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Update on Guidelines for Medical Writers and Publication Planners

by Elizabeth Wager

Executive summary

Publication practices in the pharmaceutical industry continue to attract widespread scrutiny. The past few years have seen the development and introduction of several new guidelines and revisions designed to provide greater clarity for publication professionals. But the wider goal of achieving uniform submission requirements amongst journals appears further away than ever.

The most significant changes to publication planning practices are detailed in the new version of Good Publication Practice (GPP2), which was issued in late 2009. Although GPP2 recommends that companies should provide authors with a copy of their publication policy, it provides little guidance on what such policies should include.

The profession still faces issues of concern: the disclosure of companies' involvement in developing publications; the relations between sponsor companies and authors; the role of professional medical writers, and how best to define and acknowledge their contributions. Transparency remains a clichéd yet essential objective, while, aligned with it, author disclosure of conflicts of interest continues to pose challenges. Likewise, companies have been strongly criticised for suppressing or failing to publish negative trial results, which has led to new requirements for trial registration and making information more publicly available.

This Expert Review, *Update on Guidelines for Medical Writers and Publication Planners*, charts the evolution of publication practice, highlighting the latest changes to guidelines and summarising their recommendations on major issues.

Contents

About the author

Elizabeth (Liz) Wager is the author of books on '*Getting Research Published: An A to Z of Publication Strategy*' and '*How to Survive Peer Review*'. She is a co-author of '*Good Publication Practice For Pharmaceutical Companies*' and the European Medical Writers Association guidelines on the role of medical writers.

After obtaining a first-class zoology degree from Oxford in 1983, she worked for Blackwell Scientific Publications, Janssen-Cilag then Glaxo-Wellcome. In 2001, she set up her own company, Sideview, which provides training, writing, editing and publication consultancy services. Since going freelance, Liz has run courses on publication strategy, medical writing and publication ethics on six continents.

She is the Chair of COPE (the Committee on Publication Ethics) and a member of: the BMJ's Ethics Committee, the World Association of Medical Editors Ethics Committee, the Council of Science Editors Research Committee, and the World Health Organization Scientific Advisory Group on trial registration.

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Update on Guidelines for Medical Writers and Publication Planners

Introduction: the current climate for publication professionals

Companies' publication activities continue to attract considerable attention – not all of it welcome or positive. The slow mechanisms of the legal process mean that cases relating to events that took place several years ago continue to be reported in the media. Naturally, journalists tend to focus on the worst aspects of publication behaviour (good news stories never seem to appeal) and rarely mention that attitudes and practices have changed considerably over the last decade. Equally, media coverage seldom reports how responsible writers and publication planners have responded to inappropriate actions by developing guidelines to prevent similar problems in the future – although this is certainly the case.

Along with the lawsuits, another reason for companies to review their publication and data dissemination policies is the Food & Drug Administration Amendments Act (FDAAA), which was passed in the USA in 2007 and has been enforced incrementally in subsequent years. Although FDAAA did not directly affect peer-reviewed publications in medical journals, it forced companies to post results summaries for many trials on ClinicalTrials.gov within 12 months of the study end.[1,2] Since results, albeit in an abbreviated format, are now publicly available on ClinicalTrials.gov for many studies, some companies have decided to complement the rather dry, tabular posting required by FDAAA with a journal article. The most ambitious companies aim to publish findings in a peer-reviewed journal by the deadline for the appearance of the results summary on ClinicalTrials.gov (i.e. within 12 months of the study end for most trials of marketed products). Other companies aim to have at least submitted an article to a journal by this deadline.

The mandatory posting of results, especially if linked to internal company targets for simultaneous journal publications, has aligned publication activities more strongly with regulatory affairs than ever before. Perhaps as a result of this closer association, or in reaction to negative publicity about the industry's previous publication practices, many companies appear to be auditing publications more formally and with greater scrutiny. But in order to audit publication activities, benchmarks for good practice, against which performance can be measured, are required.

How did we get here?

The development of the major guidelines relating to publications is outlined in Figure 1; a list of the major guidelines available is given in Table 1; all the guidelines discussed in this review can be found in this table.

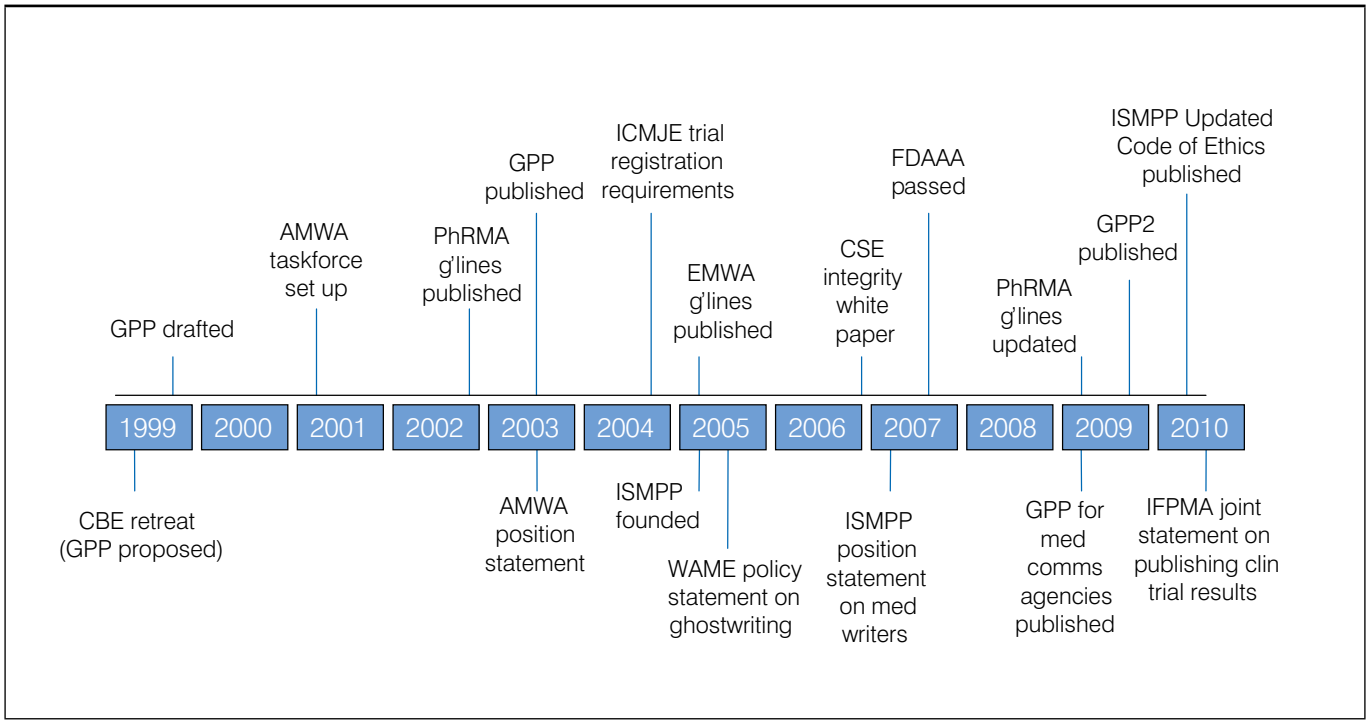

Figure 1. The development of the major publication guidelines since 1999.
FDAAA = Food and Administration Amendments Act (2007); for other abbreviations, refer to Table 1.

Organisation		Title	Date	Available at	Reference
ICMJE	International Committee of Medical Journal Editors	Uniform requirements for manuscripts submitted to biomedical journals	1979 – then updated most years	icmje.org	
PhRMA	Pharmaceutical Research & Manufacturers of America	Principles on communication of clinical trial results	2002/2007	phrma.org	
GPP Working Group	Good Publication Practice Working Group	Good publication practice for pharmaceutical companies	2003	ismpp.org/initiatives/gpp2.html#archive gpp-guidelines.org	Wager E, Field EA, Grossman L. *Curr Med Res Opin* 2003; 19:149–54
AMWA	American Medical Writers Association	Position statement on medical writers	2003	amwa.org	
WAME	World Association of Medical Editors	Policy statement on ghostwriting	2005	wame.org	
EMWA	European Medical Writers Association	Guidelines on role of medical writers	2005	emwa.org	
CSE	Council of Science Editors (formerly Council of Biology Editors [CBE])	White paper on the integrity of publications	2006	councilscienceeditors.org	
ISMPP	International Society for Medical Publication Professionals	Position statement on role of medical writers	2007		Norris R, Bowman A, Fagan JM *et al*. *Curr Med Res Opin* 2007;23:1837–40
WMA	World Medical Association	Declaration of Helsinki	Revised 2008	wma.net	
ISMPP	International Society for Medical Publication Professionals	GPP2	2009	ismpp.org/initiatives/gpp2.html#archive	Graf C, Battisti W, Bridges D *et al*. *BMJ* 2009;339:b4330
AXIS group of companies		GPP for medical communications agencies	2009		Bareket-Samish A, Denny M, Ruzicka B *et al*. *Curr Med Res Opin* 2009;25:453–61
ISMPP	International Society for Medical Publication Professionals	Code of Ethics	2010	ismpp.org	
IFPMA/EFPIA/JPMA/PhRMA	International Federation of Pharmaceutical Manufacturers & Associations/European Federation of Pharmaceutical Industries and Associations/Japan Pharmaceutical Manufacturers Association/Pharmaceutical Research and Manufacturers of America	Joint statement on publishing clinical trial results	2010	ifpma.org	

Table 1. Key guidelines relating to publications.

Since the last Expert Review on this topic was produced in 2007,[3] several guidelines or position statements have been published or revised. The most important changes of which medical writers, publication planners and pharmaceutical companies need to be aware occur in the new version of Good Publication Practice (GPP2). This was published in late 2009 after extensive consultation coordinated by a team from the International Society for Medical Publication Professionals (ISMPP).

The aim of this review is to summarise changes to the relevant guidelines.

Changes to existing guidelines

What are the issues?

The main areas of concern for journal editors remain the disclosure of companies' involvement in the development of publications and the relations between sponsor companies and academic or clinical authors. The appropriate roles and contributions of professional medical writers, and the best way to acknowledge these, also remain contentious. Continuing the theme of transparency, journals are also keen to ensure that authors disclose any conflicts of interest.

One main area of concern for journal editors is the disclosure of companies' involvement in the development of publications

Companies have been strongly criticised for suppressing or failing to publish negative results. Requirements for trial registration, inclusion of registration numbers in publications and posting summary results on public websites have arisen largely as a result of concern about the damaging effects of publication bias and the need to ensure that all results are publicly available.

Publication policies

GPP2 recommends that companies should provide authors with a copy of their publication policy – the strong implication being that they should have one! However, while the guidelines describe the general features of publications (i.e. integrity, completeness, transparency, accountability and responsibility) and include many recommendations that should probably be reflected in a company policy, they do not describe exactly what such a policy should cover.

Publication agreements

GPP2 recommends that companies should have written agreements with authors and members of writing groups or publication steering committees (see next paragraph). It also provides a checklist of items that should be included in such agreements. It recommends that publication agreements relating to research studies should be made "at the earliest opportunity – for example, when the protocol is finalised". For other types of publication, GPP2 recommends that the agreement "should be made before the authors begin work".

Publication steering committees

GPP2 states that "it may be useful to form a publication steering committee of authors and contributors to oversee and produce articles and presentations from a research study". It goes on to suggest that such a committee might include:

- members of the study steering committee
- investigators who are willing to interpret the data and write or review articles and presentations
- employees or contractors working for the sponsor company, such as statisticians and medical writers.

The guidelines note that membership of the steering committee does not automatically equate with authorship.

The steering committee proposed by GPP2 is therefore envisaged as more than simply a writing group. This is different from the original GPP guidelines, which suggested that forming "a writing committee involving the medical writer" might be helpful. In the section on publication planning, GPP2 suggests that steering committees will be involved with planning but that "authors retain responsibility for decisions about articles and presentations from individual studies".

Publication planning

The original GPP guidelines stated that "companies should be responsible for coordinating the publication of multicentre trials to ensure that they are reported in a responsible and coherent manner". Apart from this, GPP made no reference to publication planning. In the section on the role of medical writers, GPP stated that "named author(s)/contributors must determine the content of the publication". GPP2 clearly recommends that authors are actively involved in publication planning, stating that publication agreements should confirm the authors' responsibility to "make decisions about practical issues concerning presentation and publication (for example, choice of congress or journal)". It also states that the authors have a responsibility to "plan and produce articles… that are accurate and complete in a timely manner". In addition to guidance on the role of medical writers, GPP2 contains a section on publication planning which, once again, stresses that "authors retain responsibility for decisions about articles and presentations". Perhaps surprisingly, ISMPP's Code of Ethics does not mention publication planning, but merely states that authors have "ultimate responsibility for publication content, including the selection of

references", but does not mention involvement in choice of journal.

Timing of publications

Although the Pharmaceutical Research & Manufacturers of America's (PhRMA) principles on communicating trial results make no mention of publication planning, PhRMA was involved in a joint announcement from the International Federation of Pharmaceutical Manufacturers & Associations (IFPMA) and the European Federation of Pharmaceutical Industries and Associations (EFPIA) in June 2010. This states that: "All industry-sponsored clinical trials should be considered for publication… at a minimum, results from all phase 3 clinical trials and any clinical trial results of significant medical importance should be submitted for publication". The announcement goes on to say that "submissions for publication… should take place in a timely manner", which it defines as "within 12 months and no later than 18 months" of the study end for marketed products or of the date of regulatory approval (or a decision to discontinue development) for investigational products.

Choice of journal

The IFPMA joint statement recommends that "whenever possible… clinical trial results should be submitted to journals indexed by online bibliographic databases (e.g. Medline)". This is reflected in some companies' publication policies. This is a more specific recommendation than the original GPP guidelines, which stated that companies should endeavour to publish the results of all clinical trials of marketed products, but did not say where these should be published (except implicitly, since the guidelines related to peer-reviewed journals).

"Whenever possible… clinical trial results should be submitted to journals indexed by online bibliographic databases (e.g. Medline)" – according to the IFPMA joint statement

Similarly, GPP2 does not stipulate where results should be published. The World Medical Association's Declaration of Helsinki (revised in 2008) uses even looser wording, simply stating that authors have a duty to make results "publicly available".

Access to raw data

One of the most important differences between the original GPP and GPP2 is the recommendation concerning authors' access to data. The earlier guidelines stated that all authors "should have access to the statistical reports and tables supporting each publication". In other words, that authors should have access to the analysed data. The new GPP2 guidelines go much further, stating that "sponsors must provide authors… with full access to study data", such as statistical reports, data tables and clinical study reports. GPP2 then states that authors should be given sufficient time "to seek further information if they wish (for example, access to raw data tables or the study database)".

Journals are increasingly asking authors to state whether they had access to the study data. In one case, a British professor was brought before the UK General Medical Council (GMC) on misconduct charges because he was an author of a publication which stated that the authors had had access to the study data when, in fact, they had not. In this case, not only had the pharmaceutical company denied the principal investigator's request to examine the raw data, but the published report had to be corrected when it was shown that the company analysis had omitted a large number of data points and was therefore misleading.[4] Interestingly, the GMC panel noted that there was an "evolving understanding of access to data" when the paper was published in 2002. However, they concluded that data meant 'raw data' even then (before the first GPP guidelines had been published).

Journals are increasingly asking authors to state whether they had access to the study data

When PhRMA revised its principles on clinical trial reporting in 2004, it stated:

"As owners of the study database, sponsors have discretion to determine who will have access to the database. Generally study databases are only made available to regulatory authorities…. Sponsors will make a summary of the study results available to the investigators. In addition any investigator… will be able to review relevant statistical tables, figures and reports... at the sponsor's facilities".

By the 2009 revision the tone had softened considerably. The PhRMA document now states: "We seek to provide investigators with meaningful access to clinical data from the studies in which they participate". The wording about reviewing tables, etc., is unchanged, but there is nothing about owning the database or controlling access to it, and no mention of access to raw data. However, the PhRMA document does state that "Investigators who are authors of study-related manuscripts will be given all study data needed to support the publication", which did not appear in earlier versions.

GPP for medical communications agencies (produced by the AXIS group of companies) states that "Access to 'raw' (source) data is not routinely necessary or warranted" (and cites the PhRMA guidelines to support this). But it goes on to suggest that "if authors have questions about the data that cannot be answered by information in the study report" the medical writer should "initiate… a dialogue between the authors and the trial

sponsor to solve such questions" and that "if requested, the sponsor should provide source data to the authors".

While ensuring that authors have access to the data they need to interpret a study and prepare or review a publication sounds reasonable in theory, it can create problems in practice. Many clinical trial datasets are huge and are formatted for specialised statistical software that investigators are unlikely to be able to use. Some companies therefore offer investigators the opportunity to review the data on company premises in the presence of a statistician. There may also be concern about data security if datasets including individual patient details are shared.

Although some proponents of transparency have called for raw data from clinical trials to be published, there are currently no requirements for this. However, some editors have started to consider the technical and ethical issues in publishing raw data and have begun to develop standards for this.[5]

Payment for authors

Another new section in GPP2 which has caused some discussion is reimbursement. The guidelines state that out-of-pocket expenses may be covered and that companies may pay "for specialised services such as statistical analysis". However, it recommends that "no honorariums are paid for authorship of peer-reviewed articles or presentations". One problem in interpreting this recommendation is that the term honorarium is not widely used outside the USA. However, the Merriam-Webster dictionary defines honorarium as "a payment for a service (as making a speech) on which custom or propriety forbids a price to be set". In other words, if a payment is being made for something for which an hourly fee could reasonably be set (such as professional writing or statistical services) this is allowable, even if the payment is made to an author, but a fee for authorship itself (for which a price cannot be set) is not acceptable. The wording is important: the GPP2 guidelines do not state that authors should not be paid, but they state that payment should not be made for authorship. My interpretation (and, as I understand, that of the GPP2 team) is that the aim was to outlaw the practice of offering payment for guest authorship (e.g. when an individual was sent a review article and offered payment in return for being listed as an author, despite having made little or no contribution to the publication). It seems illogical that a company may pay a professional writer who is not an author, but may not pay for writing work done by anybody who is an author. However, some companies are interpreting GPP2 in this way.

GPP for medical communications companies takes a similar line to GPP2, stating that "MedComm GPP guidelines prohibit remuneration on behalf of the sponsoring company for authoring a manuscript or other publication".

GPP2 recommends that "no honorariums are paid for authorship of peer-reviewed articles or presentations"

Authorship

GPP2 endorses the International Committee of Medical Journal Editors' (ICMJE) authorship criteria more strongly than the original GPP (which merely suggested they were a good starting point). The revised guidelines also support use of the contributorship model, in which every individual's role in the research and publication is described. GPP2 makes a distinction between authors (i.e. those who fulfil the ICMJE criteria) and other contributors (who played a role that does not fulfil the criteria), and makes it clear that the role of all contributors should be clearly described and that "particular care is taken to ensure appropriate acknowledgement of the contributions made by medical writers and to describe their funding". The PhRMA principles also endorse the ICMJE authorship criteria and note that staff involved in analysing data or producing manuscripts should be named either as authors or in the acknowledgements "depending on their level of contribution".

Interestingly, the latest ICMJE guidance on authorship (revised in 2010) places less emphasis on the three well-known criteria for authorship (Table 2) than previous versions but notes that they are "still appropriate for journals that distinguish authors from other contributors". However, the ICMJE urges editors "to develop and implement a contributorship policy", which it defines as publishing information about the contributions to studies from persons "listed as authors and in Acknowledgments".

The World Association of Medical Editors (WAME) also encourages the practice of listing contributions and notes that "not all contributors necessarily qualify for authorship".

The ISMPP position statement notes that "ISMPP strongly endorses the concept of contributorship because it provides the most explicit description of the actual work of all persons responsible for conducting and reporting on the scientific research". It also reiterates the European Medical Writers Association (EMWA) guidelines' view that medical writers "generally… do not meet ICMJE authorship criteria as they relate to reporting the results of original research". The ICMJE guidelines also imply that writers may not qualify as authors, since they suggest that people "who provided purely technical help [or] writing assistance" "should be listed in an acknowledgments section".

Thus, GPP2, ICMJE, WAME, EMWA and ISMPP all distinguish authors from other contributors who should be listed (together with a description of their roles) in the Acknowledgements. However, while many journals still do not list contributions but retain the traditional author

Authorship credit should be based on:

1) substantial contributions to conception and design, or acquisition of data, or analysis and interpretation of data;
2) drafting the article or revising it critically for important intellectual content; and
3) final approval of the version to be published.

Authors should meet conditions 1, 2, and 3.

- Acquisition of funding, collection of data, or general supervision of the research group, alone, does not justify authorship.
- All persons designated as authors should qualify for authorship, and all those who qualify should be listed.
- Each author should have participated sufficiently in the work to take public responsibility for appropriate portions of the content.
- All contributors who do not meet the criteria for authorship should be listed in an acknowledgments section. Examples of those who might be acknowledged include a person who provided purely technical help, writing assistance, or a department chair who provided only general support. Financial and material support should also be acknowledged.

Table 2. ICMJE authorship criteria.

by-line (listing names but no description of roles) those that have adopted contributorship have not done so consistently.

GPP2, ICMJE, WAME, EMWA and ISMPP all distinguish authors from other contributors

The *BMJ* notes that the ICMJE authorship criteria have "some serious flaws" but nevertheless distinguishes authors (who are listed at the beginning of a paper) from contributors (listed at the end of the paper) – some of whom may not be included as authors. *The Lancet* uses a similar system and asks "all authors and all contributors (including medical writers and editors) to specify their individual contributions at the end of the text". However, *JAMA*'s instructions state that "authors' specific contributions will be published in the Acknowledgment section". It is therefore important to check the target journal's requirements carefully to determine how to list authors, contributors and/or acknowledgees. Just to add to the confusion, Medline sometimes lists 'collaborators' (or investigators) as well as authors. These appear to be taken from lists of investigators.

One or two journals appear to have abandoned, or reinterpreted, ICMJE requirements that authors should have been involved in the study, *and* in preparing the publication *and* in approving the final version. For example, *Neurology* defines an author as somebody who has made a substantive contribution to one or more of the following:

- design or conceptualisation of the study
- analysis or interpretation of the data
- drafting or revising the manuscript.

The *Neurology* guidelines make this explicit by stating that "professional writers employed by pharmaceutical companies… or commercial entities who have drafted or revised the intellectual content of the paper must be included as authors".

Some journals will accept the involvement of a professional writer in the preparation of a primary research paper, but not a review article. *Blood* notes that it would be "very unlikely…[to] accept a review article authored primarily by a person working for a pharmaceutical company". However, it notes that involvement of a writer is acceptable for primary research articles if:

- the authors act as guarantors
- the writer consulted the authors before writing
- the writer is transparently acknowledged
- the writer has "appropriate expertise and background to provide substantive input to the background research or writing… the article".

However, it does not say how the journal might seek to establish the writer's expertise.

The Oncologist states that it "will not accept review articles if they are written by a ghost writer paid directly or indirectly by a drug sponsor" and that the journal will not accept articles "if the hired writer has had the primary responsibility for writing and submitting the paper, but is not identified as an author".

In September 2009, *Blood* rejected a review article, despite receiving positive reviews, because a reviewer noted that "a person thanked in the Acknowledgements section was an employee of a pharmaceutical company, without disclosure that the employee worked for the company and without clarifying the role this employee played in the work".

Submission of manuscripts

The original version of GPP recommended that the lead author should be responsible for submitting the manuscript to the journal (although I'm happy to admit now that this was the one recommendation I never agreed with). GPP2 strikes a more reasonable note by suggesting that "authors may delegate to the medical writer (or to an assistant) the administrative tasks

associated with submitting the article or presentation to a journal or congress". GPP for medical communications companies spells this out in more detail, noting that "Although it is preferable for corresponding authors to submit their own manuscripts for publication… authors often prefer the agency submit on their behalf". However, it recommends that the agency should obtain "documented permission" from the corresponding author to submit on his/her behalf. It also describes a scenario in which the agency makes "all preparations for online submission", such as populating information screens and uploading files, but then transfers responsibility for approving the submission to the corresponding author.

Disclosing conflicts of interest

Virtually all journals ask authors to disclose potential competing interests. The WAME policy statement (published in 2009) provides one of the clearest definitions, stating "Conflict of interest (COI) exists when there is a divergence between an individual's private interests (competing interests) and his or her responsibilities to scientific and publishing activities such that a reasonable observer might wonder if the individual's behavior or judgment was motivated by considerations of his or her competing interests". The policy statement also notes the importance of disclosing non-financial as well as financial interests. However, it notes that "No generally accepted standard, nor evidence-based consensus, exists for precisely defining the degree of financial COI or the timeframe that creates a substantial risk of bias or damage to the journal's reputation".

Guidance on what constitutes a conflict of interest that should be disclosed, in terms of the amounts of money involved and the relevant timeframe, varies considerably between journals. In response to this, the ICMJE has developed a uniform disclosure form which was piloted in 2009 and launched in mid-2010.[6] Despite being five pages long (three of which have to be completed by every author), the form focuses almost exclusively on financial relationships and study funding. Provision of writing assistance (rather bizarrely) is lumped together with provision of medicines, equipment or administrative support. The form is designed to be completed on submission by all authors but notes that journals will ask authors to confirm, and if necessary update, their disclosures at the time of manuscript acceptance.

Guidance on what constitutes a conflict of interest varies considerably between journals

The ICMJE requires authors to disclose any funding for the submitted work including "all sources of revenue paid… over the 36 months prior to submission of the work". Authors are also expected to disclose grants for other work "from entities that could be perceived to be affected financially by the published work" but need not disclose funding from "government agencies, charitable foundations or academic institutions".

The ICMJE form has been adopted by ICMJE members, including the *NEJM, BMJ* and *The Lancet*, but not by many other journals (e.g. journals published by the Public Library of Science, BioMed Central and Nature Publishing Group, as well as many specialist journals, which use their own disclosure forms). Therefore, as with authorship, it is important to check the individual requirements for each journal for disclosing competing interests, and it seems that, despite the attempts of the ICMJE, these are a long way from being uniform.

Reporting standards

The CONSORT (Consolidated Standards of Reporting Trials) Statement – regarded by many as the gold standard guideline for reporting randomised trials and now endorsed by over 600 journals – was revised in 2010. The authors describe the changes as " evolutionary not revolutionary" and most involve clarification of wording and the splitting of items that were previously grouped. The CONSORT checklist (which some journals require to be submitted alongside the manuscript) now includes 25 items. The CONSORT diagram is unchanged except for one word. Guidance on reporting abstracts for conferences or journal articles to complement CONSORT was developed in 2008. Both these statements, and dozens of other reporting guidelines for a wide range of study designs and therapy areas, are available on the EQUATOR Network website (www.equator-network.org), which was launched in 2008.

The CONSORT Statement is regarded by many as the gold standard guideline for reporting randomised trials

Other developments

The Medical Publishing Insights and Practices initiative was started in 2008 by publication professionals from companies including Amgen, AstraZeneca, GlaxoSmithKline and Pfizer. It has organised meetings to encourage dialogue between pharmaceutical industry employees and journal editors and publishers.[7] One concrete development of the initiative has been the development of an authors' toolkit.[8] The toolkit aims to provide "a new resource for authors that tackles practical questions about manuscript preparation and the submission process that are incompletely addressed in existing guidance documents". It covers authorship, conflict of interest disclosures, publication planning and journal selection. The toolkit also gives practical tips on how companies should interact with journals including guidance on pre-submission enquiries, handling rejections and preparing the cover letter – even providing a template cover letter that authors can adapt. Reflecting

one of the concerns of many drug companies that some studies are difficult to publish, the toolkit includes a section rather coyly entitled 'publishing research findings of "specialized interest"', which notes that "it can be challenging to publish results that are perceived as being negative, merely confirmatory, or otherwise of "specialized interest"'. It provides examples of journals that will consider such submissions and there is also a list of journals that accept manuscripts describing negative studies on the Medical Publishing Insights and Practices (MPIP) website (www.mpip-initiative.org).

Several new journals have been launched (or are about to be launched) by major publishers that appear to cater for 'specialized interest' publications (or, in other words, papers that would be unlikely to be accepted by their flagship journals). Nature Publishing Group launched *Nature Communications* in April 2010 and will launch *Nature Scientific Reports* in mid-2011. *BMJ Open* published its first paper in late February 2011. These follow in the successful footsteps of *PLoS ONE*, which started in late 2006 and now has an impact factor of 4.35, which is remarkable for a new journal with such a high acceptance rate. All these journals offer rapid peer review, high acceptance rates and Open Access publication in return for a publication fee of between $1400 and $5000.

Another trend in journal publishing has been the launch of several titles publishing case histories (which were previously quite hard to publish). Recognising the commercial opportunities of Open Access publishing involving publication fees, several publishers have started case study journals including *BMJ Case Reports* (launched late 2008) and *JRSM Short Reports* (launched mid-2010). However, another outlet for case reports, the journal *Cases* (published by BioMed Central), was short-lived. It started in May 2008 but stopped publishing in December 2009 – presumably because it was not commercially viable – although its editor Richard Smith (former editor of the *BMJ*) says he would like to find another venue for it. Another journal that stopped publishing quite recently is *Medscape General Medicine* – virtually the only free-access journal that did not charge authors for publication – which died in December 2007 after the sponsoring company, Medscape, decided not to fund it any more.

Where next?

Some trends in publication guidelines and requirements are apparent, whereas others are harder to predict. Increasing numbers of journals are following the ICMJE's lead by requiring information about trial registration, or making registration a requirement for publication. It is less clear whether journals will also adopt the ICMJE disclosure policy for competing interests. Many editors regard the ICMJE form and disclosure wording as cumbersome and therefore prefer to retain their own policies and systems. There is no consensus on the time limit for disclosing conflicts (e.g. ICMJE has adopted three years but the Public Library of Science uses five years as the cut-off point) so this is likely to remain variable across different journals for some time.

Concern about inappropriate data analysis has led to calls for public disclosure of raw data. No journals mandate this, but a few are encouraging it. For example, the author guidelines for *BMJ Open* state: "We encourage authors to share raw data either as additional electronic material or through direct links to data repositories" and the journal (like its big sister, the *BMJ*) requires each paper to include a "data sharing statement".

Conclusions

Medical writers and publication planners have to balance the needs of authors, journal editors, reviewers, research sponsors and regulators. Keeping abreast of the changes to guidelines affecting publications is a complex task. Hopefully, this summary of recent major guideline updates will help writers and publication planners to meet this challenge.

References

1. Wager E. *FDAAA Legislation: Global Implications for Clinical Trial Reporting and Publication Planning*. Keyword Pharma Expert Review, Network Pharma 2008. Available from networkpharma.com
2. Wager E. *The International Publication Planning Association's 7th Annual Meeting*. Keyword Pharma Conference Insights, Network Pharma 2009. Available from networkpharma.com
3. Wager E. *Medical Writers and Peer-Reviewed Journals: Understanding the Rules and Responsibilities.* Keyword Pharma Expert Review, Network Pharma 2007. Available from networkpharma.com
4. Dyer C. Aubrey Blumsohn: academic who took on industry. *BMJ* 2009;339:b5293.
5. Hrynaszkiewicz I, Norton ML, Vickers AJ *et al*. Preparing raw clinical data for publication: guidance for journal editors, authors, and peer reviewers. *BMJ* 2010;340:c181.
6. Drazen JM, de Leeuw PW, Laine C *et al.* Toward more uniform conflict disclosures. The updated ICMJE conflict of interest reporting form. *JAMA* 2010;304:212–3.
7. Clark J, Gonzalez J, Mansi B *et al.* Enhancing transparency and efficiency in reporting industry-sponsored clinical research: report from the Medical Publishing Insights and Practices initiative. *Int J Clin Pract* 2010;64:1028–33.
8. Chipperfield L, Citrome L, Clark J *et al.* Authors' submission toolkit: a practical guide to getting your research published. *Curr Med Res Opin* 2010;26:1967–82.

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Executive Summary

Publication planning in the global life science industries continues to attract regulatory scrutiny. Evolution of the sector over the past 12 months has been driven by a steady stream of new guidelines, requirements and recommendations, with the promise of more on the horizon. The joint statement issued by the International Federation of Pharmaceutical Manufacturers and Associations (IFPMA), European Federation of Pharmaceutical Industries and Associations (EFPIA), Japan Pharmaceutical Manufacturers Association (JPMA) and Pharmaceutical Research and Manufacturers of America (PhRMA) in June 2010 established an industry-wide minimum standard for publishing clinical trials. The Sunshine Act in the USA, officially introduced from January 2010, dictates that pharma and medical device companies must publicly disclose the honoraria or payments made to physicians or investigators. Financial interests have long threatened scientific integrity when they foster real or perceived bias in the presentation of research findings and, to overcome this, transparency has become a watchword. But, for publication planners, the concepts of transparency and compliance as priorities are nothing new.

The publications environment is rapidly evolving. Online channels, including the exponential growth of social media tools, are fundamentally changing the way information is disseminated and accessed, and expanding the reach of medical publications well beyond journals' circulation lists. Metrics for measuring the impact and influence of scientific information are becoming more sophisticated, whereas collaboration between industry, academia and governments continues to improve. At the same time, a paradigm shift in the way research is being conducted is underway, with the emergence of comparative effectiveness research revolutionising clinical trial methodology and creating new challenges for publication planners.

The 8th Annual Meeting of the International Publication Planning Association (TIPPA) presented an update on the evolving regulatory landscape for publication planning, and explored how industry, both pharma and medtech, can work within it to raise standards. The meeting shared insights into all aspects of publication planning, including audit trails, the role of marketing, managing competing interests, sponsorship, social media and the evolution of clinical trial methodology. This *Conference Insights* report provides a summary of the meeting, capturing perspectives from publication planning professionals, journal editors, pharmaceutical executives and academics.

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