI Involving Authors

Several evolving issues have arisen over the past decade relevant to COI.[12] First, many scientific journals now include multimedia (such as podcasts or videos) as part of their editorial content, and it will be important for individuals (such as authors or other invited guests) who participate in these multimedia activities to report their potential COIs, which should be included in the multimedia content. Second, at most journals authors do not declare the amount of compensation in the form of payments received for consultation, as honoraria, or for other activities or relationships. For some authors, the amount of compensation is substantial, raising the possibility that creating categories for reporting levels

Downloaded from academic.oup.com/book/58841 by guest on 17 October 2026

of income may be helpful to indicate the potential magnitude of the financial COI. Third, some academic medical centers and other health care–related entities have developed intellectual property (eg, patents, licenses) involving drugs, devices, or other products, and thereby have an institutional COI in the use of those products. Whether an author from these institutions who is publishing an article that supports the use of these products should declare that their institution or employer has a potential COI related to the subject matter of their manuscript remains to be determined, especially if the author is unaware of any such intellectual property rights of their institutions. However, in the spirit of full transparency, authors who are aware of these relationships within their institution generally should consider notifying the journal about them. Fourth, some ethicists have suggested there is no "potential COI," but that COI simply exists, and all financial relationships should be declared.[13] The challenge of this approach is that it may be difficult for editors, reviewers, or readers to recognize the relevant COIs.[12]

Peer Reviewers and Potential COI

Editors also consider potential COIs involving peer reviewers. Reviewers are expected to disclose any potential COIs (financial or otherwise) to the editors at the time they are invited to review a submitted manuscript. The JAMA Network journals include the following instructions regarding conflicts of interest in the letter sent requesting an individual to review a manuscript: "While most conflicts of interest are not disqualifying, if you perceive that you have a disqualifying interest, either financial or otherwise, please contact the reviewing editor immediately (if possible, with the names of alternative reviewers). This will not affect your reviewer status."[8] Reviewers who cannot provide an objective review should consider declining to review the manuscript.

Based on evaluation of the information regarding potential COI that the reviewer reports, the editor will determine if the conflict should disqualify the reviewer from participating in the peer review of the manuscript.[7] Not all COIs necessarily preclude an individual from serving as a reviewer for a manuscript. In some cases, depending on the nature and extent of the COI and if the editor and reviewer agree that the reviewer can provide meaningful substantive comments related to the subject matter of the manuscript, the editor may request that the reviewer complete the review and disclose any COI and will evaluate the content and objectivity of the review while considering the reviewer's potential COI. In addition, all peer reviewers are required to disclose any potential COIs or disclose no COIs when they complete and submit a review. Although it is essential that reviewers report potential COIs to the journal, at most journals reviewers serve as consultants to the editors, and editors make the final decisions regarding the disposition of manuscripts (ie, decline, revise, accept).

Downloaded from academic.oup.com/book/58841 by guest on 17 October 2026

Moreover, in all cases, any information peer reviewers or potential reviewers receive about a manuscript must be kept strictly confidential, is not to be shared with any third parties, and must not be used to further their own interests or the interests of any others. (See also Chapter 29, Reviewing Manuscripts for Peer-Reviewed Journals.)

Editors and Potential COI

While authors must be forthcoming about reporting their potential COIs, journal editors also have an important responsibility in ensuring that all articles, including research reports, reviews, and opinion pieces, accurately reflect scientific evidence, regardless of the COI disclosures of authors. In addition, editors also have a responsibility to manage their own COIs. Many journals (including *JAMA* and the JAMA Network journals) have formal policies for disclosure and management of potential COIs of editors.[7] These may include, among other requirements, that all editors at the journal complete a COI disclosure statement at least annually, in which any potential conflicts and relationships are disclosed and reported to the editor in chief. If an editor has a potential COI with a specific manuscript or author, that editor is recused from the editorial evaluation and peer review processes. This COI could be financial or nonfinancial, or the COI could be professional, such as may occur with familiarity with a research project if, for instance, an editor had served as a consultant to the project or had collaborated with the authors. If an editor has a COI with the topic of a submitted manuscript or with the authors, the manuscript, review, and editorial decisions are managed by another designated editor without a COI related to the manuscript. As stipulated in the *JAMA* and JAMA Network journal Instructions for Authors, "final decisions regarding manuscript publication are made by the editor in chief or a designated editor who does not have any relevant COIs."[8]

In part because of concern about possible COI of handling editors, many journals maintain an appeals policy, whereby authors can appeal a decision made by the journal. (See also Chapter 30, Communicating and Interacting With Journal Editors, and Chapter 31, Responding to Journal Decision Letters and Reviewers' Comments.)

Conclusion

Conflicts of interest are common among authors of articles in biomedical journals and are likely to become more prevalent and more challenging to manage. Despite increased awareness and attention, problems have persisted with COI reporting by authors of reports submitted to and published in biomedical

Downloaded from academic.oup.com/book/58841 by guest on 17 October 2026

journals, including failure to disclose, incomplete or inconsistent disclosures, and misinterpretation of what represents a relevant disclosure. It is critical that authors report COI information accurately, completely, and transparently so editors, reviewers, and readers can evaluate whether the information in the article could be influenced or biased because of issues related to authors' COIs.

ACKNOWLEDGMENT

This chapter is an updated version of the following previously published articles: Fontanarosa P, Bauchner H. Conflict of interest and medical journals. *JAMA*. 2017;317(17):1768-1771. doi:10.1001/jama.2017.4563; and Bauchner H, Fontanarosa PB, Flanagin A. Conflicts of interests, authors, and journals: new challenges for a persistent problem. *JAMA*. 2018;320(22):2315-2318. doi:10.1001/jama.2018.17593

References

1. Roles and responsibilities of authors, contributors, reviewers, editors, publishers, and owners. International Committee of Medical Journal Editors. Updated January 2024. Accessed April 12, 2024. https://www.icmje.org/recommendations/browse/roles-and-responsibilities
2. Lo B, Field MJ; Institute of Medicine (US) Committee on Conflict of Interest in Medical Research, Education, and Practice. *Conflict of Interest in Medical Research, Education, and Practice*. National Academies Press; 2009.
3. Open Payments. US Centers for Medicare & Medicaid Services. Accessed April 12, 2024. https://openpaymentsdata.cms.gov/
4. Dollars for Docs. ProPublica. Accessed April 12, 2024. https://projects.propublica.org/docdollars
5. Rothman DJ. Academic medical centers and financial conflicts of interest. *JAMA*. 2008;299(6):695-697. doi:10.1001/jama.299.6.695
6. National Institutes of Health. Financial conflict of interest. Updated November 21, 2023. Accessed April 12, 2024. https://grants.nih.gov/grants/policy/coi/index.htm
7. Flanagin A. Conflicts of interest. In: Christiansen S, Iverson C, Flanagin A, et al, eds. *AMA Manual of Style: A Guide for Authors and Editors*. 11th ed. Oxford University Press; 2020. Accessed April 12, 2024. https://academic.oup.com/amamanualofstyle/book/27941/chapter/207564250?searchresult=1#414753076
8. Instructions for Authors. JAMA Network. Updated April 3, 2024. Accessed April 12, 2024. https://jamanetwork.com/journals/jama/pages/instructions-for-authors
9. Taichman DB, Backus J, Baethge C, et al. A disclosure form for work submitted to medical journals: a proposal from the International Committee of Medical Journal Editors. *JAMA*. 2020;323(11):1050-1051. doi:10.1001/jama.2019.22274
10. Disclosure of financial and non-financial relationships and activities, and conflicts of interest. International Committee of Medical Journal Editors. Updated January 2024. Accessed April 12, 2024. https://www.icmje.org/recommendations/browse/roles-and-responsibilities/author-responsibilities--conflicts-of-interest.html

Downloaded from academic.oup.com/book/58841 by guest on 17 October 2026

11. Working Groups on Harmonization. Harmonization of Financial Disclosure Reporting in Biomedical Journals: A Shared Responsibility. Association of American Medical Colleges; 2021. Accessed September 14, 2023. https://www.aamc.org/media/46506/download?attachment
12. Bauchner H. Conflicts of interest: ubiquitous, unrelenting, and forever challenging. *J Clin Epidemiol*. 2022;149:172-174. doi:10.1016/j.jclinepi.2022.06.002
13. McCoy MS, Emanuel EJ. Why there are no "potential" conflicts of interest. *JAMA*. 2017;317(17):1721-1722. doi:10.1001/jama.2017.2308

Downloaded from academic.oup.com/book/58841 by guest on 17 October 2026

CHAPTER 38

Legal Issues in Biomedical Publication

Joseph P. Thornton, JD

Downloaded from academic.oup.com/book/58841 by guest on 17 October 2026

KEY POINTS

- Publishing in a biomedical journal is akin to entering into a contract; authors should read, understand, and fully perform the commitments made as part of this agreement and as indicated in manuscript submission systems and authorship forms.
- Journals offer authors various options with regard to copyright assignment or retention and publication licenses and models for public access or open access.
- Authors who publish open access content with a Creative Commons Attribution (CC BY) license yield control over reuse of their work; CC BY licenses permit tweaking, adaption, and commercial use of published content without permission provided attribution to the original source is given.
- Narrow or internally inconsistent hospital consent forms do not meet the needs of international medical journals to protect patients' rights to privacy in publication.
- Authors are expected to cooperate with journals to address postpublication concerns, questions, or errors and when either or both are subpoenaed, sued, or faced with a retraction demand following publication of an author's manuscript.
- Authors who are overly defensive, deflect responsibility, and do not provide plausible and candid explanations risk alienating editors who would otherwise support them from unfair attack.

An author's relationship with a journal begins the moment a manuscript is submitted and continues long after acceptance and publication. While clearly an editorial and scientific endeavor, the manuscript submission and publication processes have legal overtones and consequences. Publishing in a biomedical journal is akin to entering into a contract, with burdens, risk, and benefits for both sides, premised on trust, responsibility, and reputation. After an accepted

manuscript is published, the journal article—and on occasion, the underlying agreement among authors, editors, and publishers—is open to assessment, use, and misuse by a critical audience of supporters and detractors, including readers, researchers, clinicians, journalists, and policymakers, as well as other content publishers and data aggregators. Savvy authors who are mindful of these legal aspects can avoid surprise and disappointment while advancing science and their professional careers.

As soon as an author begins completing an electronic manuscript submission for a journal, legal and ethical implications arise. Disclosures and representations are made regarding originality of the content, authorship, potential conflicts of interest, funding, and postpublication access to content and data. Other chapters will discuss some of those items at greater length (see also Chapter 5, Formulating an Organized Critical Argument in a Scientific Manuscript; Chapter 23, Brief Reports and Research Letters; Chapter 25, Editorials; Chapter 35, Ethical Issues in Biomedical Publication; and Chapter 37, Conflict of Interest and Biomedical Publication).

This chapter will address aspects of authorship from a legal perspective, as included in the following sections: Copyright; Public Access, Open Access, and Publication Licenses; Permissions; Defamation and Libel; Privacy; and Liability and Postpublication Concerns and Cooperation.

Authors need a basic understanding of these main legal issues so they can focus on producing compelling and high-quality research and manuscripts and avoid the legal distractions and threats that could distract from and undermine their work. Most journals require authors to complete authorship forms that solicit critical facts and elicit specific pledges as a condition to considering a manuscript, subjecting the manuscript to editorial and peer review, and publishing the article with the imprimatur implied by that journal's reputation. These attestations concern the following:

- The validity and originality of the work
- A representation that the manuscript is an accurate representation of that work
- The veracity of the work
- Authorship and contributions to the work
- Indication of data availability and sharing and an assurance that data will be made available to the editors for examination, if requested
- Funding sources and potential conflicts of interest
- Whether the manuscript has been published elsewhere or posted on a preprint server
- Who owns the manuscript, as a predicate to publication and reuse rights

Downloaded from academic.oup.com/book/58841 by guest on 17 October 2026

Copyright

A copyrightable interest arises when a work is captured in tangible form. Copyright is a form of legal protection provided to the author of published and unpublished original works.[1] An author, or any entity (such as a publisher) to whom an author transfers copyright, is the owner of copyright in the work.

Beginning with the end goal of publication in mind, authors and journals need to know who owns the intellectual property rights associated with the manuscripts, tables, figures, data sets, and supplemental material that authors submit. The capital investment and operating expenses of biomedical publishing are often overlooked or underappreciated by readers and contributors to journals. Intellectual property rights create opportunities for revenue to sustain the infrastructure, personnel, software applications, and websites that are critical to curating, distributing, and maintaining access to compelling, useful, and reliable medical and scientific information and research.

Many journals require assignment of copyright or a publication license to the journal by each coauthor of the work. Some require the assignment at submission but return the copyright if the manuscript is not published.[2] Others make the assignment effective if and only when the manuscript is published.[3] With assignment of copyright, the author typically pays nothing (or relatively little), but with a full assignment of copyright, a publisher can generate revenue to support the resources needed for editing, producing, printing, distributing, and providing access to the published content. The infrastructure of journals includes processes for triage of submitted manuscripts; peer review; editing; copyediting; typesetting and composition; layout; issue and website design, distribution, and hosting; and postpublication amplification via news and social media and enhanced search and discovery.

Publishers may claim copyright in the new works they create during revision and copyediting of the manuscript, including presentation of tables and figures, which are published in the distinctive design, layout, and format of a journal's trade dress or trademarks. Copyrighted work may not be used, copied, modified, or displayed without first obtaining a license or the written permission of its owner. A work in the public domain is not subject to copyright restrictions or claims for infringement, but the fact that an article can be found and read on the internet does not mean it is public domain. Authors should look for and respect copyright notices before assuming an item or data set can be downloaded and used without permission. Publishers and other copyright owners may issue takedown notices, cease and desist letters, or copyright infringement claims when they identify articles bearing their copyright and trademarks posted on websites or social media without permission. (For more information about copyright terms, public domain, fair use, and when permissions are needed, see Section 5.6, Intellectual Property: Ownership, Access, Rights, and Management, in the *AMA Manual of Style*.[4])

Downloaded from academic.oup.com/book/58841 by guest on 17 October 2026

Public Access, Open Access, and Publication Licenses

As defined in the *AMA Manual of Style*, *public access* "is the free access to content and typically permits users to read, download, print, search, and link to content, but with some copyright restrictions or limitations on sharing and reuse."[4] *Open access* "is the free and unrestricted online availability of content. In its most liberal application, open access publishing means that users have unrestricted access without typical copyright restrictions and can freely read, download, copy, distribute, print, search, or link to full text of articles, as well as reuse and modify such content in part or whole for any lawful purpose provided that authors are properly acknowledged and cited."[4] Many journals offer authors various publication options:

1. A traditional publishing model, in which the content is accessible only to individual or institutional journal subscribers. In this model, research articles are often made free public access on the journal website, typically after an embargo period (eg, 6 or 12 months after publication). In this model, authors assign copyright or a publication license to the journal. However, some journals, such as the JAMA Network journals, have adopted policies on public access to research that permit authors of original research reports to deposit their accepted manuscript in a public repository immediately on the day the article is published by the journal.
2. An open access model, in which authors typically pay an article processing charge (APC) or fee and the content is freely available. In this model, authors typically retain copyright but assign a publication license to the journal.
3. A hybrid model, in which authors may choose either the traditional model or open access.

Authors are advised to review journals' instructions for authors for information about these options and any publication fees before deciding to which journal to submit their manuscripts. When authors choose to publish in an open access journal, they retain copyright ownership of their submitted work, give the journal a license to publish it, and simultaneously grant to the entire world a royalty-free Creative Commons (CC) license.[5] These "share alike with attribution licenses" come in several varieties, with Creative Commons Attribution (CC BY) being the most popular. Anyone is free to share and adapt the CC BY material, provided they give appropriate credit, typically far less than the standard citation that authors might prefer. Sharing includes copying and redistributing the material in any medium or format; adapting includes the right to tweak, remix, transform, and build on the material for any purpose, even commercially.[5]

Authors or their funders pay APCs or fees to journals when they elect open access status. The article is free to read and download at publication, so it

Downloaded from academic.oup.com/book/58841 by guest on 17 October 2026

might be seen by more readers sooner than a work published in a journal with a subscription paywall.

Authors and journals might prefer manuscripts subject to Creative Commons licenses that restrict commercial reuse (CC BY-NC) and derivative works (CC BY-NC-ND), which balance editorial integrity and potentially wide distribution, and some authors realize these licenses afford more protection for their work. Authors who publish with CC BY licenses may not know who is using their research study or capitalizing on their article, such as by reuse in a book or in other materials. While Creative Commons contends these authors retain a copyright in their work, downstream users do not need to seek the permission of the original authors or notify them, but they are required to provide attribution to the original work and author.

The appeal of APCs as revenue streams spawned an exponential increase in the number of open access journals, including so-called predatory journals that offer little or no peer review and accept and publish almost every submission, often with mistakes and on obscure websites with limited functionality and reach. Many research funders require publication in open access journals, but open access has not been the panacea some had hoped and touted. When weighing the pros and cons of retaining copyright in exchange for payment of APCs, authors should consider other factors, such as the reputation of the journal and its commitment to manuscript editing and accuracy and consistency of data, digital marketing and search engine discoverability, audience reach and engagement (such as distribution and media interest), and key metrics such as the Journal Impact Factor and article citations and measures of digital reach (eg, article views and media coverage). (See also Chapter 3, Selecting a Journal.) Authors may not enjoy the satisfaction of advancing science and their careers if they select a journal that merely posts submissions without editorial curation, peer review, and postpublication support for impact and reach. There also are important concerns about equity for authors without funding or other means to afford the APCs to be able to publish in open access journals.

Journals that accept CC BY manuscripts typically ask authors to sign publishing agreements that grant first right of publication to the journal and articulate other rights between the parties. Publishers often register their copyright claims in the compilation of versions of record articles published as an issue or edition, even when it includes content published under open access licenses. This is an appropriate allocation of intellectual property rights in the emerging and evolving world of scholarly publishing.

Permissions

Owners of a copyrighted work can restrict, deny, or approve the use of their property. An author whose manuscript includes a table, figure, or video owned

Downloaded from academic.oup.com/book/58841 by guest on 17 October 2026

by another must obtain written permission from the institution, publisher, or researcher who holds or manages the copyright to it (unless it was published with a CC license). A journal will expect the author to secure permission for republication in all formats and without restrictions. Grants of permission typically specify a mandatory credit line and copyright notice. When the complementary material was published under a CC BY license, the journal nevertheless retains a record of the license associated with the item to be republished and includes attribution to the original author and source. Authors who published under a CC BY license, however, waive their right to be consulted for reuse, even commercial reuse. As explained above, a worldwide license (or a grant of permission) to adapt, reuse, and exploit the author's work is issued via the CC BY license at first publication and it cannot be revoked.

Defamation and Libel

Defamation is a tort, a legal cause of action that an individual or firm can file against an author or journal that publishes statements alleged to be false. *Libel* describes a written defamatory statement, and *slander* refers to an oral or spoken defamatory statement. In most jurisdictions, the elements of the tort of defamation or libel can be summarized as the following:

- A false statement of fact (something that is verifiable, not an opinion)
- made or published about another (of and concerning a person or a company, regarding its character, work, product, therapy, etc) to a third party
- without a legal privilege
- but with fault (negligence, gross negligence, or actual malice)
- that causes injury to reputation and damages.

Complaints alleging libel are easier for plaintiffs to file than win but impose considerable expense and angst among those named as defendants.[6,7] Defending allegations of libel distracts researchers from their work and can chill speech, including the traditional scientific scrutiny and critiques so vital to sound science and medicine.[7,8] Unless a libel suit can be disposed of with an early motion to dismiss, the authors, journal editors, and journal publisher may face extensive and invasive discovery, which can include the production of correspondence, research notes, manuscript drafts, and statistical analysis of data sets. Authors and editors might be subpoenaed to produce documents or testify in depositions or at trial. While journals can successfully assert editorial privileges against compelled production in third-party litigation,[9-11] in some jurisdictions a journal named a defendant may have a more difficult time persuading a judge that editorial material and witnesses are not relevant or probative. Even a legal victory, involving the withdrawal or dismissal of a

Downloaded from academic.oup.com/book/58841 by guest on 17 October 2026

defamation claim or a ruling quashing a subpoena, can be expensive. Fees for defense counsel, initial discovery, and successful motions can quickly run into 6 figures, which is why authors and journal editors need to vet manuscripts for their vulnerability to litigation.

Most reputable publishers purchase libel insurance policies to mitigate some of the litigation expense and judgments for defamation or invasion of privacy. Authors who receive a subpoena or litigation threat related to an article they published in a journal should contact the editors of that journal to inform them about these issues and to potentially explore a joint defense, if appropriate.

More suits involving defamation are threatened than filed, but the risk of defaming the subject of a manuscript is real and yet manageable. While truth is the ultimate defense, less than perfect statements that are substantially true or inaccurate statements based on a government document or judicial proceeding can be legally privileged. For instance, authors should attribute statements to governmental agencies (eg, the US Food and Drug Administration or European Medicines Agency), international organizations (eg, the World Health Organization), or a specific judicial ruling, rather than a law firm or company press release or an individual's social media post.

A valuable technique is for authors to preserve evidence as they conduct their research and draft manuscripts, especially opinion articles that are likely to be seen as critical and controversial. For example, authors who contend that a drug or device maker touts an unproven indication or treatment should take and save a screenshot of the website, company brochure, or social media post, using technology that clearly captures the date on which the information was accessed. Journal lawyers have encountered situations in which websites of would-be plaintiffs have been scrubbed, web pages pulled down, and troublesome errors or misstatements purged before sending letters alleging defamation or demanding retractions. Authors who can provide such proof of their diligence and the accuracy of their assertions during editorial review, compared with authors who lack such supporting evidence, are more likely to have articles based on such information published and will be able to support their assertions if a formal complaint is lodged just before or after publication. (For additional guidance on these concerns, see Section 5.9, Defamation, Libel, in the *AMA Manual of Style*.[7])

Privacy

Medical journals are not covered entities subject to the rules of the US Health Insurance Portability and Accountability Act (HIPAA) or other countries' similar regulations as they are not providing health care to patients or seeking payment for health care services. Authors who conduct research involving

Downloaded from academic.oup.com/book/58841 by guest on 17 October 2026

human research participants and draft manuscripts that describe the protected health information of patients and patient outcomes are subject to several ethical and legal requirements, including the Common Rule, HIPAA, state and country privacy regulations, and journal policies designed to support the principles of patient privacy.

To be ethical, manage malpractice claims, and guard against claims of battery, physicians (especially surgeons and interventionists) require patients to sign forms consenting to medical tests, procedures, treatments, and therapies that might be invasive and often pose serious risk. Many hospitals and academic medical centers use forms in which the patient provides consent to the use of personal data, family history, condition, disease, and other information in research or education at and by the hospital or beyond that entity. Forms of this type fall short of the informed consent and protection against liability that journals require as conditions to publication and some contain internally inconsistent language (ie, granting permission for publication but not on the internet). Especially in small case studies and observations, patients may become identifiable to themselves, friends, or family, posing a legal risk and ethical violation of privacy in the event these reports are published. For this reason, most journals require use of their consent for publication forms, with authors obtaining fresh consent from potentially identifiable patients. Patients who may be identifiable in a specific manuscript should be given a copy of the manuscript in advance of publication or expressly waive the right to review the manuscript. However phrased, consent forms ideally release the authors, the journal, and the journal's publisher and authorize publication worldwide, in print and on websites, in social media or other media not yet invented, plus cover images and videos used to illustrate the article. Comprehensive patient consent forms minimize the risk of invasion of privacy lawsuits, breaches of HIPAA and other countries' privacy regulations, and formal investigations. (A full discussion of patient rights and journal consent forms can be found in Section 5.8, Protecting Research Participants' and Patients' Rights in Scientific Publication, in the *AMA Manual of Style*.[12])

Liability and Postpublication Concerns and Cooperation

Demands for retraction of published reports often arrive with threats of litigation. Authors have a duty to readers, journals, and their coauthors to cooperate with editors when faced with a retraction demand, lawsuit, subpoena, or formal inquiry about their work. The same is true when an author is accused of failing to disclose potential conflicts of interest to a journal and its readers. Misrepresentation of potential conflicts can have legal ramifications, and alleging failures to disclose is a common method by zealots who try to discredit work and findings with which they disagree, even when the methodology and

Downloaded from academic.oup.com/book/58841 by guest on 17 October 2026

conclusions of the published article are solid and not suspectable to legitimate scientific criticism. Increasingly, lawyers for manufacturers and others with commercial interests are alleging undisclosed conflicts of interest when issuing retraction demands. They imply that an author's failure to make a full disclosure is malicious, not mere oversight, warranting a retraction or removal of an article from a journal website as the only remedy for criticism of a company's product or service and the decline in market value of its stock, product, or service.[13]

For example, articles that have been cited by the US Food and Drug Administration in guidance regarding black box warnings or the removal of a product from the market have sparked litigation threats, calls for the removal of editors, and boycotts of journals.[14] On occasion, stock trades that occurred while journal articles were still under embargo and study details were not yet publicly available have sparked investigations by the US Securities and Exchange Commission and allegations of insider trading.[15-17]

Data sets that authors have accessed and analyzed must be retained and available to journal editors on request and demand by those contending scientific errors or misconduct. At the time of submission of their work, authors represent to journals that their manuscripts will be accurate and their work valid. In addition, many journals and funders encourage or require authors to make the data on which their research articles are based publicly available.[18]

Authors are expected to cooperate with journals when either or both are sued or subpoenaed following publication of an author's article. Authors have a professional and ethical duty to themselves and their coauthors and, as this chapter demonstrates, a contractual duty to the journals they implore to publish their work.

Authors served or threatened with a retraction demand, subpoena, or summons should not ignore the allegations or attempt to manage them on their own. Honest mistakes or statistical errors can and should be addressed forthrightly, in candid conversations with journal editors, so the scientific record can be corrected, reputations can be maintained, and relationships enhanced. Authors should alert the journal promptly if they are alerted by a reader about possible errors in their published articles or if they discover such errors on their own. Avoiding surprise, admitting mistakes, and cooperating with editors are effective, ethical, and smart ways to manage risk and potential harm. Authors who do not thoughtfully consider the potential merit of criticism, especially those who respond with indignation, often invite more scrutiny by their institutions, grant funders, readers, and journalists.

When journals inquire about a retraction demand, allegation of misconduct, or claim of defamation, authors have a singular opportunity to explain their actions, procedures, and decisions regarding their research and resulting published articles. Trust and confidence in authors can be enhanced or undermined in the first exchanges with journal editors who receive allegations

Downloaded from academic.oup.com/book/58841 by guest on 17 October 2026

about a published article. Authors who are overly defensive, assail the motives of others, deflect responsibility, and do not provide a plausible and candid explanation for what happened and why risk alienating editors who are otherwise prone to support, if not defend, the authors from unfair attack.

Conclusion

Submitting a manuscript is tantamount to offering to contract with a journal. The agreement benefits authors, editors, peer reviewers, readers, clinicians, researchers, and publishers, and given that publication is performed in public, it is fraught with opportunities for criticism, fair and feigned. Editors rely on the statements of facts and representations made at and after submission, during peer review and revision prior to publication, and in response to a postpublication inquiry or litigation. Authors' careers, academic promotions, and funding opportunities are tied to successful publication in quality journals. However, reputations of authors, editors, and journals may be at risk following allegations of unintentional or intentional errors, lapses, or failures, even those without merit. In such cases, editors will guide and support authors to manage risk and resolve any concerns. Authors and editors expect each other to be fair, forthright, and transparent when reporting studies and publishing other types of articles and for responding to any postpublication ethical concerns, errors, questions, or allegations of wrongdoing. Letters to the Editor, corrections, and, although much less common, retractions are remedies for correcting the scientific record. Trust, candor, mindfulness, and frequent communication are critical to an author's success in publishing often and in the best journals.

References

1. Copyright Law of the United States. US Copyright Office, Library of Congress. December 2022. Accessed October 22, 2023. https://www.copyright.gov/title17
2. Copyright transfer and authorship statement. *New England Journal of Medicine*. Updated July 7, 2017. Accessed October 22, 2023. https://www.nejm.org/pb-assets/pdfs/NEJM-CTA-2017-1511304215203.pdf
3. The JAMA Network journals' authorship responsibility, acknowledgment, disclosure of potential conflicts of interest, and publishing agreement for corresponding author. Instructions for Authors. JAMA Network. Accessed October 22, 2023. https://jamanetwork.com/DocumentLibrary/InstructionsForAuthors/SampleAuthorshipForm.pdf
4. Flanagin A. Intellectual property: ownership, access, rights, and management. In: Christiansen S, Iverson C, Flanagin A, et al, eds. *AMA Manual of Style: A Guide for Authors and Editors*. 11th ed. Oxford University Press; 2020. Accessed April 12,

Downloaded from academic.oup.com/book/58841 by guest on 17 October 2026

2024. https://academic.oup.com/amamanualofstyle/book/27941/chapter/207564250#395779184
5. Attribution 4.0 International (CC BY 4.0). Creative Commons. Accessed October 22, 2023. https://creativecommons.org/licenses/by/4.0/
6. Finn R. Libel concerns are a reality for scientists who speak out in public. *The Scientist*. March 17, 1996. Accessed August 8, 2023. https://www.the-scientist.com/profession/libel-concerns-are-a-reality-for-scientists-who-speak-out-in-public-58098
7. Flanagin A. Defamation, libel. In: Christiansen S, Iverson C, Flanagin A, et al, eds. *AMA Manual of Style: A Guide for Authors and Editors*. 11th ed. Oxford University Press; 2020. Accessed April 12, 2024. https://academic.oup.com/amamanualofstyle/book/27941/chapter/207564250#395779686
8. Hall-Lipsy E, Malanga S. Defamation lawsuits: academic sword or shield? *EMBO Mol Med*. 2017;9(12):1623-1625. doi:10.15252/emmm.201708489
9. DeAngelis CD, Thornton JP. Preserving confidentiality in the peer review process. *JAMA*. 2008;299(16):1956. doi:10.1001/jama.299.16.jed80000
10. *In re Bextra & Celebrex Marketing Sales Practices & Product Liability Litigation*, 8 C 402, 2008 WL 4345158 (ND Ill Mar 14, 2008).
11. *In re Bextra & Celebrex Marketing Sales Practices & Products Liability Litigation*, 249 FRD 8 (D Mass 2008).
12. Flanagin A. Protecting research participants' and patients' rights in scientific publication. In: Christiansen S, Iverson C, Flanagin A, et al, eds. *AMA Manual of Style: A Guide for Authors and Editors*. 11th ed. Oxford University Press; 2020. Accessed April 12, 2024. https://academic.oup.com/amamanualofstyle/book/27941/chapter/207564250#395779605
13. *Pacira Biosciences, Inc v Am Soc'y of Anesthesiologists, Inc*, 583 F Supp 3d 654 (DNJ 2022); *Pacira Biosciences, Inc v Am. Soc'y of Anesthesiologists, Inc*, 63 F4th 240 (3d Cir 2023).
14. US Food and Drug Administration. FDA Drug Safety Communication: FDA evaluating risk of stroke, heart attack and death with FDA-approved testosterone products. January 31, 2014. Accessed October 22, 2023. https://wayback.archive-it.org/7993/20161022203724/http://www.fda.gov/Drugs/DrugSafety/ucm383904.htm
15. Pfizer's novel COVID-19 oral antiviral treatment candidate reduced risk of hospitalization or death by 89% in interim analysis of phase 2/3 EPIC-HR study. Pfizer.com. November 5, 2021. Accessed October 22, 2023. https://www.pfizer.com/news/press-release/press-release-detail/pfizers-novel-covid-19-oral-antiviral-treatment-candidate
16. U.S. Attorney announces charges in four separate insider trading cases against 10 individuals, including drug company employees, investment firm executive director, and SPAC investors. US Attorney's Office, Southern District of New York. June 29, 2023. Accessed October 22, 2023. https://www.justice.gov/usao-sdny/pr/us-attorney-announces-charges-four-separate-insider-trading-cases-against-10
17. Silverman E. SEC charges former Pfizer statistician with insider trading over Paxlovid clinical trial results. *STAT*. June 29, 2023. Accessed October 22, 2023. https://www.statnews.com/pharmalot/2023/06/29/pfizer-insider-trading-paxlovid-covid19/
18. Flanagin A, Curfman G, Bibbins-Domingo K. Data sharing and the growth of medical knowledge. *JAMA*. 2022;328(24):2398-2399. doi:10.1001/jama.2022.22837

Downloaded from academic.oup.com/book/58841 by guest on 17 October 2026

PART 7

Current and Evolving Issues

Downloaded from academic.oup.com/book/58841 by guest on 17 October 2026

Downloaded from academic.oup.com/book/58841 by guest on 17 October 2026

CHAPTER 39

Data Sharing

Howard Bauchner, MD, and
Phil B. Fontanarosa, MD, MBA

Downloaded from academic.oup.com/book/58841 by guest on 17 October 2026

KEY POINTS

- Data sharing is a process by which the primary investigators of a scientific study agree to share their data and related information with other researchers.
- Data sharing has several potential benefits, including verification of the primary results, generation and testing of new hypotheses, and facilitation of reporting of secondary analyses.
- Authors should be aware that policies related to data sharing vary among journals and should consult the information for authors for the journal to which they intend to submit their manuscript for specific journal requirements for data sharing.
- Authors also should be aware that policies regarding data sharing vary among funders of biomedical research, such as US federal agencies, some European government agencies, foundations, and industry, including some with policies that require the underlying data on which peer-reviewed publications are based to be available on the day of publication.
- Authors of manuscripts based on shared data they have obtained and reanalyzed should ensure that information regarding the data sources and original investigators are clearly described and transparently reported.

Data sharing has emerged as an important concept in science and in biomedical research. Data sharing is a process by which the primary investigators of a scientific study share their data and related information (potentially including data sets, protocols, statistical analysis plans, data dictionaries, computer codes, and other materials) with other researchers or with others who may request the data for reasonable purposes. While the principles of data sharing are

not new, the concept represents the increasing movement toward achieving a more open and transparent scientific process.

Authors of biomedical research reports should be aware of several important issues related to data sharing, including the key concepts involved with data sharing, potential benefits and concerns related to data sharing, responsibilities with respect to requirements and commitments for sharing data, policies of biomedical journals regarding data sharing, and information to include in manuscripts based on shared data.

Key Concepts

Sharing data from clinical trials and other types of clinical studies has several principal purposes, including verification of the original analysis, use in meta-analyses and replication studies, and hypothesis generation for new studies. Data sharing has the potential to advance scientific discovery and increase knowledge gained from data collected in clinical research studies. The data sharing process has generated challenges and controversies, such as, for example, which data should be shared, with whom, and how quickly, and how the investigators who collected the original data should be credited and acknowledged.

The discussion around the need for data sharing has focused on several key issues.[1] One concern is that the evidence base resulting from primary research publications may be incomplete, and data could be lost to the research and patient communities if they are not shared (or never published) and made available for reanalysis or new analyses. In support of this hypothesis is the important contribution that meta-analysis of published data has had in advancing clinical care. However, there is even greater potential for deriving new insights from meta-analysis of individual participant data, which requires sharing of data and collaboration among investigators. Routine sharing of data from clinical trials and other types of studies could facilitate individual participant data meta-analyses, potentially producing estimates of the effects of interventions studied in individual investigations that are more precise, accurate, and directly applicable to different types of patients.

Another important issue is that some researchers either intentionally or inadvertently do not always report important findings from their investigations. The advent and widespread implementation of clinical trial registration and the detailed review of trial registration information, trial protocols, and statistical analysis plans in the evaluation of manuscripts reporting clinical trials, as well as availability of prespecified protocols and analytic plans and other information regardless of the study type, by editors, peer reviewers, and readers has likely reduced inaccurate reporting of clinical trials but cannot eliminate the problem. However, by having all data available for reexamination and

Downloaded from academic.oup.com/book/58841 by guest on 17 October 2026

replication of analyses, data sharing may help ensure that the publications have fidelity to the prespecified plan. Moreover, this approach may inhibit withholding important results, or at least allow them to be discoverable.

Perhaps the most compelling reason in support of data sharing has received less attention: the responsibility to study participants. According to a position statement from the International Committee of Medical Journal Editors (ICMJE), "The ICMJE believes that there is an ethical obligation to responsibly share data generated by interventional clinical trials because participants have put themselves at risk."[2] Such risks may include not only major physical or psychological harms, but also more minor and common harms such as discomfort, inconvenience, and loss of work time. The informed consent process makes clear that participants in research investigations should not expect to benefit personally from their participation. The social contract for research participants taking these risks and potentially experiencing these harms imposes an ethical obligation that the study results should lead to the greatest possible benefit to society.

This social contract is not fulfilled if the research investigation fails to provide useful information; for example, when a clinical trial is underpowered and the findings may be uninterpretable because inaccurate assumptions were made about the potential effect of the intervention, or when a trial is executed in a way that leads to extremely high dropout or introduces other sources of bias. The contract is also not fulfilled if society is not able to make full use of the data generated by trial participants, if the analyses are invalid or incomplete, or if the data, regardless of publication, are not made publicly available. Because it is unlikely that the original researchers can or will conduct all useful analyses, making the data available to other researchers may enable them to gain additional insights or replicate the findings. The absence of data sharing therefore also represents a failure of the obligation of researchers to the study participants, and therefore a failure of the ethical underpinnings of conducting clinical research.

Potential Benefits and Concerns

Data sharing has several potential benefits, including verification of the primary results, generation and testing of new hypotheses, and facilitation of reporting of secondary analyses, either by the original investigators or other investigators. Enabling secondary analyses without having to collect new data to explore related research questions could potentially save time, effort, and costs.

Several potential concerns have been raised about data sharing. Among them is inappropriate use of shared data, including analyses conducted with a primary intention of disproving or discrediting the original study based on the data. If researchers who obtain the shared data are not qualified to conduct the

Downloaded from academic.oup.com/book/58841 by guest on 17 October 2026

analyses or have a biased approach or agenda, analyses based on shared data could be misleading or biased, creating unwarranted confusion with apparent refutation of initial studies. Another concern might be unwelcome scrutiny or examination of data by competing research groups or companies, with the goal of obtaining competitive knowledge or possible advantage. An additional concern that has emerged has been the politicization of science, and whether data sharing could be a way to undermine important findings in controversial areas such as, for example, climate change and reproductive health.[3]

In considering these issues, it may be important to differentiate between the use of shared data for verification of the original analyses and for novel hypothesis generation and analysis. Christakis and Zimmerman[4] suggested an approach to reanalysis focused on verification of findings of the original analyses: (1) the methodological approach must be explicitly stated and justified in advance; (2) the issue of financial conflict of interest and intellectual bias should be minimized in the reanalysis; (3) differences in outcomes between analyses should be described in detail; and (4) authors of the initial analysis should be able to review and comment on the reanalysis. Novel analyses should meet the same standards regarding a priori specification of hypotheses and methods, as well as conflicts of interest, but there may be less of a role for review and comment by the original authors.

Data Sharing Requirements

Sharing data that underpin clinical trials and other studies is an increasingly common requirement mandated by research organizations and sponsors of clinical trials. Data sharing has been supported by numerous groups, including the US National Academy of Medicine, the European Medicines Agency, and the ICMJE.

The US National Institutes of Health (NIH), the leading single international supporter of clinical research, has had long-standing policies on data sharing, and in 2019 proposed an updated NIH Policy for Data Management and Sharing.[5] According to the updated policy and guidance,

> To promote effective and efficient data management and data sharing, NIH expects researchers to manage scientific data resulting from NIH-funded or conducted research and prospectively plan for which scientific data will be preserved and shared. Under this Policy, individuals and entities would be required to provide a Data Management and Sharing Plan (Plan) describing how scientific data will be managed, including when and where the scientific data will be preserved and shared, prior to initiating the research study. Shared data should be made accessible in a timely manner for use by the research community and the broader public.[5]

Downloaded from academic.oup.com/book/58841 by guest on 17 October 2026

According to the NIH Data Management and Sharing Policy that became effective January 2023, NIH-funded researchers must "prospectively plan for how scientific data will be preserved and shared through submission of a Data Management and Sharing Plan," and the policy established "the expectation for maximizing the appropriate sharing of scientific data generated from NIH-funded or conducted research, with justified limitations or exceptions."[6] This announcement applies to data from all biomedical research, not just data from clinical studies; however, the NIH did not mandate data sharing for all research it conducts or funds.

In August 2022, the US Office of Science and Technology Policy (OSTP) directed all federal agencies to develop or update their policies to ensure that peer-reviewed publications and the underlying data resulting from federal funds are freely available and publicly accessible at the time of publication,[7] effectively ushering in a new era of data sharing.[8] However, the OSTP mandate did not address several key challenges in data sharing, including funding for data repositories to enable sharing and how to ensure that those who collected the data are appropriately credited. The current NIH policy may not fulfill the OSTP directive since it encouraged but did not mandate data sharing of all its funded research.

Other major research organizations have policies on data sharing for their grant recipients, such as the UK Medical Research Council and Wellcome Trust. Some major companies involved in drug and device research also have developed data sharing policies, such as Merck, Roche, Johnson and Johnson, Medtronic, and others. Some companies have developed relationships with academic medical centers or other organizations to provide oversight for and administration of requests for shared data.[9] However, the industry has not committed to data sharing of all its sponsored research.

Ethical and Practical Issues

Authors of scientific investigations should be aware of requirements of funders regarding data sharing, some of which may involve consideration of ethical and practical issues. For example, if an investigator is obligated to share data, especially individual patient data, this issue must be addressed prospectively with ethics committees and during the informed consent process.

As an ethical obligation to the individual study participants, the shared data must be deidentified for their protection. It is increasingly clear that effective data deidentification may be difficult to achieve. Regardless of whether an investigator believes data are deidentified, it is important that the actual success of deidentification be validated.

During the informed consent process at the time of enrollment into a clinical trial or any prospective study, study participants must be made aware that

Downloaded from academic.oup.com/book/58841 by guest on 17 October 2026

their deidentified data may be shared, and they must have an opportunity to decline to participate in the investigation because of this specific mandate. It is possible that 2 levels of consent may be necessary, one for consent to participate in the current study and to have data used by these researchers, and a second to authorize having the data shared with other researchers not involved with the study. However, it is also possible that some vulnerable groups of patients who have had concerns about participating in research because of past ethical lapses by investigators may be less willing to participate in research if they are asked to share their data. If so, this could lead to underrepresentation of marginalized populations in some studies, with consequent limitations in the ability to generalize the trial results.

Moreover, a system of sharing data must be efficient. Investigators who have conducted clinical trials are aware of the complexities of contemporary trial design and the underlying statistics and methods. Clinical trials and other research studies, such as those that use data from large administrative databases, often include detailed procedures and documentation about how each data element and variable are coded. Even with a detailed analytic plan, data interpretation may be necessary during the analytic phase. If researchers not involved with the conduct of the initial study try to verify an analysis, it will be important to determine who is responsible for ensuring that precisely the same procedures are followed, and who will provide the resources that this replication requires. If funders mandate sharing of data, they should provide support for the original investigators to maintain the data in a format suitable for sharing or to submit those data to a repository with public access, and thereby enable other investigators to access the data. If support for data sharing is unavailable or insufficient from the study sponsors, it may be necessary for those requesting the data and who need assistance to provide support for the effort required by the original investigators.

Other issues also need to be considered. For example, should there be a fixed time after study conclusion or primary publication during which period there would be a moratorium on publications by investigators other than the original researchers? When must investigators, regardless of whether the primary findings have been published, make the entire data set available? What other information is needed for effective use and reuse of shared data (eg, study protocol, data dictionary, analytic code)? Should an independent and neutral group determine the appropriateness of requests for the data? How should the investigators who collected the data be credited in subsequent publications?

Journal Policies and Requirements Regarding Data Sharing

Biomedical journals have developed policies on data sharing (beyond or in addition to requirements of research funders or sponsors) for manuscripts that

Downloaded from academic.oup.com/book/58841 by guest on 17 October 2026

report the results of original research.[10] While data sharing can apply to virtually any type of research, sharing of clinical trial data has been a priority.

In 2017, the ICMJE issued a data sharing statement policy that applies to manuscripts reporting the results of clinical trials,[2] as follows:

> "As of 1 July 2018 manuscripts submitted to ICMJE journals that report the results of clinical trials must contain a data sharing statement. … Clinical trials that begin enrolling participants on or after 1 January 2019 must include a data sharing plan in the trial's registration. … If the data sharing plan changes after registration this should be reflected in the statement submitted and published with the manuscript and updated in the registry record."

Data sharing statements must indicate the following: whether individual deidentified participant data (including data dictionaries) will be shared ("undecided" is not an acceptable answer); what data in particular will be shared; whether additional, related documents will be available (study protocol, statistical analysis plan, etc); when the data will become available and for how long; and by what access criteria data will be shared (including with whom, for what types of analyses, and by what mechanism).[2]

Authors should be aware that the policies related to data sharing vary from journal to journal and should consult the journal's information for authors for the specific policies of the journal to which they intend to submit their manuscript.

Some journals have taken an approach that requires authors to commit to data sharing as a condition of considering a manuscript for possible publication. For instance, the *BMJ* has had a policy on data sharing for clinical trials of drugs and devices since January 2013 and currently requires that all reports of clinical trials will be considered for publication only if the authors agree to making the relevant anonymized patient-level data available on reasonable request.[11] Likewise, the policies of the Public Library of Science (PLOS) journals, including *PLOS Medicine*, indicate that "PLOS journals require authors to make all data necessary to replicate their study's findings publicly available without restriction at the time of publication" and indicate that "Publication is conditional on compliance with this policy. If restrictions on access to data come to light after publication, we reserve the right to post a Correction, an Editorial Expression of Concern, contact the authors' institutions and funders, or, in extreme cases, retract the publication."[12]

Similarly, according to policies for journals in the Nature Portfolio, "A condition of publication in a Nature Portfolio journal, including *Nature Medicine*, is that authors are required to make materials, data, code, and associated protocols promptly available to readers without undue qualifications. Any restrictions on the availability of materials or information must be disclosed to

Downloaded from academic.oup.com/book/58841 by guest on 17 October 2026

the editors at the time of submission. Any restrictions must also be disclosed in the submitted manuscript."[13]

Many journals do not require data sharing as a condition for consideration of the manuscript for publication but may require a data sharing statement. Since 2016, *JAMA* and the JAMA Network journals have required data sharing statements for reports of clinical trials. Effective October 2022, these journals expanded the requirement for authors to provide a data sharing statement for all research reports (not just for clinical trials).[14] According to this policy,

> "at the time of manuscript submission of any research article, authors are asked a series of questions regarding their plans to share data. Authors are asked to identify the data that will be made available to others, including individual patient data, a data dictionary that defines each field in the data set, and supporting documentation (eg, statistical/analytic code); when, where, and how the data will be available (eg, a link to a data repository); types of analyses that are permitted; and if there will be any restrictions on the use of the data. Authors also have the option to explain why data may not be shared. While the JAMA Network journals endorse the principle of data sharing and have adopted this policy to encourage the sharing of data, sharing is not mandated by the JAMA Network. An author's intention to share data or not will not be considered in the editorial decision."

Similarly, *Annals of Internal Medicine* publishes a statement with every original research article, systematic review and meta-analysis, and brief report indicating the authors' willingness to share the study protocol, the statistical code used to generate results, and the data set on which the results were derived.[15] Authors are required to indicate their willingness to share and any conditions for sharing, which may range from completely unrestricted (eg, free availability on an open access website) to restricted (eg, certain portions of the items available to approved individuals through written agreements with the author or research sponsor).[15]

In addition to policies on data sharing requirements and statements, journals may have policies and procedures for other aspects related to data sharing. An important concern involves whether and how journals should respond if authors do not fulfill their stated data sharing commitments. While some journals may choose to become involved with these disputes, in most cases journals are not able to adjudicate or resolve issues or disagreements related to data sharing, such as determining the appropriateness of requests for shared data and enforcing adherence with sharing obligations. Cases of such disagreement may be resolved more effectively at the institutional level or with the research sponsor. (For more information on data sharing policies, see Section 5.6.1.3, Data Sharing, Deposit, and Access Requirements of Journals, in the *AMA Manual of Style*.[10])

Downloaded from academic.oup.com/book/58841 by guest on 17 October 2026

Each journal also may make determinations about the approach used for evaluation of and responsibilities related to manuscripts based on analyses of shared data from reports that were previously published in that journal, or in other journals. For instance, the journal will determine whether the report based on shared data should be shared with and reviewed by original authors as part of the manuscript evaluation process. Each journal also may determine its responsibility to evaluate and publish reports based on shared data of studies originally published in that same journal (ie, by definition, post hoc analyses), especially for those that report findings that may refute or contradict findings in the original report.

Manuscripts Based on Shared Data

Authors of manuscripts based on shared data they have obtained and reanalyzed should ensure that information regarding the data sources and original investigators is clearly described and transparent. In addition, the content of the manuscript must be fair to and should respect the investment and contributions of the original study investigators.

The source of the original data that have been shared should be clearly identified. This information should be reported in the cover letter that accompanies the submitted manuscript. Journals may have various approaches for reporting details in manuscripts that involve shared data. For instance, this information could be described in detail in the Methods section of the manuscript (or in a supplemental document referenced in the manuscript), including an indication of exactly what was shared (data sets, statistical codes, etc). Any selective use of shared data and any differences from the original analytic approach should be described in detail. A description of the original data source and citations to any original publication and the data repository (if that is how the shared data were accessed) also should be included in the Methods section of the manuscript (or in a supplemental document). The authors of the manuscript also should provide a detailed disclosure of all financial interests and relationships they have (along with other relevant interests), especially those that may be perceived as potentially introducing bias in the analysis, results, and interpretation of studies involving shared data.

In addition, the original investigators who provided the shared data should be appropriately credited in the manuscript. This information should be clearly stated in the Acknowledgment section at the end of the manuscript, and the authors of the manuscript should obtain the permission of the original investigators to be named as providing the shared data. Authors may consider other potential mechanisms to ensure that appropriate credit is given to those individuals who have participated in the original data collection. For instance,

Downloaded from academic.oup.com/book/58841 by guest on 17 October 2026

should one or all the authors of the original investigation be offered the opportunity to participate in the reanalysis or to serve as coauthors on the manuscript? Depending on the intent of the reanalysis this may not be appropriate. Should the original authors have no role in authorship but be invited to assist the individuals in the reanalysis if questions arise during this process? The same criteria for authorship should govern decisions about authorship of manuscripts of shared data.

Conclusion

Data sharing has emerged as an important advance in the conduct of clinical research. Despite the complexity of the task, and the concerns that this may generate among investigators, sharing data from clinical trials and other investigations will most likely become the norm in biomedical research.

Authors of biomedical manuscripts should be aware of the issues surrounding data sharing and their responsibilities related to data sharing as mandated by journals and funders. In addition, authors should follow the instructions and policies of journals to which they submit manuscripts regarding data sharing statements and requirements and should ensure that manuscripts based on shared data acknowledge the sources of those data clearly and completely.

ACKNOWLEDGMENT

This chapter is an updated and modified version of the following previously published article: Bauchner H, Golub RM, Fontanarosa PB. Data sharing: an ethical and scientific imperative. *JAMA*. 2016;315(12):1238-1240. doi:10.1001/jama.2016.2420

References

1. Bauchner H, Golub RM, Fontanarosa PB. Data sharing: an ethical and scientific imperative. *JAMA*. 2016;315(12):1237-1239. doi:10.1001/jama.2016.2420
2. Taichman DB, Sahni P, Pinborg A, et al. Data sharing statements for clinical trials: a requirement of the International Committee of Medical Journal Editors. *JAMA*. 2017;317(24):2491-2492. doi:10.1001/jama.2017.6514
3. Fineberg HV, Allison DB. The use and misuse of transparency in research: science and rulemaking at the Environmental Protection Agency. *JAMA*. 2020;323(7):605-606. doi:10.1001/jama.2019.22026
4. Christakis DA, Zimmerman FJ. Rethinking reanalysis. *JAMA*. 2013;310(23):2499-2500. doi:10.1001/jama.2013.281337
5. Draft NIH Policy for Data Management and Sharing. NIH Office of Science Policy. US National Institutes of Health. November 2019. Accessed July 21, 2023. https://

Downloaded from academic.oup.com/book/58841 by guest on 17 October 2026

osp.od.nih.gov/wp-content/uploads/Draft_NIH_Policy_Data_Management_and_Sharing.pdf
6. Final NIH Policy for Data Management and Sharing. NIH Office of Science Policy. US National Institutes of Health. October 29, 2020. Accessed July 21, 2023. https://grants.nih.gov/grants/guide/notice-files/NOT-OD-21-013.html
7. Nelson A. Memorandum for the heads of executive departments and agencies: ensuring free, immediate, and equitable access to federally funded research. Office of Science and Technology Policy. August 25, 2022. Accessed September 23, 2023. https://www.whitehouse.gov/wp-content/uploads/2022/08/08-2022-OSTP-Public-Access-Memo.pdf
8. Bauchner H, McDermott MM, Butte AJ. Data sharing enters a new era. *Ann Intern Med*. 2023;176(3):400-401. doi:10.7326/M22-3479
9. Ross JS, Waldstreicher J, Bamford S, et al. Overview and experience of the YODA Project with clinical trial data sharing after 5 years. *Sci Data*. 2018;5:180268. doi:10.1038/sdata.2018.268
10. Flanagin A. Data sharing, deposit, and access requirements of journals. In: Christiansen S, Iverson C, Flanagin A, et al, eds. *AMA Manual of Style: A Guide for Authors and Editors*. 11th ed. Oxford University Press; 2020. Accessed April 12, 2024. https://academic.oup.com/amamanualofstyle/book/27941/chapter/207564250#38278995
11. Loder E, Groves T. *The BMJ* requires data sharing on request for all trials. *BMJ*. 2015;350:h2373. doi:10.1136/bmj.h2373
12. Data availability. PLOS One. Accessed September 23, 2023. https://journals.plos.org/plosone/s/data-availability
13. Reporting standards and availability of data, materials, code and protocols. Nature Portfolio. Accessed July 21, 2023. https://www.nature.com/nature-portfolio/editorial-policies/reporting-standards
14. Flanagin A, Curfman G, Bibbins-Domingo K. Data sharing and the growth of medical knowledge. *JAMA*. 2022;328(24):2398-2399. doi:10.1001/jama.2022.22837
15. Information for authors. Annals of Internal Medicine. July 12, 2023. Accessed July 21, 2023. https://www.acpjournals.org/pb-assets/pdf/AnnalsAuthorInfo-1677093169627.pdf

Downloaded from academic.oup.com/book/58841 by guest on 17 October 2026

CHAPTER 40

Preprints, Preprint Servers, and Biomedical Publication

Gregory D. Curfman, MD

Downloaded from academic.oup.com/book/58841 by guest on 17 October 2026

KEY POINTS

- A preprint is the posting of a complete manuscript on a preprint server before the manuscript undergoes peer review and is published by a journal.
- More than 60 preprint platforms now serve a diverse group of scholarly disciplines.
- In June 2019, medRxiv was launched as the first preprint server devoted exclusively to the medical, clinical, and health-related sciences.
- Preprint servers enable researchers to share, comment, and receive feedback on their work prior to journal publication and allow documentation of the provenance of ideas, acting as a guidepost to timeliness, priority, authenticity, novelty, and ownership.
- A potential concern about preprints in clinical research is the posting of unvetted material that could be misleading and possibly harmful to patients.
- Researchers should review journals' policies about preprints when submitting a manuscript that was previously posted as a preprint and should report the preprint (with a citation and link) at the time of submission to a journal.
- Preprint servers are meant to complement traditional peer-reviewed journals, not replace them.

A preprint is the posting of a complete manuscript on a preprint server by authors before the manuscript undergoes peer review and is published by a journal.[1] In many scholarly disciplines, posting the original version of an unpublished manuscript on a preprint server is an accepted step on the pathway toward eventual publication in a peer-reviewed journal. The use of preprints in biomedicine has recently become increasingly common and served as an

important mechanism for the rapid dissemination of preliminary reports of findings related to the SARS-CoV-2 virus and the COVID-19 pandemic.

This chapter reviews the development of preprint servers in scholarly disciplines and in biomedicine, describes the potential benefits and challenges of preprint servers for health sciences, and discusses issues related to preprints that authors should be aware of when submitting their manuscripts to peer-reviewed journals for consideration for publication.

Development of Preprint Platforms

More than 60 preprint platforms serve a diverse group of scholarly disciplines.[2,3] One of the earliest preprint servers, launched in 1991 and operated by Cornell University, is arXiv, which principally serves scholars in mathematics, physics, computer science, and related disciplines. In 2023, this server listed 2.3 million scholarly preprints.[4] Research Papers in Economics (RePEc), officially established in 1997, is another notable example of an early preprint server, and as of 2023 listed 4.5 million works in economics throughout the world.[5] The principal motivation behind the establishment of these preprint servers was to share scholarly information widely, seek comments from other experts in the fields, permit young investigators to begin to develop a track record of scholarship for disciplines in which formal publication in peer-reviewed journals may take years to achieve, and to claim provenance of an idea.

SSRN, formerly known as the Social Sciences Research Network, was first established in 1994 as a preprint server for scholarship in the social sciences and humanities. Following its acquisition by Elsevier in 2016, SSRN expanded in scope and covers numerous additional areas of scholarship, including health sciences, life sciences, and physical sciences.[6] As of 2023, the SSRN eLibrary contained approximately 1.3 million preprints from 70 academic disciplines.[6] Authors may directly upload PDFs of their unpublished manuscripts, and SSRN provides an email service to distribute preprints to registered users. Authors have the option to remove their preprints from the server following publication of an article in a peer-reviewed journal. In some disciplines, such as economics and certain areas of legal scholarship, authors routinely post preprints on SSRN following completion of a research manuscript prior to formal publication.

In 2013, a preprint repository for the life sciences, bioRxiv, was founded; it is hosted by the Cold Spring Harbor Laboratory and funded by the Chan Zuckerberg Initiative. As of 2023, this server included more than 200000 preprints.[7]

Downloaded from academic.oup.com/book/58841 by guest on 17 October 2026

Preprint Servers in Medicine and Health Sciences

Although many preprint platforms serve numerous scholarly disciplines, the biomedical sciences have been more reticent to develop a preprint community. In 1961, the US National Institutes of Health initiated a preprint program for sharing preprints in biological science. The program, known as Information Exchange Groups, was discontinued in 1967 when journals refused to consider manuscripts that had been posted previously as preprints.[1]

In June 2019, medRxiv was launched as a "sister" to bioRxiv by the Cold Spring Harbor Laboratory, Yale University, and the *BMJ* as the first preprint server devoted exclusively to research reports in the medical, clinical, and health-related sciences.[8] Before posting, submitted manuscripts are screened by clinicians to ensure they are legitimate research that has been conducted according to ethical standards. Manuscripts reporting research, systematic reviews and meta-analyses, clinical research design protocols, and data reports may be posted. Preprints may be revised by the authors and reposted after initial posting.[8]

During its first year, medRxiv received 11 052 submissions, and 7695 (69%) were posted.[9] The medRxiv screening process resulted in a 31% denial rate, but data on the reasons for submissions to fail screening criteria have not been reported. As of August 2023, more than 45 000 preprints had been posted on medRxiv.[8]

Between 2020 and 2022, the US National Library of Medicine posted 3300 preprints reporting COVID-19 research that was supported by the US National Institutes of Health (NIH) in PubMed Central and indexed these in PubMed/MEDLINE.[10] In 2023, this was expanded to all research reports supported by the NIH or with an NIH-affiliated author.[11] The NIH encourages investigators to use preprints, defined as "interim research products," "to speed dissemination, establish priority, obtain feedback, and offset publication bias."[12] The NIH is interested in maximizing the communication of interim research products that are created with NIH funding. Therefore, the NIH expects investigators to promote wide public access to interim research products, particularly preprints, funded by the Institutes.[10,11]

Preprints may be cited as formal references and should include standard bibliographic information, such as author names, title, name of preprint server, indication that it is a preprint, date of posting, date of access, and a digital object identifier (DOI) or link to the preprint. Individual preprints often include "cite as" information, and the *AMA Manual of Style* provides guidance for citing preprints in reference lists.[13]

Authors of preprints retain copyright for their work and post their work under Creative Commons open access licenses. (See also Chapter 38, Legal Issues in Biomedical Publication.) Preprint servers have policies to guide authors in updating, revising, and correcting their preprints, including options for withdrawing preprints, as well as linking to subsequent versions published

Downloaded from academic.oup.com/book/58841 by guest on 17 October 2026

in peer-reviewed journals. Authors can check specific preprint servers for guidance on such options.

Potential Benefits of Preprints in Health Sciences

According to information from medRxiv,[14] the posting of preprints has 5 principal benefits for individual researchers and for the biomedical research community. First, posting preprints allows researchers to share, comment, and receive feedback on their work prior to journal publication. Other scholarly communities, such as the economics community, have found this type of feedback from international colleagues to be valuable in revising their work in preparation for submission for formal peer-reviewed publication. In this manner, scholarly preprint servers are intended to complement traditional peer-reviewed journals, not replace them, and represent a potentially helpful step in the path to scientific publication.

Second, preprint servers aim to improve the openness and accessibility of research findings, enhance collaboration among researchers, and, by promoting collaboration among investigators, help to build a better research enterprise. Because preprint servers may be accessed worldwide, they may foster international collaboration, which may promote and enhance the scientific mission.

Third, preprint servers permit interested readers to view early versions of manuscripts later published in peer-reviewed journals. By comparing versions, readers may better appreciate the evolution of the research product and the influence of the peer-review process on the final published article.

Fourth, posting initial drafts of research reports on preprint servers provides a way of documenting the provenance of ideas, acting as a guidepost to timeliness, priority, authenticity, novelty, and ownership. There have been instances of a manuscript under review by a journal being rejected by the editors when a similar study appeared in another (often competing) biomedical journal. It is often difficult, if not impossible, to establish which body of research was completed first, and the authors of the rejected manuscript may rightfully believe that they have been treated unfairly. Posting manuscripts on preprint servers provides documentation of the temporal progress of the research and may help prevent investigators from being "scooped."

Fifth, and perhaps most important from the standpoint of the research community, posting preprints helps to inform ongoing and planned research through more timely reporting of completed research. The new research findings become available much sooner than by waiting for formal peer-reviewed publication. Although preprints have not been formally vetted in a rigorous peer review process, other researchers may better understand the status of and

Downloaded from academic.oup.com/book/58841 by guest on 17 October 2026

progress in a research discipline. While awaiting formal journal publication, the posting of preprints may inform and accelerate the scientific mission.

However, there is concern that some preprints are not subsequently published in peer-reviewed journals in a timely manner or ever, and there may be concerns about the quality of preprints that are not subsequently published. For example, a 2018 study of bioRxiv preprints reported that according to the platform's records that link preprints to external publications, 15 797 preprints had been published, representing 42% of all preprints on the site.[15] Preprints that had been posted more recently were less likely to have been reported as published, whereas of those posted between 2013 and 2016, 67% had been published.[15] A cross-sectional study of 3343 COVID-19 preprints posted on medRxiv in 2020 reported that 1742 (52.1%) had been flagged as having been published in peer-reviewed journals by October 2022.[16] However, a subsequent cross-sectional study that used the preprint server record linking and an additional manual web search found higher rates of publication.[17] Of 1399 preprints of clinical studies posted on medRxiv in September 2020, 1077 (77%) had been published 2 years later, as of September 2022.[17] Another cross-sectional study evaluated publication outcomes of 236 preprints of COVID-19 clinical trials that were posted to medRxiv between 2020 and 2021 and found that 182 (77%) had been published as of November 15, 2022.[18] This study also reported that the 23% of unpublished preprints were less complete and more likely to have "spin" (bias) than preprints that were eventually published.

Authors who post research manuscripts on preprint servers should make a commitment to submit their manuscripts to peer-reviewed journals, revise these manuscripts to address concerns about quality, and attempt to achieve timely publication of their research in the peer-reviewed literature.

Potential Challenges of Preprints in Health Sciences

Preprints involving research in the health sciences pose several challenges, but 2 among them are especially relevant for biomedical publications. Medical and health science authors who are considering posting their work on a preprint server should be aware of these issues and consider them carefully.

First, concern has been raised that health information made accessible to physicians, other health professionals, and the public that has not undergone peer review could possibly pose risks to patients. There are, however, some counterarguments to this concern. For example, before articles are posted on medRxiv, they undergo 2 levels of screening (administrative screening and content screening) to eliminate posting of articles that might be potentially misleading or harmful to patients.

Furthermore, the medRxiv website provides this notice: "Caution: Preprints are preliminary reports of work that have not been certified by peer

Downloaded from academic.oup.com/book/58841 by guest on 17 October 2026

review. They should not be relied on to guide clinical practice or health-related behavior and should not be reported in news media as established information."[8] Readers are given clear notice that preprints report on work in progress and may not be ready for clinical application. Regulatory agencies in the US and around the world are ultimately responsible for the approval of new therapies, which cannot be marketed without the approval from these agencies. Thus, the concern that preprints may pose a risk to patients' well-being is generally unfounded, and the potential benefits of information sharing likely outweigh any risks. However, concerns about the quality of preprints that are not subsequently published do have merit, and readers of preprints should heed notices of caution.

Second, some researchers had previously expressed concern that if a manuscript is posted on a preprint server, that manuscript will no longer qualify for publication in a peer-reviewed journal. This notion derives from the so-called Ingelfinger Rule, promulgated in 1969 by the editor of the *New England Journal of Medicine*, Franz Ingelfinger, MD.[19] The rule states that the journal will not publish articles if the substance of which has been published previously, either in other medical journals or in the public media. Ingelfinger was very firm in the application of the rule, which was carried forward by subsequent editors of the *New England Journal of Medicine* and also has been applied by some other research journals. The clinical research community and the public media are generally aware of the consequences of infractions of the Ingelfinger Rule and abide by it. However, it must be questioned whether this 50-year-old rule, which may have been quite reasonable at the time, is still reasonable today, and it appears that preprints along with meeting presentations are now acceptable exceptions to this rule.

As an indication that journal editors' views about the Ingelfinger Rule are changing with regard to preprints, many biomedical journals have partnered with medRxiv to facilitate direct transfer of manuscripts posted on medRxiv to the journals (referred to as *M2J*) for review for publication. Among the more than 140 partner journals are *BMJ Open*, *JAMA Network Open*, and *PLOS Medicine*.[8] It is anticipated that other journals and publishers will become partners with existing preprint servers or may develop their own preprint servers as the advantages of direct transfer become more widely appreciated. In a 2020 survey of preprint policies among the 100 clinical journals with the highest impact factors, 86% allowed submission of manuscripts previously posted as preprints, 13% evaluated manuscripts that had been posted as preprints using a case-by-case determination, and only 1 journal (1%) had a policy to not consider manuscripts that have been posted on a preprint server.[20] These are examples of how preprint servers are meant to complement peer-reviewed journals, not replace them.

Downloaded from academic.oup.com/book/58841 by guest on 17 October 2026

Considerations for Authors Submitting Manuscripts Previously Posted as Preprints

Authors also should be aware of the policies regarding preprints that are followed by the peer-reviewed journals to which they plan to submit their manuscripts. For instance, *JAMA* and the JAMA Network journals will consider manuscripts that have been posted on preprint servers. Many journals, including *JAMA*, expect authors to indicate whether manuscripts that are submitted for publication are posted on preprint servers, as follows: "When the manuscript is submitted, authors must provide information about the preprint, including a link to it and a description of whether the submitted manuscript has been revised or differs from the preprint."[21] In addition, authors should not post a manuscript that has been submitted to and is under evaluation by a journal on a preprint server (or disseminate it otherwise) without permission of the journal editors.

Conclusions

The future of preprints and preprint servers in biomedical research will certainly evolve in a larger context of new incentives, pressures, and approaches to publication and new modes of communicating research findings. For example, open access publication is one such publishing model, and an increasing number of traditional biomedical journals offer open access publication options or hybrid options, in which journals publish some research articles open access and publish other research articles using the traditional public access publishing model. In addition, funders are adding requirements for the immediate public access to the results of funded research, including posting of preprints. However, it is unknown if preprints and preprint servers will continue to serve as venues for immediate release and sharing of research findings before peer review and publication in journals or will otherwise evolve with other new modes of research dissemination and access.

Preprint servers have had a central role in diverse areas of scholarship over the past 4 decades, and more recently, preprint servers have had an increasingly important role in the dissemination of preliminary research reports on the pathway to more formal biomedical publication. How large that role may become remains to be determined. While preprint servers such as medRxiv have opened a new pathway, other experiments with preprint platforms for biomedical research may also develop. While this experimentation should be guided by sound clinical and ethical judgment, the prudent application of preprint servers to biomedical publication may be reasonably expected to contribute to a better informed and more productive research community, without negatively affecting authors' opportunities to publish their research in peer-reviewed journals.

Downloaded from academic.oup.com/book/58841 by guest on 17 October 2026

References

1. Flanagin A, Fontanarosa PB, Bauchner H. Preprints involving medical research—do the benefits outweigh the challenges? *JAMA*. 2020;324(18):1840-1843. doi:10.1001/jama.2020.20674
2. Kirkham JJ, Penfold NC, Murphy F, et al. Systematic examination of preprint platforms for use in the medical and biomedical sciences setting. *BMJ Open*. 2020;10:e041849. doi:10.1136/bmjopen-2020-041849
3. Preprint server directory. ASAPbio. Accessed October 26, 2023. https://asapbio.org/preprint-servers
4. arXiv. Cornell University. Accessed October 26, 2023. https://arxiv.org/
5. RePEc. Accessed October 26, 2023. http://repec.org/
6. SSRN. Elsevier Inc. Accessed October 26, 2023. https://www.ssrn.com/index.cfm/en
7. bioRxiv. Accessed October 26, 2023. https://www.biorxiv.org/
8. medRxiv. Accessed October 25, 2023. https://www.medRxiv.org
9. Krumholz HM, Bloom T, Sever R, Rawlinson C, Inglis JR, Ross JS. Submissions and downloads of preprints in the first year of medRxiv. *JAMA*. 2020;324(18):1903-1905. doi:10.1001/jama.2020.17529
10. NIH preprint pilot. US National Library of Medicine. Updated April 5, 2023. Accessed October 26, 2023. https://www.ncbi.nlm.nih.gov/pmc/about/nihpreprints/
11. Funk K. NIH preprint pilot expands to include preprints across NIH-funded research. National Institutes of Health blog. February 8, 2023. Accessed October 26, 2023. https://nexus.od.nih.gov/all/2023/02/08/nih-preprint-pilot-expands-to-include-preprints-across-nih-funded-research/
12. US National Institutes of Health. Reporting preprints and other interim research products. Notice number NOT-OD-17-050. March 24, 2017. Accessed October 26, 2023. https://grants.nih.gov/grants/guide/notice-files/not-od-17-050.html
13. Fisher L, Frank P. Preprints and publication of unedited manuscripts. In: Christiansen S, Iverson C, Flanagin A, et al, eds. *AMA Manual of Style: A Guide for Authors and Editors*. 11th ed. Oxford University Press; 2020. Accessed October 26, 2023. https://academic.oup.com/amamanualofstyle/book/27941
14. About medRxiv. Accessed October 25, 2023. https://www.medrxiv.org/content/about-medrxiv
15. Abdill RJ, Blekhman R. Tracking the popularity and outcomes of all bioRxiv preprints. *Elife*. 2019;8:e45133. doi:10.7554/eLife.45133
16. Llor C, Moragas A, Maier M. Evaluation of publication of COVID-19-related articles initially presented as preprints. *JAMA Netw Open*. 2022;5(12):e2245745. doi:10.1001/jamanetworkopen.2022.45745
17. Janda G, Khetpal V, Shi X, Ross JS, Wallach JD. Comparison of clinical study results reported in medRxiv preprints vs peer-reviewed journal articles. *JAMA Netw Open*. 2022;5(12):e2245847. doi:10.1001/jamanetworkopen.2022.45847
18. Spungen H, Burton J, Schenkel S, Schriger DL. Completeness and spin of medRxiv preprint and associated published abstracts of COVID-19 randomized clinical trials. *JAMA*. 2023;329(15):1310-1312. doi:10.1001/jama.2023.1784
19. Definition of sole contribution. *N Engl J Med*. 1969;281(12):676-677. doi:10.1056/NEJM196909182811208

Downloaded from academic.oup.com/book/58841 by guest on 17 October 2026

20. Massey DS, Opare MA, Wallach JD, Ross JS, Krumholz HM. Assessment of preprint policies of top-ranked clinical journals. *JAMA Netw Open*. 2020;3(7):e2011127. doi:10.1001/jamanetworkopen.2020.11127
21. Instructions for Authors. JAMA Network. Updated July 14, 2023. Accessed October 26, 2023. https://jamanetwork.com/journals/jama/pages/instructions-for-authors

Downloaded from academic.oup.com/book/58841 by guest on 17 October 2026

CHAPTER 41

Interacting With the News Media

Deanna Bellandi, MPH, and Philip Greenland, MD

Downloaded from academic.oup.com/book/58841 by guest on 17 October 2026

KEY POINTS

- Authors should respect the journal embargo and be aware of what the specific journal expects and what the authors' institution would like them to do when interacting with the news media.
- Authors should be prepared to educate the reporter. Communicate clearly and keep to the message while avoiding any hype or spin. Authors should not make claims to the media that journal editors would not allow in the article.
- Authors should prepare a roadmap of highlights to help reporters understand a study so that the findings are correctly reflected in news reports.
- It is helpful for authors to try to reserve time when the article is published to speak with reporters who will be on a tight deadline.
- After publication and dissemination of the study findings in the media, authors should enjoy their moment in the spotlight.

"Congratulations, your manuscript was accepted for publication" is welcome news to all authors. In addition to having the study results or other information in the manuscript communicated to the scientific community, authors often also look forward to the opportunity to interact with the news media and disseminate the study findings via coverage in newspapers, television, radio, news websites, and social media. Before reaching out to contact media outlets such as newspapers, television and radio news, news websites, blogs, and others, authors should be aware of journal policies for such interactions and information dissemination so that they do not run afoul of the policies and potentially jeopardize publication of their article. Journals do not all have the same policies but undoubtedly 2 of the most important issues to understand are journal embargo policies and journal rules around the timing of media outreach.

The Journal Embargo

In biomedical publishing, articles that have been accepted for publication will be scheduled for publication at a certain date and time and will be released online, in a formal issue, or both. The journal embargo is the requirement that the information in the accepted articles will not be released to the public until the specific date and time of publication (ie, such release is embargoed until that date and time).

At many journals, such as the JAMA Network journals, manuscript acceptance letters inform authors not to disclose that their manuscript has been accepted "to anyone, except coauthors and contributors, and … without permission of the editor." Since these manuscripts are embargoed until they are published, most authors should not immediately reach out to the media to seek or attempt to promote news coverage of their upcoming publication. But authors can, and should, communicate with their institution's media relations office to begin to coordinate the production of any news releases. This is also the time when authors can connect with the journal's media relations department, if they have one, to learn the rules around the timing of media outreach and to confirm an embargo date and time for publication of their article. Authors also should connect their institution's media relations department with the journal's media relations department.

Navigating an embargo to coordinate news releases and media coverage is not as complicated as it may seem, as long as authors pay attention to the details about when they can share what, and with whom, about their study before it is published. Embargoes are set by journals, vary among journals, and may differ among individual articles, especially those timed to coincide with presentation at medical meetings. Embargo breaks (when a news story is published or broadcast about an article ahead of journal publication) are a serious issue, so both authors and the media are expected to adhere to journal embargo rules.

Why do embargoes exist? According to the *BMJ*, "We do not place embargoes on our material for the fun of it—they are there to ensure that important health information reaches the public domain in a responsible manner. Embargoes also enable competing journalists to work to a common deadline, giving them ample time to contact authors and other related experts, clarify any misunderstandings and write the story well."[1] In an informal poll of news writers conducted in 2017 by the JAMA Network media relations department, the vast majority of respondents indicated that they prefer to have embargoes maintained because it gives them time in advance to work on their stories.

Embargoed early access to upcoming articles scheduled for publication is typically granted to reporters registered or credentialed with journals. That status allows reporters to access journal content in advance (typically, a few

Downloaded from academic.oup.com/book/58841 by guest on 17 October 2026

days before publication) so that they can read studies and work on their stories, which also means interviewing authors and other sources on the condition that no information will be published or shared publicly until after the embargo lifts when the study is published. At the JAMA Network, the embargoed access period generally ranges from 2 to 3 business days prior to the scheduled publication date, although the access period can be longer or shorter. For instance, some articles, especially those with public health importance or urgency, may be released rapidly, without time for prepublication sharing of content with reporters.

During the period of embargoed media access to JAMA Network journals, journal content and related news releases produced by the JAMA Network media relations department are posted online at a password-protected site for credentialed reporters.[2] To be credentialed, members of the media must provide recent examples of their work and they must be reporters, writers, editors, and producers with staff credentials from newspapers, magazines, online news services, wire services, or radio or television networks and stations. Independent journalists (including bloggers) and editors who regularly cover health-related topics also can be credentialed, according to guidelines provided on the JAMA Network website.[3]

The *New England Journal of Medicine* (*NEJM*) typically gives "qualified journalists" embargoed online access to upcoming weekly issues on the preceding Friday before its journal embargo lifts at 5 PM eastern time on Wednesdays, according to the journal website.[4] To qualify for that advanced access, members of the media must produce content daily or weekly and agree in writing to the journal's embargo policy, according to instructions on its website.[5] *NEJM* also cautions on its website that authors "are expected to refrain from discussing their research with reporters prior to publication except during the embargoed access period."[4]

While the embargo remains in place at many journals, the embargo system and reporters' access to scientific content will evolve as changes in biomedical publishing continue to promote more rapid availability of scientific information. (See also Chapter 2, Scientific Journals and the Dynamic Publication Landscape.) Among these developments are an increased proportion of biomedical articles published in open access journals, some journals allowing authors to post copies of their accepted manuscripts on institutional websites or other outlets, and increased posting of research manuscripts as preprints, which raise reporters' awareness of preliminary, non–peer-reviewed research findings and knowledge of forthcoming publication of research reports. (See also Chapter 40, Preprints, Preprint Servers, and Biomedical Publication.) Authors should be aware of the policies of journals to which they submit their manuscript regarding these and other evolving issues related to the journal embargo system and the release of information to reporters and the public.

Downloaded from academic.oup.com/book/58841 by guest on 17 October 2026

Interacting With Reporters

During the time of embargoed access to journal content for the media, authors and their institutions also may engage in media outreach of their own to encourage news coverage. Once reporters are interested in covering soon-to-be-published research articles, authors could take several steps to help ensure the stories are as accurate and complete as possible. Authors should remember that most reporters are not physicians or scientists. In some instances, the reporter assigned to write or produce a story may have never read a peer-reviewed study and would not know the difference between an observational study and a randomized clinical trial. For these reasons, authors should keep descriptions of the research simple without sacrificing important details. To do so effectively means working ahead (prior to participating in the interview with the reporter) to translate a study into a handful of easy-to-communicate and understandable bullet points about the study to help even the most novice reporter not make mistakes while reporting on what a study did and what it found. This guidance is especially true if a study is on a complicated topic, and for the general public many topics are complicated.

Translating a study (this does not mean just sharing the abstract) into key points and a handful of important details with a dose of context is akin to drawing a roadmap for reporters to help them see their way to a story. Authors should work closely with their institution's media relations department so that any news release they might issue is based on that roadmap. The more that can be done to help the media correctly report study findings, the better.

A 2012 observational study published in the *BMJ* reported that higher quality news releases from medical journals were associated with better reporting in subsequent news stories.[6] The JAMA Network writes hundreds of news release briefs each year to help draw media attention to studies in its family of journals, and these news releases are made available to reporters with the embargoed journal content on the JAMA Network For the Media site. Those short news briefs strive to cover the top-line findings, provide some description of the study design, and include mention of limitations of the study so that reporters will then go to the original source full-length article for more details. Even when a study is straightforward in its methods and findings, it is still helpful to provide a study roadmap to reporters who can use it to fact-check their stories before publication. These roadmaps also are helpful references for authors to use when talking to reporters in an interview by telephone or on camera. In addition, authors should not forget the most basic details: Make sure reporters can spell the authors' names correctly, know their primary affiliations, and know the accurate title of the journal publishing the study.

Reporters typically will not share a news story or interview in its entirety with authors before it is published but they often do reach out to authors to recheck facts. Authors should encourage this interaction because it is one

Downloaded from academic.oup.com/book/58841 by guest on 17 October 2026

more opportunity for an author to make sure the reporter really understands the study.

Studies have limitations. The findings should not be exaggerated or overstated in the hope of getting more media attention. Authors should point out absolute risk to reporters and explain why and how absolute risk is important for placing the study findings in context, and they also should explain that relative risk is different but may make the findings look more impressive or appealing because the relative numbers are larger. Authors should be sure to tell reporters when (this is in most cases) a study cannot show causation and instead shows only an association and how the 2 are substantially different. Authors should not gloss over study limitations, but rather should take ownership of the limitations and provide explanations for them. Limitations are important for reporters to understand and to include in news stories so that readers and viewers have important context.

Authors should not be surprised when news stories about their study include outside sources critiquing the work. It is standard practice for reporters to share the article work with other researchers who were not part of the study to offer context, much like expert witnesses in court who weigh in on matters with which they had no direct involvement. When the news stories about their research are disseminated through the media, authors should try to enjoy their moment in the 24-hour news cycle because it may not last long!

(For additional guidance on author relations with the news media, see Section 5.13, Release of Information to the Public and Relations With the News Media, in the *AMA Manual of Style*.[7])

References

1. Resources for media. *BMJ*. Accessed October 27, 2023. https://www.bmj.com/about-bmj/resources-media
2. For the Media. JAMA Network. Accessed October 27, 2023. https://media.jamanetwork.com/
3. Frequently asked questions. JAMA Network. Accessed October 27, 2023. https://media.jamanetwork.com/faqs/
4. Embargo policy. *NEJM*. Accessed October 27, 2023. https://www.nejm.org/author-center/embargo-policy
5. NEJM Media Center. *NEJM*. Accessed October 27, 2023. https://www.nejm.org/media?query=footer
6. Schwartz LM, Woloshin S, Andrews A, Stukel TA. Influence of medical journal press releases on the quality of associated newspaper coverage: retrospective cohort study. *BMJ*. 2012;344:d8164. doi:10.1136/bmj.d8164
7. Flanagin A. Release of information to the public and relations with the news media. In: Christiansen S, Iverson C, Flanagin A, et al, eds. *AMA Manual of Style: A Guide for Authors and Editors*. 11th ed. Oxford University Press; 2020. Accessed October 27, 2023. https://academic.oup.com/amamanualofstyle/book/27941/chapter/207564250#395780044

Downloaded from academic.oup.com/book/58841 by guest on 17 October 2026

Downloaded from academic.oup.com/book/58841 by guest on 17 October 2026

INDEX

For the benefit of digital users, indexed terms that span 2 pages (eg, 52-53) may, on occasion, appear on only 1 of those pages.

Tables and figures are indicated by an italic *t* and *f*, following the page number.

abbreviations, 66, 104
  in editorials, 205
  as pet peeve of journal editors, 260
  for titles, 87
abstract
  Conclusions and Relevance section, 96-97
  Design section, 94
  formats, 91-92
  general principles of, 92-93
  Importance section, 93
  IMRAD format, 91
  Interventions or Exposures section, 95
  Main Outcome and Measures section, 95
  Objective section, 93
  overview, 90-91
  Participants section, 94
  peer review of, 234
  randomized clinical trials, 168-169
  Results section, 95-96
  Setting section, 94
  writing, 55-56
academic libraries, 10-11
active voice
  modifiers and, 78-79
  passive voice vs, 76-77
  readability and, 54
adverse events, presentation tables for, 151-153, 152*f*
AI. *See* artificial intelligence
alternative metrics (Altmetrics; Altmetric score), 14, 23, 25, 29-30
AMA Manual of Style
  abstracts, formatting, 92
  author appeals, 253
  authorship, 268-271
  conflicts of interest, 305
  data sharing, 336
  editorial decisions, 215
  ethical issues, 284, 285
  figures and tables, 134, 141, 156
  inclusive language, 207, 210
  legal issues, 317
  meta-analysis, 178
  news media, 353
  open access, 30, 319
  peer reviewers, requirements for, 238
  plagiarism, 297
  preprints, citing, 342
  public access, 319
  references, 130-132, 130*t*
  research misconduct, 284
  scientific style and format, 65
  statistical methods, 109
  types of articles, 183, 194
  titles and subtitles, 87
ambiguity, 58-59
  modifiers and, 78-79
  as pet peeve of journal editors, 259-260
  pronouns and, 67-68, 77-78
American Statistical Association, 117
Annals of Internal Medicine
  data sharing, 336
  format for abstract, 91
  Journal Impact Factor, 12
  review articles, 187-188
archival tables, 145
article processing charges (APCs), 16, 319-320
articles
  Brief Reports, 194-195, 198
  clinical trials, 165-166
  Editorials, 203-207
  Letters to the Editor, 199-202
  meta-analysis, 175-181
  opinion articles, 208-211
  overview, 6-7
  randomized clinical trials, 166-173
  Research Letters, 194-198
  Review articles, 182-192
artificial intelligence (AI), 233, 271
  peer review and, 228
  search industry, 29
  writing tools, 50-51

Downloaded from academic.oup.com/book/58841 by guest on 17 October 2026

arXiv, 341
audience
  defining terms in table for, 146
  distal, 103
  as factor in selecting journal, 23
  proximate, 103
  social media and, 26
  understanding target audience, 44
author-editor communication, 240-249, 241*t*
  "author outreach" events, 248-249
  cover letters, 244-245
  general recommendations, 241-242
  manuscript submissions, 245
  overview, 240-241
  postacceptance, 248
  postsubmission, 245-246
  presubmission, 242-243
  response letter to revision requests, 246-248
"author-friendly" journals, 23-24
authors
  Brief Reports and Research Letters, 198
  group authors, 277-279
  team science research reports, 277-279
authorship
  author roles and agreement, 267-268
  authorship criteria, 268-269
  changes in, 272-273
  conflicts of interest, 304-314
  corresponding authors, 272
  designating authorship and contributions, 269-271
  honorary and ghost authors, 269
  overview, 6-7
  resolving disagreements among authors, 273
  shared author responsibilities, 271
  team science and, 275-282
  See also ethics and ethical issues

Background (Importance) section, abstract, 93
biomedical journals
  abstract, 55-56
  alternative metrics, 25, 29-30
  Altmetric score, 14, 23
  article processing charges, 16
  audience, 23
  "author-friendly" journals, 23-24
  characteristics of, 10-11
  common writing mistakes to avoid, 58-59
  confidentiality, 286-287
  conflicts of interest and, 304-314
  Creative Commons licenses, 16-17
  Declaration on Research Assessment, 12-13
  Discussion section, 57
  duplicate publication, 287, 288
  duplicate submission, 287, 288
  editing writing for, 54-55
  electronic publishing, 25-31
  ethics in publishing, 17
  evaluation of conflicts of interest, 308-310
  5-Year Journal Impact Factor, 13
  fully open access journals, 17
  general discussion, 8-10
  general writing approach to, 53-54
  h-index, 13
  hybrid journals, 17
  Immediacy Index, 13
  inadvertent pervasive error, 292-293
  incremental publication, 288
  informed consent, 286
  institutional review board, 285-286
  investigating allegations of misconduct, 290-292
  Journal Impact Factor, 11-12, 13, 23
  journal submission process, 22
  legal issues, 316-325
  metrics, 11-14
  misrepresentation, 288-290
  multimedia, 27-28
  open access publishing model, 15, 16-17, 30-31
  overview, 6
  policies on data sharing, 334-337
  predatory journals, 17-18
  preprints, 18, 288
  public access, 15
  publication costs, 23
  publishing models, 14-18
  references, 58
  relative citation ratio, 13
  research misconduct, 284-285
  Scimago Journal Rank indicator, 13
  search, 28-29
  selecting, 21-24
  social media and, 13-14, 26-27
  tables and figures, 58
  traditional publishing model, 15-16
  visual abstracts, 28
bioRxiv, 341, 344
BMJ
  data sharing, 335
  interacting with reporters, 352
  journal embargos, 350
  Journal Impact Factor, 12
  launch of medRxiv, 342
  parameters for full-length research report, 45
BMJ Open, 345
boasts of primacy, 62-63
boilerplate plagiarism, 299

Downloaded from academic.oup.com/book/58841 by guest on 17 October 2026

Bonferroni adjustment, 116
book citations, 129
box-plot graph, 158, 159*f*
brevity and clarity, importance of, 53, 55, 72-74. *See also* conciseness
Brief Reports
  author requirements, 198
  overview, 194-195
  structure of, 195
Burnham, J.C., 224

caveats and limitations, editorials, 205
CC BY (Creative Commons Attribution) licenses, 16, 17, 316, 319, 320-321
CC BY-NC (Creative Commons licenses that restrict commercial reuse), 320
CC BY-NC-ND (Creative Commons licenses that restrict commercial reuse and derivative works), 16-17, 320
Cell, 12
Chan Zuckerberg Initiative, 341
character-preserving plagiarism, 299
chatbots, 50, 228
Chubin, D.E., 222
Citing Medicine, 130-131
Clarivate Analytics, 11
clichés and superlatives, 58-59, 60, 66, 88
clinical guidelines, review articles, 184
clinically meaningful differences of outcome measures, 114-115
clinical significance, RCTs, 172
clinical trials, 165-166. *See also* randomized clinical trials
Cochrane Collaboration's tool, 177
Cohen, J., 117
Cohen *d* value, 117
COIs. *See* conflicts of interest
Cold Spring Harbor Laboratory, 341
collaborators. *See* nonauthor collaborators
comments, editorials, 205. *See also* peer review
Committee on Publication Ethics (COPE)
  plagiarism, 300
  scientific misconduct, 290
Common Rule, 284, 322-323
compensation
  conflicts of interest and, 311-312
  Journal Impact Factor and, 13
conciseness
  abstract, 92
  brevity and clarity, 53, 55, 72-74
  Research Letters, 196-197
  research manuscript titles, 87
Conclusions and Relevance section, abstract, 96-97
confidentiality
  biomedical publications, 286-287
  multimedia in medical journals, 28
  peer review, 226, 228, 233
conflicts of interest (COIs), 304-314
  allegations of undisclosed COI, 310-311
  author's responsibility, 305-308
  bias, 309-310
  biomedical journals' evaluation of, 308-310
  compensation and, 311-312
  evolving issues, 311-312
  intellectual property and, 311-312
  journal editors and, 313
  multimedia and, 311-312
  opinion articles and, 309-310
  overview, 304-305
  peer review, 238
  peer review and, 312-313
  research reports and, 308-309
consent
  confidentiality and, 323
  informed consent, 286, 333-334
Consolidated Standards of Reporting Trials (CONSORT), 112
  guideline, titles, 86-87
  randomized clinical trials, 166-168, 167*f*
contributors, team science, 277
COPE. *See* Committee on Publication Ethics
copyright, 318
cover letters, 244-245, 260
Creative Commons Attribution (CC BY) licenses, 16, 17, 316, 319, 320-321
Creative Commons licenses that restrict commercial reuse (CC BY-NC), 320
Creative Commons licenses that restrict commercial reuse and derivative works (CC BY-NC-ND), 16-17, 320
Crick, F.H.C., 55, 62-63
critical arguments, formulating, 37-41
  Discussion section, 38, 39
  IMRAD acronym, 38
  Introduction section, 38, 39
  Methods section, 38, 39
  outline, 39-41, 40*b*
  Results section, 38, 39
critiquing previous research, 61-62
current and evolving issues
  data sharing, 329-338
  news media, 349-353
  preprints and preprint servers, 340-346

dangling participles, 79
data fabrication, 284
data falsification, 284

Downloaded from academic.oup.com/book/58841 by guest on 17 October 2026

data sharing
ethics and, 333-334
fixed parameters for, 334
informed consent, 333-334
journal policies and requirements regarding, 334-337
key concepts, 330-331
manuscripts based on, 337-338
overview, 329-330
potential benefits and concerns, 331-332
randomized clinical trials, 173
requirements, 332-333
social contract, 331
support for, 334
Declaration on Research Assessment (DORA), 12-13
defamation, 321-322
demographics, 69-71
dependent variable (Y), titles, 86
Design section, abstract, 94
digital object identifiers (DOIs), 129
direct plagiarism, 299
Discussion section
acknowledging strengths and weaknesses of study, 122, 124
addressing implications, 124
appropriate study conclusions, 121-123
biomedical journals, 57
clinical importance of findings, 122
concluding statement, 124-125
content and structure, 120-121
editorials, 205
identifying key result, 121
overview, 120
peer review of, 235
placing results in context, 123-124
purpose of, 121
randomized clinical trials, 171-172
referencing previous studies in, 61-62
Research Letters, 197
research manuscript, 38, 39
Review articles, 191
statistical significance of findings, 122
terminology and language, 122
DOIs (digital object identifiers), 129
DORA (Declaration on Research Assessment), 12-13
double-anonymous peer reviews, 225-226, 227*t*
D-PICO-T format, abstract, 96-97
duplicate publication, 287, 288, 297
duplicate submission, 287, 288, 297
duplication of effort, avoiding, 49

editorial process, 54-55
author-editor communication, 240-249, 241*t*
first editorial decisions, 218-219
handling rejections, 250-253
life cycle of manuscript, 217-218
manuscript assessment, 216-217
overview, 6-7
peer review and, 215-221
pet peeves, 259-263
provisional acceptance, 220, 258
reducing manuscript length, 257
rejection decisions, 220-221
revise and reconsider decisions, 219-220
revision requests, 253-257
See also peer review
Editorials
comments, 205
conciseness, 206
description of caveats and limitations, 205
discussion, 205
evidence-based conclusion, 205
format, 204-205
introductory paragraph, 204
opinion articles vs, 208
overview, 203-204
summary of study, 204-205
terminology and language, 206-207
what to avoid in, 205-206
effect size metrics, 117-118
electronic publishing, 25-31
alternative metrics, 29-30
multimedia, 27-28
open access, 30-31
search, 28-29
social media and, 26-27
Enhancing the Quality and Transparency of Health Research (EQUATOR) Network reporting guidelines, 105, 112, 166
ethics and ethical issues
biomedical journals, 17
biomedical publications, 283-294
confidentiality, 286-287
conflicts of interest, 304-314
data sharing and, 333-334
duplicate publication, 287, 288
duplicate submission, 287, 288
honorary and ghost authors, 269
inadvertent pervasive error, 292-293
incremental publication, 288
informed consent, 286
institutional review board, 285-286
investigating allegations of misconduct, 290-292
legal issues, 316-325
misrepresentation in manuscripts, 288-290
overview, 6-7
plagiarism, 296-302
preprints, 288
research misconduct, 284-285

Downloaded from academic.oup.com/book/58841 by guest on 17 October 2026

evidence-based conclusion, editorials, 205
exaggeration, avoiding, 60-61
exposures, Methods section, 107-108
Expression of Concern notice, 292

figures. *See* graphics and figures; tables and figures
first editorial decisions, research manuscripts, 218-219
5-Year Journal Impact Factor, 13
footnotes
  shared author responsibilities, 271
  tables and figures, 140-141, 146, 301
FORCE11 community, 131-132
forest plot, meta-analysis, 179*f*
format and formatting
  abstract, 91-92
  Editorials, 204-205
  Introduction section, 100-101
  as pet peeve of journal editors, 260-261
  print vs electronic format, 85
  references, 129-131
  tables and figures, 137
free writing, 48-49
fully open access biomedical journals, 17

Grammarly, 300
graphics and figures
  box-plot graph, 158, 159*f*
  choosing, 158-159
  effective use of, 156-158
  enhancing interpretation of, 159-160
  figure legends, 160
  histograms, 158
  Kaplan-Meier curve, 158-159
  meta-analysis, 157*f*
  overview, 155
  scatterplots, 158
  structural figures, 157*f*, 157-158
  survival plot, 158-159
  tables and, 135-136
  Tukey plot, 158
  use of color in, 159
group authors, 277-279

Hacket, E.J., 222
Health Insurance Portability and Accountability Act (HIPAA), 322-323
h-index, 13
histograms, 158
Huth, Edward, 37-38
hybrid biomedical journals, 17
hybrid publishing model, 319

ICMJE. *See* International Committee of Medical Journal Editors
idea-preserving plagiarism, 299
Immediacy Index, 13
Importance (background) section, abstract, 93
inadvertent pervasive error, 292-293
incremental publication, 288
independent variable, titles, 86
Information Exchange Groups, 342
informed consent
  biomedical publications, 286
  data sharing, 333-334
Ingelfinger, Franz, 345
Ingelfinger Rule, 345
institutional review board (IRB), 285-286
intellectual property, 297, 311-312, 318, 320
intentional plagiarism, 299
International Committee of Medical Journal Editors (ICMJE)
  authorship criteria, 268-269
  clinical trial definition, 165-166
  conflicts of interest, 306
  data sharing, 173, 331, 335
  ethical issues, 290
  trial registration, 172-173
interquartile range (IQR), 149
interventions, RCTs, 107
Interventions or Exposures section, abstract, 95
Introduction section, 38, 39, 56
  avoiding critiques of other studies in, 61-62
  background, 99
  content and format, 100-101
  establishing importance of topic, 99-100
  objective, 100
  overview, 98
  peer review of, 234
  randomized clinical trials, 169
  Research Letters, 197
  review articles, 189
  structure, 99-100
introductory paragraph, editorials, 204
IQR (interquartile range), 149
IRB (institutional review board), 285-286
iThenticate, 299-300

JAMA and JAMA Network journals, 44, 66-67
  authorship, 278-279
  Conclusion subhead in Discussion section, 124-125
  conflicts of interest, 305-306, 312
  consent and confidentiality, 286-287
  data sharing, 336
  editors and potential COI, 313
  guidance for use of AI writing tools, 51
  handling rejected manuscripts, 220-221
  interacting with reporters, 352
  Introduction section, guidelines for, 100-101
  JAMA Cardiology, 10

Downloaded from academic.oup.com/book/58841 by guest on 17 October 2026

JAMA and JAMA Network journals (*cont.*)
JAMA Internal Medicine, 12, 217
JAMA Network Open, 16, 17, 63, 345
JAMA Oncology, 10, 17
life cycle of manuscript, 217, 246
Notice of Retraction and Replacement, 293
opinion articles, 209-210
parameters for full-length research report, 45
peer review, 226-227
preprints, 346
references, guidelines for, 127
Review articles, 187, 189
Special Communication articles, 208
statistical vs clinical significance, 172
systematic reviews, 183
tables and figures, instructions for, 136-137
team science research reports, 278-279
titles and subtitles, 86-87
Viewpoints, 209-210
JIF (Journal Impact Factor), 11-12, 13, 23, 29
Joint Declaration of Data Citation Principles, 131-132
Journal Citation Reports, 11
journal editors
conflicts of interest, 313
overview, 240-241
pet peeves, 259-263
postacceptance communications, 248
postsubmission communication, 245-246
See also author-editor communication
journal embargo, 350-351
Journal Impact Factor (JIF), 11-12, 13, 23, 29

Kaplan-Meier curve, 158-159
Kronick, D.A., 223-224

Lancet, The, 66-67
article processing charges, 16
format for abstract, 91
Journal Impact Factor, 12
Notice of Retraction and Replacement, 293
parameters for full-length research report, 45
language. *See* terminology and language
large language models (LLMs), 228, 271
legal issues
copyright, 318
defamation, 321-322
libel, 321-322
open access, 319-320
overview, 316-317
permissions, 320-321
privacy, 322-323
public access, 319-320
publication licenses, 319-320
retractions and liability, 323-325
slander, 321
legends, tables and figures, 140-141, 160
Letters to the Editor, 199-202
don'ts, 201
do's, 200-201
opinion articles vs, 208
libel, 321-322
living reviews, 188
LLMs (large language models), 228, 271

machine learning, 51, 116, 271
Main Outcome and Measures section, abstract, 95
Manhattan plots, 140
manuscript components
abstract, 90-97
Discussion section, 120-125
figures and graphics, 155-160
Introduction section, 98-101
Methods section, 102-110
overview, 6
presentation tables, 144-153
references, 126-132
Results section, 111-118
tables and figures, 134-141
titles and subtitles, 85-88
See also research manuscripts
Medical Essays and Observations, 223-224
MEDLINE database, 9, 29, 199
medRxiv, 340, 342, 344, 346
mega journals, 30-31
meta-analysis
Cochrane Collaboration's tool, 177
common problems with, 180
forest plot, 179*f*
interpreting results, 178-180
MOOSE statement, 177, 180
overinterpretation, 175
overview, 175-176
pooled studies, 177-178
PRISMA statement, 177, 180
publication bias, 177
purpose of, 176
registering, 176-177
reporting guidelines, 177
Meta-Analysis of Observational Studies in Epidemiology (MOOSE) reporting guidelines, 177, 180
Methods section
biomedical journals, 56
exposures, 107-108
general principles of, 103-105
interventions, 107
outcomes, 108
overview, 102-103
participants, 106
peer review of, 234-235

Downloaded from academic.oup.com/book/58841 by guest on 17 October 2026

power and sample size, 108-109
preamble, 106
randomized clinical trials, 107, 169-170
Research Letters, 197
research manuscript, 38, 39
Review articles, 189-190
statistical methods, 109
subsections, 105-109
metrics, biomedical journals, 11-14
misconduct, research
biomedical publications, 284-285
data fabrication, 284
data falsification, 284
Expression of Concern notice, 292
investigating allegations of, 290-292
Notice of Retraction, 292
plagiarism, 284, 296-302
misrepresentation in manuscripts, 288-290
modesty, importance of, 62-63
modifiers, 78-79
MOOSE (Meta-Analysis of Observational Studies in Epidemiology) reporting guidelines, 177, 180
mosaic plagiarism, 299
multimedia
biomedical journals and, 27-28
conflicts of interest and, 311-312

narrative reviews, 183-184, 188
National Institutes of Health (NIH), 13, 15
data sharing, 332-333
Information Exchange Groups program, 342
National Library of Medicine (NLM), 9, 15
National Science Foundation, 298
Nature, 12
Nature Medicine
data sharing, 335-336
Journal Impact Factor, 12
parameters for full-length research report, 45
New England Journal of Medicine (*NEJM*), 44, 66-67
format for abstract, 91
guidelines for references, 127
Ingelfinger Rule, 345
journal embargo, 351
Journal Impact Factor, 12
parameters for full-length research report, 45
review articles, 187
news media
interacting with reporters, 350-351
journal embargo, 350-351
overview, 349
NIH. *See* National Institutes of Health
NLM (National Library of Medicine), 9, 15
nonauthor collaborators
defined, 278
JAMA and JAMA Network journals, 270-271, 278, 279
listing in acknowledgment section, 269
PubMed, 280
in research group, 279-280
noninferiority study design, 104-105
nonstop (free) writing, 48-49
Notice of Retraction, 292
null hypothesis statistical testing, 115-117
numerical values, 74-75

objective, Introduction section, 100
Objective section, abstract, 93
Office of Research Integrity (ORI), 297
Office of Science and Technology Policy (OSTP), 333
open access, biomedical journals, 30-31, 319-320
defined, 15
open access publishing model, 16-17
open peer reviews, 227*t*
defined, 225
perpetual open review, 225
postpublication open review, 225, 228
prepublication open review, 225
opinion articles
conflicts of interest, 309-310
Editorials vs, 208
flexibility of, 210-211
JAMA and the JAMA Network journals, 209-210
Letters to the Editor vs, 208
overview, 208
Special Communication articles vs, 208
titles, 86, 88
ORI (Office of Research Integrity), 297
OSTP (Office of Science and Technology Policy), 333
outcomes, Methods section, 108
outline, research manuscript, 40*b*

paragraph composition and structure, 79-80
closing sentence, 80
supporting evidence, 79-80
topic sentences, 79-80
transitional terms, 80
parallel sentence construction, 78
participants, Methods section, 106
Participants section, abstract, 94
passive voice
active voice vs, 76-77
readability and, 54
patchwork plagiarism, 299
patient-first language, 71

Downloaded from academic.oup.com/book/58841 by guest on 17 October 2026

peer review
Abstract, 234
acknowledgement and credit for, 228
advice and suggestions for reviewers, 231-239
artificial intelligence and, 228
avoiding conflicts of interest, 238
benefits of, 238-239
brief history of, 223-224
chatbots and, 228
collaboration, 226
comments to editors, 236-237
confidentiality, 226, 228, 233
conflicts of interest, 312-313
Discussion section, 235
double-anonymous review, 225-226, 227*t*
editorial process and, 215-221
general approach to, 232-233
general comments, 233-234
humility and, 232
Introduction section, 234
large language models and, 228
Letters to the Editor, 199-202
limitations and weaknesses, 224
Methods section, 234-235
models of, 227, 227*t*
open review, 225, 227*t*
overview, 222
purposes and roles of, 222-223
references and, 129
References section, 235
Results section, 235
single-anonymous review, 225-226, 227*t*
specificity in comments, 232-233, 236
supplements, 235-236
timeliness of, 237-238
title, 233-234
types of, 225-226
people and populations, demographics, 69-72
permissions, 320-321
perpetual open peer reviews, 225
persistent identifiers (PIDs), 129
person-first language, 71
pet peeves, journal editors, 259-263
abbreviations, 260
ambiguity, 259-260
formatting issues, 260-261
not revising cover letter, 260
terminology, 259-260
Philosophical Transactions, 223-224
PICO format, abstract, 96-97
PIDs (persistent identifiers), 129
plagiarism
avoiding, 301-302
character-preserving plagiarism, 299
defined, 284, 297
idea-preserving plagiarism, 299
overview, 296
plagiarism detection software, 299-300
ramifications of, 300-301
scope of, 298-299
self-plagiarism, 297, 298, 300-301
semantics-preserving plagiarism, 299
syntax-preserving plagiarism, 299
types of, 299
planning framework, scientific writing, 44
PLOS journals. *See* Public Library of Science journals
PLOS Medicine, 345
article processing charges, 16
Journal Impact Factor, 12
Policies on Research Misconduct, 296
pooled studies, meta-analysis, 177-178
position papers, 188
postacceptance communications, 248
postpublication open peer reviews, 225, 228
postsubmission communication, 245-246
power and sample size, Methods section, 108-109
preamble, Methods section, 106
predatory biomedical journals, 17-18, 30-31
Preferred Reporting Items for a Systematic Review and Meta-Analysis (PRISMA) statement, 177, 180, 191-192
preprints, 18
benefits of, 343-344
biomedical publications, 288
defined, 340
disadvantages of, 344-345
policies regarding, 346
references and, 129
preprint servers
arXiv, 341
bioRxiv, 341, 344
development of, 341
in medicine and health sciences, 342-343
medRxiv, 340, 342, 344-345, 346
overview, 340-341
Social Sciences Research Network, 341
prepublication open peer reviews, 225
presentation tables
adverse events, 151-153, 152*f*
noncount descriptive statistics, 146
number precision, 146
overview, 144-145
recommendations for, 145-147
reporting results, 150*f*
for results, 149-151
sample characteristics, 147-149, 148*f*
presubmission inquiries, 242-243
prewriting, 43-44

Downloaded from academic.oup.com/book/58841 by guest on 17 October 2026

PRISMA (Preferred Reporting Items for a Systematic Review and Meta-Analysis) statement, 177, 180, 191-192
privacy
  biomedical journals, 322-323
  multimedia in medical journals, 28
  See also confidentiality
Proceedings of the National Academy of Sciences, 91
procrastination, overcoming, 45-46
pronoun usage, 77-78
proofreading, 58
providers, 71-72, 206, 259-260
provisional acceptance, 220, 258
public access, biomedical journals, 319-320
  defined, 15
  traditional publishing model, 15-16
publication costs, 23
publication licenses, 16-17, 319-320
Public Library of Science (PLOS) journals
  data sharing, 335
  PLOS Medicine, 12, 16, 345
publishing models, biomedical journals, 14-18
PubMed Central, 9, 15, 155
PubMed database, 9, 29
  authorship, 279, 280
  titles, 86
P values, 115-118

randomized clinical trials (RCTs)
  abstract, 168-169
  Consolidated Standards of Reporting Trials (CONSORT) statement, 166-168, 167*f*
  data sharing, 173
  describing in Methods section, 107
  Discussion section, 171-172
  EQUATOR Network reporting guidelines, 166
  Introduction section, 169
  Methods section, 169-170
  power and sample size, 108-109
  reporting, 166-168
  Results section, 170-171
  statistical vs clinical significance, 172
  title, 168
  trial registration, 172-173
Rankin Scale Score comparisons, 140
rapid reviews, 188
RCR (relative citation ratio), 13
RCTs. *See* randomized clinical trials
references
  biomedical journals, 58
  book citations, 129
  choosing which to include, 127-129
  digital object identifiers, 129
  emerging practices, 131
  formatting, 129-131, 130*t*
  importance of, 126-127
  Instructions for Authors, 128
  overview, 126
  peer-reviewed articles, 129
  peer review of, 235
  persistent identifiers, 129
  preprints and, 129
  reference management software tools, 131, 132*t*
  resources for, 130-131
  website, 129
registering
  meta-analysis, 176-177
  RCT trial registration, 172-173
rejections, 220-221
  appealing rejection decisions, 252-253
  handling, 250-253
  with review, 251-252
  without review, 251
relative citation ratio (RCR), 13
Rennie, Drummond., 222-223
RePEc (Research Papers in Economics), 341
reporting guidelines
  EQUATOR Network, 105, 112, 166
  CONSORT statement, 86, 112, 166
  MOOSE statement, 177, 180
  PRISMA statement, 177, 180, 191-192
  STROBE statement, 86, 112
Research 4Life Hinari program, 31
research groups, team science, 279-281
Research letters
  author requirements, 198
  conciseness, 196-197
  Discussion section, 197
  format, 197-198
  Introduction section, 197
  Methods section, 197
  overview, 194-195
  reporting outcomes, 196
  Results section, 197
  structure of, 195-198
research manuscripts
  assessment criteria, 216-217
  based on data sharing, 337-338
  conflicts of interest and, 308-309
  Discussion section, 38, 39
  Introduction section, 38, 39
  life cycle of, 217-218
  Methods section, 38, 39
  outline, 39-41, 40*b*
  Results section, 38, 39
  See also editorial process; manuscript components; peer review

Downloaded from academic.oup.com/book/58841 by guest on 17 October 2026

Research Papers in Economics (RePEc), 341
Results section
  abstract, 95-96
  biomedical journals, 56-57
  clinically meaningful differences of outcome measures, 114-115
  effect size metrics, 117-118
  EQUATOR Network reporting guidelines, 112
  null hypothesis statistical testing, 115-117
  organization of, 112-113
  overview, 111
  peer review of, 235
  presenting outcome data, 113-115
  primary outcomes, 95-96
  purpose of, 118
  P values, 115-118
  randomized clinical trials, 170-171
  reporting statistical testing, 115-118
  Research Letters, 197
  research manuscript, 38, 39
  Review articles, 190-191
  secondary outcomes, 96
  use of tables and figures, 112, 113
retractions and liability
  biomedical journals, 323-325
  Notice of Retraction, 292
  Notice of Retraction and Replacement, 293
Review articles
  Annals of Internal Medicine, 187-188
  clinical guidelines, 184
  Discussion section, 191
  factors to consider before writing, 184-186
  Introduction section, 189
  JAMA and JAMA Network journals, 187
  journal guidelines for, 186-188
  Methods section, 189-190
  narrative reviews, 183-184
  New England Journal of Medicine, 187
  overview, 182
  preparing, 188-192
  Results section, 190-191
  scoping reviews, 184
  systematic reviews, 183
  tables and figures, 191-192
  titles, 189
  umbrella reviews, 184
revise and reconsider decisions, 219-220
revision requests
  reducing manuscript length, 257
  responding to, 246-248, 253-257
Royal Society of Edinburgh, 223-224
Royal Society of London, 223-224

salami publication, 288
scatterplots, 158
Scheffé procedure, 116
scholarly tone of writing
  avoiding spin and boasting, 68
  first-person pronoun usage, 67-68
  language, 66-67
  objectivity, 68
  overview, 65-68
Science
  format for abstract, 91
  Journal Impact Factor, 12
scientific writing
  abstract, 55-56
  active vs passive voice, 76-77
  adapting for selected journal, 45
  artificial intelligence and, 50-51
  biomedical journals, 53-59
  common mistakes to avoid, 58-59
  conducive environment for, 47
  Discussion section, 57
  duplication of effort, avoiding, 49
  editing, 54-55
  finding writing zone, 46-48
  formulating critical arguments, 37-41, 40*b*
  general approach to, 53-54
  Introduction section, 56
  managing and tracking source materials, 49-50
  Methods section, 56
  modifiers, 78-79
  overcoming procrastination, 45-46
  overview, 6
  paragraph composition and structure, 79-80
  parallel construction, 78
  planning framework, 44
  prewriting, 43-44
  pronoun usage, 77-78
  purpose of, 42-43
  references, 58
  Results section, 56-57
  scheduling writing sessions, 47
  sentence structure, 75-76
  spin and boasting, avoiding, 60-63
  subject-verb agreement, 77
  tables and figures, 58
  terminology and language, 68-75
  tone, 65-68
  understanding target audience, 44
  verb tense, 77
  writer's bock, 48-49
Scimago Journal Rank indicator, 13
scoping reviews, 184
search, biomedical journals, 28-29
segmented publication, 288
self-plagiarism, 297, 298, 300-301
semantics-preserving plagiarism, 299
sensationalizing data, avoiding, 60-61

Downloaded from academic.oup.com/book/58841 by guest on 17 October 2026

sentence structure, 75-76
clauses, 75
complex sentence, 76
compound-complex sentence, 76
compound sentence, 75-76
overview, 75
phrases, 75
simple sentence, 75-76
Setting section, abstract, 94
Similarity Check, 299-300
single-anonymous peer reviews, 225-226, 227*t*
site licenses, academic libraries, 10-11
slander, 321
SMD (standardized mean difference), 149
social media, 13-14, 26-27
Social Sciences Research Network (SSRN), 341
Software Citation Principles, 131-132
source materials, 49-50. *See also* references
Special Communication articles, 208
spell-check, 58
spin and boasting, avoiding, 68
boasts of primacy, 62-63
claims of clarity and strength, 62
disparaging previous research, 61-62
learning from others, 63
overview, 60
sensationalizing data, 60-61
SSRN (Social Sciences Research Network), 341
stakeholders, 72, 206, 259-260
standardized mean difference (SMD), 149
statistical methods, describing, 109
statistical significance, RCTs, 172
Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) reporting guidelines, 86-87, 112
structural figures, 157*f*, 157-158
structure
Brief reports, 195
Discussion section, 120-121
Introduction section, 99-100
paragraph composition, 79-80
Research Letters, 195-198
sentence structure, 75-76
subject-verb agreement, 77
submissions, manuscript, 245
subsections, Methods section, 105-109
exposures, 107-108
interventions, 107
outcomes, 108
overview, 105-109
participants, 106
power and sample size, 108-109
preamble, 106
RCTs, 107
statistical methods, 109
subtitles, research manuscript, 87
summary of study, Editorials, 204-205
supplemental material
peer review, 235-236
research letters, 195, 197
survival plot, 158-159
syntax-preserving plagiarism, 299
systematic reviews, 183

tables and figures
archival tables, 145
binary comparison table example, 137, 138*t*
biomedical journals, 58
box plots and Kaplan-Meier curve, 138-140, 139*f*
conveying most important findings in, 135
example of table and forest plot for a subgroup analysis, 142*f*
figures and graphics, 155-160
figure-table false dichotomy, 141
footnotes, 140-141
general principles of, 135
graphics and, 135-136
journal guidelines, 136-137
legends, 140-141
multipanel figures, 156
overview, 134
presentation tables, 144-153
in Results section, 112, 113
review articles, 191-192
titles, 140-141
types of figures, 140
visual format, 137
task shifting, 48
team science and authorship, 275-282
authors, 277
collaborators, 278
contributors, 277
group authors, 277-279
JAMA and the JAMA Network, 278-279
overview, 275-277
research groups, 279-281
terminology, 277-278
Writing Committee, 280-281
template plagiarism, 299
terminology and language
brevity and clarity, 53, 55, 72-74
demographics, 69-71
numerical values, 74-75
overview, 68-75
patient-first and person-first language, 71
people and populations, 69-72
as pet peeve of journal editors, 259-260
provider, 71-72
stakeholders, 72

Downloaded from academic.oup.com/book/58841 by guest on 17 October 2026

titles, 85-88
  conciseness, 87
  CONSORT reporting guideline, 86-87
  dependent variable, 86
  first impressions, 85
  including study design in, 86-87
  independent variable, 86
  opinion piece titles vs manuscript titles, 86, 88
  peer review of, 233-234
  print vs electronic format, 85
  randomized clinical trials, 168
  review articles, 189
  subtitles, 87
  tables and figures, 140-141
tone of writing
  avoiding spin and boasting, 68
  first-person pronoun usage, 67-68
  language, 66-67
  objectivity, 68
  overview, 65-68
traditional publishing model, 15-16, 319
translational paraphrasing, 299
trial registration, RCTs, 172-173
Tukey plot, 158
Tukey test, 116
Turnitin, 299-300

umbrella reviews, 184
US Code of Federal Regulations, 284
US Preventive Services Task Force, 184
US Public Health Service, 296, 297

verbatim plagiarism, 299
verb tense, 77
Vimeo, 27
Viper, 300
visual abstracts, 28

Watson, J.D., 55, 62-63
White House Office of Science and Technology Policy, 15
World Association of Medical Editors (WAME), 297
writer's block, 48-49
  defined, 48
  free writing, 48-49
  task shifting, 48
  visualizing ideas, 48-49
Writing Committee, 280-281
writing zone, finding, 46-48

X (independent variable), titles, 86

Y (dependent variable), titles, 86

Downloaded from academic.oup.com/book/58841 by guest on 17 October 2026

Downloaded from academic.oup.com/book/58841 by guest on 17 October 2026

Downloaded from academic.oup.com/book/58841 by guest on 17 October 2026