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Publication ethics from the ground up

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Summary

It is relatively easy to begin policy documents with a general assertion that ethics will be followed. Less obvious is how to ensure that day-to-day activities are consonant with ethical standards. We suggest that using day-to-day publication activities as the driver for building policies and procedures can promote ethical practices from the ground up. Although basic principles of ethical publication practice may seem straightforward to some, for others this information may require explanation, interpretation and context. Effective policy development includes big-picture items as well as more day-to-day tactical responsibilities such as those discussed below. Research questions, disciplinary practices, applications and team structures may vary. Thus, no single publication plan or policy solution is right for all teams. It is up to team members to review guidelines for best practices and find the optimal implementation for their situations. Experts in publication management, planning and writing can help large teams manage publication activities. These experts have an obligation to maintain and enhance their skills continually. A strong acumen in publication best practices will allow these publication professionals to better address any possible ethical dilemmas in the future.

1 | INTRODUCTION

Good publications are based on high-quality science, and high-quality science requires adherence to ethical principles. Medical publications ethics—broadly defined—are a key concern of many professional societies, such as the Committee on Publication Ethics (COPE) and the International Society for Medical Publications Professionals (ISMPP). The broad definition of ethics in the context of publications includes an array of beliefs and practices, from essential bioethical principles through to tactical efforts to comply with accepted guidelines and codes. The proliferation of associated guidance documents and codes (Table 1) requires considerable time and effort to read, synthesise and apply in day-to-day practice. Thus, in today's resource-constrained working environments, various publications professionals often take responsibility for staying abreast of these guidelines and setting

strategies and developing day-to-day approaches that foster compliance. Yet, despite a general agreement that ethical publication practices are essential[1-4] (Table 1), logistical questions remain, largely as a result of differing interpretation of high-level principles. We advocate a focus on ethical practices in everyday publication activities that can then drive policies and procedures, promoting ethical practices "from the ground up".

It is relatively easy to begin policy documents with a general assertion that ethics will be followed. Less obvious are the exact practices that will be consonant with ethical standards and higher-level principles. For example, compliance with regulatory requirements and corporate integrity agreements may necessitate auditable, evidence-based publication plans or monitoring programmes to ensure timely and complete data dissemination, measures that are not an immediately obvious extension of high-level ethical principles like

transparency.[2,5-9] The first step is ensuring that ethical considerations, derived from both general principles and more tactical approaches, underpin each activity that contributes to publications planning, development and management. In other words, because the separation between everyday practice and grounding ethical principles is wide, we believe that beginning policies by considering the ethics of each step of a process can enhance compliance, creating a more thoughtful and effective working environment.

Variations in the use of terminology can create confusion; therefore, we begin this discussion with a few definitions. We use the term *publication(s) practice(s)* to include all activities associated with publications planning, development and management, including the work of medical writers and steering committee members as well as any other contributors to publications and publication plans. *Publication plans* are documents that outline specific logistical steps for publication practices and capture publication concepts for a specific team. The best publication plans integrate regulatory and legal requirements, contextual dissemination of data, clinical relevance to patients and the intellectual interests that drive peer-reviewed publications.[1]

Publication planning includes the development of publication plan documents as well as other activities that contribute to planning an individual publication or group of publications. *Publication management* includes oversight of all logistical steps (including planning) that are necessary to see a publication from an initial plan through authoring, review and to final publication. A core rationale for publication planning and management is to support the scientific objectives of research and clinical development.

> **What's known**
>
> - Medical publications should be developed following ethical principles.
>
> **What's new**
>
> Carefully considering the ethics inherent in each step of publication development will enhance the integrity of:
> - publication policies
> - publication plans
> - authorship and contributorship
> - transparency
> - individual publications including abstracts, posters, oral presentations and manuscripts

Publication development is not a precisely defined term. We use it here to indicate activities (such as authoring and contributions) related to the production of an individual manuscript, poster or presentation. In general, we use the term *development* to indicate activities required to produce some sort of product (such as a publication plan, policy document or manuscript). We use the term *publication professional* broadly and in keeping with the membership profile of ISMPP because experts with many titles such as publication manager, publication associate, medical writer or publication director may contribute to the planning and execution of publications.

TABLE 1 Ethical guidelines and codes that affect publication practice

Issuing group and type of statement or code	Website or citation
American Medical Writers Association (AMWA). Code of Ethics	http://www.amwa.org/
American Medical Writers Association Position Statement on the Contribution of Medical Writers to Scientific Publications.	www.amwa.org/files/About%20Us/AMWA_PositionStatement_Contributions.pdf
Committee on Publication Ethics (COPE)	http://publicationethics.org/
CONSORT statement	www.consort-statement.org
Council of Science Editors (CSE). White paper on Promoting Integrity in Scientific Journal publications	www.councilscienceeditors.org/i4a/pages/index.cfm?pageid=3313
EQUATOR network	www.equator−network.org/2013/10/31/reporting−guidelines−can−their−use−make−the−work−of−systematic−reviewers−and−guideline−developers−better/
European Medical Writers Association (EMWA). Increasing Author Disclosure Requirements: What Does This Mean For Medical Writers Involved In The Manuscript Development Process?	www.emwa.org/Home/Webeditorial-2.html
AMWA/EMWA/ISMPP Joint statement on the role of the medical writer	See www.ismpp.org
GPP3	See www.ismpp.org
International Committee of Medical Journal Editors (ICMJE) Recommendations	http://www.icmje.org/recommendations/
International Society for Medical Publication Professionals (ISMPP) Code of Ethics	http://www.ismpp.org/
Medical Publishing Insights & Practices (MPIP)	https://www.mpip-initiative.org/transparencymatters/whytransparencymatters.html
The Pharmaceutical Research and Manufacturers of America (PhRMA) Code	www.phrma.org/sites/default/files/105/042009_clinical_trial_principles_final.pdf
World Association of Medical Editors (WAME) Conflict of Interest in Peer-Reviewed Medical Journals.	www.wame.org/conflict-of-interest-in-peer-reviewed-medical-journals

2 | TRANSPARENCY AS A DRIVER FOR ETHICAL PUBLICATION PRACTICE

Transparency, offering information clearly and openly, is an ethical cornerstone of biomedical publication management, in part because publication ethics stem from bioethics as opposed to the types of ethical considerations that inform other modes of technical communication. As the need for transparency informs all areas of clinical research, so openness and honesty also impact publications. The ICMJE, a key source for explanatory interpretations of bioethics for the purposes of publication, recommends only publishing the results of studies that are included in trial registries—a measure of transparency—as well as the disclosure of negative results. The ICMJE position is supported by medical experts and Good Publication Practice (GPP) guidelines.[3,6,7,10] Integrity and accountability are impossible without transparency.

Publication transparency extends beyond disclosure of trials and results. In the past decade, the transparency of biomedical authorship has been of increasing interest not only to the medical community, but also to the general public. It is vital to know who interprets the relevance of clinical data for publication. Improper authorship practices, such as ghostwriting and guest authorship, obscure the identities of those who contribute to the published literature, raising questions not only about the validity of the publications, but also about trial conduct and data integrity more generally.[11,12] Thus, even well-conducted research can be harmed by any appearance of authorship impropriety. Unethical authorship practices devalue the medical literature and tarnish the reputations of research institutions and even the medical profession.

Data transparency generally refers to information provided in tabular formats and datasets as opposed to the clinical and statistical interpretations that appear in publications. On a practical level, therefore, data transparency includes clinical trials databases and results repositories such as ClinicalTrials.gov or the EudraCT clinical trial databases, which will increasingly include study report summaries. In addition, many sponsors provide protocols, clinical study reports (CSRs), statistical analysis plans and/or anonymised patient-level data on their websites.[13-15] The increasing availability of study data without the context provided by a publication adds complexities to publication practices.

In practice, publications planning and management requires attention to general forms of transparency (or honesty), specific measures for data transparency as well as transparency regarding authorship and other contributions to manuscripts. Publication teams with clearly defined roles and responsibilities, as well as effective management of both processes and documents, are essential to fostering all types of transparency.[3,7] Ideally, policies and procedures should be anchored in practices that promote transparency.

2.1 | Establishing roles and responsibilities

Not only do the minutiae of publication practice require specialised skills, but even small missteps can undermine transparency, casting integrity and accountability into doubt.[6,7] In large-scale clinical trials or development programmes, each task necessary for publication development and management should be shared across teams with an appropriate spectrum of skills. In line with the latest two iterations of GPP,[6,7] a steering committee should be formed for studies or groups of studies expected to generate multiple related publications, to ensure consistency and efficiency of products and process steps. However, simply forming a team is not enough.

Individual roles should be clearly defined and apportioned in such a way as to leverage the strengths of each team member without creating undue burdens. For example, a principal investigator could serve as the chair of a publications steering committee and/or an author for publications on the primary results as a natural extension of their research role. Of course, the roles and responsibilities of each author should be clear, and accepted criteria for authorship and contributor identification, such as the ICMJE recommendations, should determine final bylines.[3] A table or diagram should be used to track team member responsibilities; an example is provided in Table 2. Mandatory steps and responsibilities should be accounted for in publication policies and procedures, which should include considerations for steering committee charters as well as document management.

Questions that authors should consider prior to publication development include the following: Who should write manuscripts? Offer logistical advice and support? Apportion new roles on an ad-hoc basis? What is the appropriate role of the medical writer or other publication professional? Once decisions have been made, specific responsibilities may be recorded on a table or diagram (see Table 2 for an example); policies and procedures should reflect realistic thinking and expectations. In team settings, it is also important to apportion accountability for work products (such as planning documents or manuscript drafts) to team members with the authority, ability and time to complete those tasks. For example, assigning accountability for draft manuscript development solely to a writer and not to the manuscript authors does not support best practices for ethical authorship.

True transparency is impossible without accuracy. To ensure both transparency and accuracy in data reporting, publications teams should designate a specific member to verify that data reported in publications are consistent with publicly available postings and that any differences are adequately explained. Some journals require these documents for the review process; hence, an appropriate team member should oversee that such documents are available. Top-tier journals may also publish redacted protocols as supplementary material to accompany the primary results of clinical trials. Effective publications management might suggest that this process occur in tandem with a final review of the publication by authors. All listed authors should be prepared to confirm the data accuracy in a manuscript and to accept public accountability for the content of the publication.

2.2 | Specialised roles of publications professionals

When reporting clinical study data, the use of professional medical writers should be discussed by a publications team, steering

TABLE 2 Sample responsible, accountable, consulted, informed (RACI) table for developing a manuscript. Appropriate steps should be added, as per the appropriate operating procedure for the collaborating and sponsoring groups

Task	Steering committee	Authors	Medical writer	Publication manager
Planning				
Author agreement signed	C/I	R/A	I	I
Schedule publication team meetings	C/I	C/I	C/I	R/A
Update publication plan	C/I	C/I	C/I	R/A
Choose target journal or presentation venue	C	R/A	I	C
Data review and content development				
Analyse, interpret and QC data	C (optional)	R/A	I	C
Data review*	C (optional)	R/A	C	I
Manuscript development				
Outline manuscript	NA	R/A	I	I
Design tables and figures	NA	A/R	C	I/C
Prepare drafts	NA	A	R	I/C
Collate comments	NA	A	R	I
Review and submission				
Collect disclosures	NA	A	I	R
Identify competing interests	C	R/A	NA	I/C
Ensure formatting is correct	NA	A	R	I/C
Medical/legal review	I/C	R	I	A
Author approval	I	A	I	I
Journal submission	I	A	R	I/C
Peer review and publishing				
Respond to peer review (medical/ scientific content)	I/C	R/A	I	I
Prepare response to peer reviewers	NA	A	R	I/C
Review page proofs	I	R/A	C	I
Disseminate published manuscript	I	C	R	A

*Recommended at each submission stage.
A, accountable; C, consulted; I, informed; NA, not applicable; R, responsible.

committee or clinical study team well before publication writing begins.[1,6,7] Under the US Physician's Payment Sunshine Act and other guidelines, such assistance may be interpreted as a reportable transfer of value or financial conflict of interest and, therefore, may not be permitted by some investigators' institutions.[10,16,17] Therefore, authors should decide whether professional writers will be employed on a specific manuscript before any writing begins. Similarly, other publications professionals, such as publications managers, should observe appropriate guidelines regarding their expected contributions to manuscript development and publication planning. If publications professionals such as writers are expected to serve as authors, this decision and the accompanying rationale for the authorship should be formally documented as for any other author involved in manuscript development. Transparency of these roles is critical in part because publications professionals, like writers or publications managers, may also be qualified scientists; therefore, the scope of their participation in individual papers should be identified prior to initiating writing.

Publication professionals, as members of or advisors to the publications team, must be advocates for good publication practices and generally take leading roles in developing publication plans and policies. Publication professionals can support the work of authors and contributors and provide general guidance on how to form a publication steering committee, manage publication activities, suggest target journals and congresses, provide regular progress updates and keep publication plans up to date. Medical writers, using their expertise with specific guidelines, may assist with assembling, formatting and submitting manuscripts, track author input, identify references, establish timelines and perform other functions to enhance quality and efficiency, allowing authors to concentrate on interpretation of scientific content.[1,6,7,10]

2.3 | Documentation and accountability

As observed above, transparency is an essential feature of publication ethics that extends beyond presenting clinical trial data; thus,

publication activities should be documented and auditable. Auditable documentation may include the publication plan, additional documents like the RACI (responsible, accountable, consulted, informed) chart (see Table 2 for an example), and records of reviews, author agreements and submission documentation. The specifics of a publication plan have been reported elsewhere and are discussed briefly below.[1,6,7]

A publication plan is a critical part of publication management[1,6,7] that should be developed, maintained and regularly updated. The format of effective publication plans can vary widely. In some organisations with few employees or publications activities, slide sets or a spreadsheet that can be incorporated into larger clinical development or product planning documents may be adequate. Larger organisations or teams with more publications may prefer to use electronic tracking and reviewing tools to manage their deliverables. Gantt charts display events over time, may be associated with any data storage method, and can provide useful information to broader audiences. Steering committee and publication team members (whichever are applicable) should have input into the format and handling of publication plans and updates, as consistent with policies and the steering committee charter. We recommend that all Phases 2 and 3 clinical development programmes have a separate, formal publication plan or formally integrate their planning within a clinical development, medical affairs, project management or data dissemination plan.

Regardless of format, publication plans should account for all presentations and manuscripts of specific datasets, including information about venues, timing, the names of relevant meetings and journals.[1] It may be helpful to include a schedule of planned steering committee or authoring group meetings, contact information and details about potential follow-up work such as meta-analyses, publications of secondary or tertiary outcomes data or book chapters.

Furthermore, publication plans should be accurate, complete and regularly reviewed and updated.[1,6,7] We recommend at least quarterly review of any stand-alone publication plan and that publication planning activities included in other documents (like a data dissemination plan) are reviewed each time these documents are updated. Steering committees, if formed, should be included in the regular review of publication plans, and such review should be mandated in policies and steering committee charters.

2.4 | Building publication policies

It may seem counterintuitive to discuss policy and process development after the logistics of team assignments and publication plans; however, an understanding of tactical information is essential to building high-quality policies and working instructions. To be effective, publication policies and working guidelines must reflect best practices and ethics as well as local logistical realities. Policies and working instructions should also identify the scope and types of documents covered; for example, meeting presentations, publication plans, steering committee charters or peer-reviewed publications.[3,8] Policies or procedures should detail required steps for planning, development, review and approval of overall publication plans (Table 2 provides a useful model) as well the individual documents included within the plans. Publications policies should not repeat process steps for other forms of data dissemination, such as trial data posting.

Policies and working instructions should specify the minimum composition of steering committees, publication planning teams and authoring teams. A process for identifying internal and external stakeholders, documenting their agreement to participate and refining the basic team membership requirements (eg, adding a serologist or epidemiologist to provide expert interpretation of study data) may be provided. An agreement or policy may also establish the process by which authorship order is determined. In corporate settings, publication planning teams can include members from clinical, scientific, regulatory, medical affairs, biostatistics, publications and legal departments. In most organisations, commercial colleagues are not included in such meetings; the parameters and limits of such participation should be designated in policy documents.

Establishing appropriate timing in publications policies can prevent ethical conundrums. For example, publication policies themselves should be established well in advance of trial data availability. International Committee on the Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH) guidelines suggest the identification of a principal investigator at the protocol stage,[13,15] and this timing could also signal the beginning of publication planning. Involving all appropriate authors and contributors from an early stage of study design promotes transparency and fosters effective communication.[1] Development of publication plans in tandem with the clinical development plan, and identification of publication teams could begin during protocol finalisation to ensure transparency and ethical data handling. Ethical publication planning requires continuing, thoughtful evaluation and adjustments to ensure transparency and meet the needs of end users of publications, such as prescribers, researchers and even patients.[1,6,7] Thus, all publication policies, like publication plans, should be subject to periodic review.

3 | DISCUSSION

Lack of transparency—of data, or authorship or trial conduct—in the past has eroded trust in pharmaceutical companies, research integrity and the medical profession.[11,18] We believe that building a mutual vision for the transparent dissemination of clinical data with investigators, medical writers, statisticians and publication managers promotes a single voice that can be reflected in publication policies and plans. Ensuring that all data, independent of the study outcome, are included in the publication plan fulfils the obligation of full transparency and validates that a good faith effort has been made to publicly disclose the study results, supporting research integrity. Furthermore, any activity that supports publications of trial data allows expert authors to contextualise results with current literature, comment on how the results may change clinical practice and expand on the minimum data allotted on clinical trial results repositories. In addition, such activity needs to be auditable to ensure the complete, transparent and ethical dissemination of the available data.

One barrier to the true transparency of publicly available materials that we have not addressed is accessibility to a broad range of reading levels. Ultimately, these data should be provided within an appropriate context for informed decision-making by patients and healthcare providers.[8,9] Some journals include patients as manuscript reviewers to obtain a critical and often overlooked perspective, and the EMA is moving towards a requirement for "lay summaries", or information accessible to the general public. The increasing move towards making data more generally accessible makes peer-reviewed publications even more important. These papers are often the primary means by which expert and academic interpretations of study data are made available to prescribers and how the need for future studies is determined. Translational work, including systematic reviews and meta-analyses, that situate primary research within a larger scientific or clinical context, is also needed.

Although basic principles of ethical publication practice may seem straightforward to some, for others this information may require explanation, interpretation and context. Consider, for example, students and early-career scientists, publication planners and physicians still learning how bioethical concerns affect publications. Effective policy development includes big-picture items as well as more day-to-day tactical responsibilities like those we have discussed above. Research questions, disciplinary practices, applications and team structures may vary. Thus, no single publication plan or policy solution is right for all teams. It is up to team members to review guidelines for best practices and find the optimal implementation for their situations. Experts in publication management, planning and writing can help large teams manage publication activities. These experts have an obligation to maintain and enhance their skills continually. A strong acumen in publication best practices will allow these publication professionals to better address any possible ethical dilemmas in the future. Building publication policies and procedures "from the ground up" will promote transparency and research integrity at every stage of manuscript planning and development.

AUTHOR CONTRIBUTIONS

All authors were involved in the conception, design, planning, authoring, review and revision of the manuscript. All authors have approved the manuscript for publication and share public responsibility for the substantive content.

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