

Publication planning: promoting an ethics of transparency and integrity in biomedical research

Biomedical research should include plans to communicate complete and accurate results to the scientific community and the public in a timely manner. All too often, however, such planning is lacking until after data have been generated. We developed a collaborative professional statement following review of the indexed biomedical literature and relevant professional society guidelines. Planning for publications before, during and after biomedical research studies are conducted promotes the timely dissemination of accurate and comprehensive results. Effective publication planning accounts for the work of all contributors, encourages full transparency and contributes to overall scientific integrity. Although the most obvious contribution of publication planning is to result dissemination, the best planning may also help improve the overall quality of research study design and the overall integrity of study conduct by keeping the final audience in the forefront of the investigators' attention. Publication planning can help biomedical researchers achieve and maintain high standards of transparency and integrity. Table 1 below highlights briefly some of the aspects to be included in a publication plan.

Introduction

Biomedical research delivers the evidence base that healthcare professionals rely on for making individual and public health decisions (1). Generally, this research is undertaken with a clear sense of the health issues under investigation; however, developing quality research questions and choosing appropriate scientific methods for generating and analysing data is not enough. A supportive and well-organised plan ensuring that the research and its results are communicated clearly to the scientific and healthcare communities as well as the general public is essential. In fact, the most basic principles of biomedical ethics outlined in the Declaration of Helsinki (2013) or the Pharmaceuticals Research and Manufacturers (PhRMA) Code (2013) indicate that timely result dissemination and publication is not only prudent but also imperative to support overall biomedical research integrity (2,3). Government research grants

and corporate integrity agreements between industry sponsors and regulators provide a further impetus for publication planning (4).

The fourth principle of the recently published "Good Publication Practice for Communicating Company-Sponsored Medical Research: GPP3" states the following: "Publication planning and development should be a collaboration among all persons involved (for example, clinicians, statisticians, researchers, and publication professionals, including medical writers) and reflect the collaborative nature of research and the range of skills required to conduct, analyze, interpret, and report research findings" (5). In order to ensure the accurate, complete and timely publication of the findings of biomedical research, publications need to be planned in accordance with the objectives and outcomes of the research.

A 'publication plan' is itself a document or an electronic repository that contains key information about all publications, abstracts and presentations intended to be generated from a given research study or clinical programme along with timing and additional information (Table 1). Many corporate integrity agreements require an auditable monitoring plan for publications, including timing (6,7). Publication plans that list abstract deadlines of scientific meetings, key data delivery dates and possible meta-analyses or subgroup analyses can facilitate resource allocation while helping to ensure complete and timely disclosure of relevant data (3,5,8,9). Although a plan is an important component of overall publication planning, it is not synonymous with such planning, which can have farther-reaching effects than simple logistics.

We consider publication planning, consistent with statements issued by the International Society of Medical Publication Professionals (ISMPP) and Good Publication Practice (GPP3), to include tasks such as scheduling, organising working groups, selecting authors and journals, supporting authors, managing

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Table 1 Information to be documented in an effective publication plan

Key element	Explanation
Authors	All persons who agree to meet the appropriate qualifications for authorship. The author list should be updated prior to submission, once the authorship criteria are verified. It may be helpful to list (as applicable) the corresponding author, a lead academic author and/or a lead sponsor author in the publication plan.
Contributors	Additional contributors to the study or manuscript, including publication planners. A key contact (with contact information) should be provided for each manuscript, abstract and presentation.
Data and timing	Specific datasets/analyses, by planned manuscript or presentation. Timing for data to be included in each manuscript, such as the date of the top line report, last subject last visit and the deadline for including data in a results registry all should be recorded or referred to the appropriate data owner (for example, the clinical tracking records for individual studies or programmes). The publication plan should clearly link primary and secondary analyses of any study, even if they appear in different manuscripts, through the use of protocol numbers or clinical trial registry numbers.
Journal(s) and other venues	The intended journal for submission and a backup in case of rejection, as well as the names and locations of all congresses, where the data are planned to be presented. Timing for congresses (submission deadlines, presentation deadlines), peer review, journal revisions and page proofs should be documented in the publication plan.
Publication team or steering committee members	If different from the authors and contributors.
Status	For initial manuscripts: draft, submitted, accepted or published. For rejected manuscripts: reformatting, resubmitted, accepted or published. Citations should be recorded for all presented or published work. It is helpful if citations for abstracts, posters and the manuscript describing the same dataset are linked in some way.

correspondence and coordinating meetings, as well as additional administrative tasks that may be required to ensure that these activities run effectively and efficiently. Publication planning can contribute to better and more responsible communication of biomedical research results. Table 1 above highlights key items to be included in a publication plan.

After making intellectual contributions to manuscripts, researchers may lack the time required to complete additional administrative tasks, and could need assistance, which has increasingly been provided by publication planning professionals. Furthermore, particularly when incorporated in the design and conduct of biomedical research, publication planning should involve an examination of how the research fits into the existing field of knowledge, which can contribute to the overall quality of a study (5,10,11). In fact, publication planning is an important part of the core framework for responsible scientific research because it promotes transparency and ethics at all stages of research as well as accurate result reporting once a study is completed.

The publication planning field arose, largely in the last twenty years, as professional medical writers and editors were called upon to assist authors with various tasks, including manuscript preparation, journal selection and correspondence (8,11). Professional publication planners engage in various planning activities and maintain publication plans, especially at medical communications agencies and in industry. The profes-

sion has been associated in the popular press and biomedical journals with deliberate publication bias, improper attribution of authorship and other ethical lapses (1,12–19). However, responsible publication planning can aid researchers and sponsors in avoiding or correcting inappropriate authoring practices or bias and ensuring the full and timely publications, thus increasing transparency. In addition, the direct involvement of advisory boards and experts responsible for study design and data interpretation in the publication planning process can lead to overall improvement in the research itself. Publication planning continues to gain importance with the global growth of health research and the proliferation of clinical trial registries, patient advocacy web sites and social media.

Box 1 Ethical Issues in Publication Planning

- Authorship
- Communicating trial results of significant clinical importance
- Contributorship
- Duplicate/redundant publication
- Plagiarism
- Publication bias
- Reportable transfers of value
- Selective submission of positive results
- Transparency

We discuss selected issues in publication ethics and the role of proper planning in improving the overall integrity of the research process, from initial design to data dissemination. Much more attention should be given to publication planning at the onset of study design. Certain key questions should be part of this discussion. How can this research contribute to the current body of knowledge in this area of medicine? What do clinical scientists, healthcare providers and patients expect? Where should we consider publishing or presenting study results? Which scientists, clinicians, patient groups and editors should understand and engage in the discussion of this research?

Publication ethics

Broadly conceived, biomedical ethics requires protection of the rights of patients and human subjects enrolled in research studies (2). This research should be conducted and communicated transparently, following applicable regulatory and professional guidelines (2,20). Special concerns for authors, contributors and editors of biomedical publications, such as authorship, financial disclosures and selective publishing of positive results, have been addressed by various groups (2,5,10,11).

The International Committee of Medical Journal Editors (ICMJE) published the initial Uniform Requirements for Manuscripts Submitted to Biomedical Journals (1978) to specify formatting standards. As they were called on to address topics such as author selection and financial disclosure, the Uniform Requirements were updated to address ethical concerns, such as authorship and the use of trial registries to help prevent redundant or duplicate publication and make results more accessible (2,5,11,20,21). The ICMJE released additional statements, notably, Sponsorship, Authorship and Accountability (2003), which detailed the need for greater transparency in industry-sponsored clinical trial conduct and manuscript preparation as well as author accountability for study results (12). In 2013, the Uniform Requirements were replaced by the Recommendations for the Conduct, Reporting, Editing and Publication of Scholarly Work in Medical Journals, which links the overall quality of research to effective publication practices (20,21).

In 1997 the Committee on Publication Ethics (COPE) was formed during an informal meeting of medical journal editors concerned to address a wide range of research misconduct from fraud to authorship disputes. COPE went on to widely expand its membership as well as developing ongoing guidance, particularly with regard to corrective measures, such as corrections or retractions, to be taken when instances of research misconduct are discovered in

connection with already published work, and also to publish case studies on a monthly basis. The COPE Guidelines, Code of Conduct and discussion documents are supplemented regularly and are a beneficial source of information about current ethical concerns and practice in biomedical publishing (22).

The introduction of Good Clinical, Laboratory and Quality Practice guidances for industry by the International Conference on Harmonization (ICH) group, particularly during the early 1990's, was designed to regularise drug development and clinical trial conduct in industry and to set minimum standards for ethical study conduct (23). The ICH Guidelines also indicated that information about planned publications should be included in clinical trial protocols and reports (24), which spurred the development of more detailed guidelines for manuscripts produced by industry sponsors. The initial 'Good Publication Practice' papers appeared in 2000 and 2003 (8,25). These publications were intended to encourage transparency of research practices and results and to reiterate the obligations and privileges associated with authorship. The recently published GPP3, the updated standard for publication planning by industry sponsors and communication agencies, introduces 10 valuable principles for guiding publication practices and begins the guideline with an entire section on publication planning. These provide valuable revisions to GPP1 and GPP2 (5,8,11,24). GPP3 extends the recommendations of GPP2 regarding the early planning for publications, the formation of steering committees, and clarifying the roles of authors and other contributors, especially professional medical writers (11).

Professional organisations provide information about publication ethics. Specific guidance for publication professionals includes the ISMPP Code of Ethics, a code that focuses on the responsibilities of authors, writers and editors. PhRMA also introduced a set of principles that recommend full disclosure of trial results in registries and publications and emphasises that results of more significant medical importance (such as findings that should affect current prescribing practice or trials of marketed products currently used in children or other vulnerable populations) be prioritised (1,3,10). Many organisations, including medical centres, corporations, academic institutions and government agencies develop and maintain publication policies; these policies may limit the abilities of authors to accept writing assistance or the potential uses of certain publications. Corporate Integrity Agreements often delineating minimum standards for industry sponsors engaged in publishing biomedical research results, including the need for publication plans and policies (26,27). All authors and contributors should be familiar with best practices and the codes of conduct and ethics for their individual professions.

How planning may address key concerns in publication ethics

Some questionable publication practices, particularly problems with acknowledgements and citations, may occur through ignorance or poor organisation and communication. Publication professionals can provide guidance about best practices and ensure adequate documentation and tracking of all stages of manuscript development, author agreements, data checking and approvals. In environments where publication planners are not available, authors should keep records of these activities. Authors or publication planners should also develop and update a formal publication plan (see Table 1) that accounts for anticipated publications and their timing on a regular basis; such a plan may stand alone or be integrated to a more general data dissemination plan that includes any public release of clinical data (for example, to trial registries or the press).

Planning should account for adequate time to perform all necessary tasks. Allotting adequate time for review may help mitigate or prevent problems such as plagiarism. Assigning responsibility and time for reference checking to one or more contributors will permit the detection of unintentional copying or insufficient citations, which can also be supported by the use of specialised software.

Authors should familiarise themselves with guidelines, such as GPP3 and the ICMJE Recommendations. Professional publication planners or lead authors should encourage and facilitate conversations about difficult topics, such as data interpretation and authorship, to ensure that actual practice meets the scientific and ethical standards of all professionals involved in discussions and authoring. Below, we discuss topics of special interest: authorship and acknowledgement, transparency and duplicate or redundant publication.

Authorship and acknowledgements

Publication planners are regularly called upon to provide advice regarding appropriate practices for author and journal selection. Where the desire to adhere to ethical practice exists, unintended problems related to authorship may be avoided through rigorous planning. For example, a missing acknowledgement of writing support results in a ghost written paper, a serious ethical lapse, which can raise concerns regarding the overall integrity of the manuscript. If the named authors did not significantly contribute to the paper, guest authorship results and can raise similar concerns. The larger the number of contributors involved in a study or publication, the greater the challenge to include and document all

expert views. Proper planning can allow authors and writers to track comments and contributions more effectively.

Planning for good authoring practice requires a familiarity with the criteria for authorship. The most commonly used criteria: contribution to the study or interpretation of data, writing or substantially editing the manuscript, and approving the paper for publication; appeared in the ICMJE Uniform Requirements in 1988 and have been cited in GPP3 and corporate integrity agreements issued in the USA (4,11,20). As with other topics in the Uniform Requirements, authorship criteria have been clarified and expanded over the years. The 2013 'Recommendations' expanded these criteria to include taking public responsibility for the work and guaranteeing that all work reported in the publication was undertaken correctly (20). This shift reflects updates to the 2002 and 2005 Uniform Requirements, which request that data be guaranteed by at least one author and that all authors should take public responsibility for the work they performed (21).

Regulatory requirements for the initiation and conduct of clinical trials allow for early attention to publication plans. GPP3, ICH Good Clinical Practice, and guidelines from the World Health Organization (WHO), European Medicines Agency (EMA) and PhRMA indicate that roles and responsibilities for trial conduct and authorship should be identified before writing begins, if possible during the study design phase, and updated as needed (3,5,11). The EMA and ICH suggest the early identification of a principal investigator who could serve as the chair of a steering committee or the lead author for primary publications (23,24). Large-scale clinical trials are generally conducted by large, multidisciplinary groups of researchers and administrators. Effective publication planning must account for different configurations of such groups and allow time for discussions to manage differing thoughts.

Assignment of roles and responsibilities for publications early in the study process can limit problems at a later stage. Authors, reviewers and professional medical writers should receive clear guidance regarding the scope and timing of their responsibilities well before publication writing begins, ideally before the statistical analysis plan is finalised. Completion of authoring tasks should be documented. Writing should never begin before careful consultation with all authors, who should be informed of their duties well in advance of data availability. Furthermore, professional medical writers should not be engaged unless all authors have had a clear opportunity to opt in or out of receiving such support, particularly when assistance might be reportable, as under the Physician's Payment Sunshine

Act, or considered a potential financial bias (6,7,11). Publication planning can create an environment in which each participant is confident that work is being undertaken only after appropriate input and permission have been received.

Effective time management may also limit the risk of certain problems. Giving sufficient notice of the expected timing for authoring, review and approval for manuscripts can help authors avoid questions about whether they meet ICMJE criteria by allowing adequate time to make substantive contributions. Providing adequate lead and review time, as well as clear instructions for authors and reviewers will help avoid problems in attributing authorship.

Transparency

The discussion of publication ethics by journal editors and scholars reflects an increasing emphasis on the need for scientific transparency (9,12–19). Publications of large-scale, randomised, controlled clinical trial results provide the most reliable data to address specific scientific questions, and therefore receive more scrutiny than review papers or results of smaller or less statistically robust studies. Requirements and guidelines for sharing clinical trial data have the overarching goal of increasing transparency by making the data more widely accessible (9,28–30).

A familiarity with guidelines on the conduct of clinical trials and standard data presentations for reports, registries and periodic safety updates may contribute to better planning by ensuring that (3,9,24) all required disclosures of clinical trial data, including the publications, are accounted for in statistical planning. Consolidated statistical analysis plans for all data dissemination may help prevent minor discrepancies between publications and clinical trial registries, which may result if statistical tables for publications are generated separately from those used in regulatory documents. Adequate planning before the statistical analysis plan is finalised can prevent unintentional data discrepancies.

Duplicate, redundant or selective publication

'Sponsorship, Authorship, and Accountability' (12) introduced the notion that all publications detailing the results of clinical trials should contain a unique identifier to help prevent redundant and duplicate publication. Additional measures may be necessary to avoid other forms of publication bias, such as selective publication of positive results.

Publishing as data become available, rather than using other priorities, may help prevent a bias towards positive results, provided that results considered to be of significant medical importance (3) are not delayed within a queue of data otherwise not

having direct application to current clinical practice. As mentioned above, the scheduling of publications could also appear in a general data dissemination plan that accounts for data posting on trial registries. Effective planning can also help identify the scientific and clinical relevance of publications, while helping to avoid inappropriate practices, such as duplicate or premature publication of partial results, especially from large multicentre studies with complex designs. Systematic publication planning provides a reliable and auditable framework to document such decisions and their scientific justification.

Electronic planning tools may be helpful in promoting transparency within authoring or study groups by making updated information available on an ongoing basis. Publication planners can ensure that such systems are chosen, maintained and updated appropriately. To promote transparency, publication plans for appropriate datasets should be available to all authors and steering committees as well as any other investigators who wish to understand the publication process or timing. Appointing a publication planner to manage communications can foster a culture of transparent communication among researchers and contributors while allowing authors to concentrate their energies on scientific discussion rather than untangling logistical issues.

The contribution of publication planning to biomedical research

The publication of biomedical research is fundamental to the scientific process and requires planning from the initial stages of protocol development. Too often, researchers are confronted with datasets for which no organised communication plan exists. In many cases, writing and results communication is overlooked until after the last patient is sent home and the data have been cleaned and analysed, resulting in delaying the dissemination of results. Research that goes unreported, or is incorrectly reported, may undermine the current body of scientific evidence and the health interventions that rely upon it. Publication planning is the most effective way to ensure that the scientific objectives of research are communicated to the medical community, health authorities and patients in a timely manner, as suggested by the Declaration of Helsinki and the PhRMA Code (2,3).

Robust and effective publication planning fosters a culture of ethical conduct and objective, truthful and transparent results reporting. Furthermore, publication planning provides an opportunity to demonstrate the scientific rigour with which clinical trials are developed and executed. Researchers seeking to integrate their findings into a broader lit-

erature can use the planning process to consider meta-analyses or to comment more systematically on study design, outcome measures, technological advances, treatment guidelines or government recommendations. In addition, planning offers an opportunity to consider the optimal means of relating regulatory reporting requirements (24) to developing contextual and explanatory scientific publications (20). Added attention to planning each step of the research process will help ensure that study data contribute to clinical practice and advances in the health sciences.

Publication plans alone cannot ensure good practice for the communication of scientific information, even if they provide important support for maintaining scientific and ethical research standards. It remains necessary for all authors and contributors to biomedical research to understand and seek to adhere to ethical guidelines while committing to acting with integrity if planning is to assist in this endeavour.

Publication planning remains a young discipline within the wide field of biomedical research. It should be recognised and valued, specifically through

its contributions to transparency and integrity. This is not to say that smaller research groups without the resources to hire professional planners should neglect publication planning. The increasing tendency of government agencies and corporate integrity agreements to mandate publication planning encourages this positive development for promoting more rigorous and trusted science and medicine in all settings: academic, governmental and corporate.

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