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Awareness and enforcement of guidelines for publishing industry-sponsored medical research among publication professionals: the Global Publication Survey

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Abstract

Objectives: To gather information about current practices and implementation of publication guidelines among publication professionals working in or for the pharmaceutical industry.

Design/ Setting: Web-based survey publicised to members of the International Society for Medical Publication Professionals (ISMPP) and other relevant organizations, November 2012 to February 2013.

Participants: 469 individuals involved in publishing industry-sponsored research in peer-reviewed journals, mainly working in pharmaceutical or device companies ('industry', n=144), communication agencies ('agency', n=238) or contract research organizations (CRO, n=15), or as freelancers (n=34). Most respondents (78%) had worked on medical publications for >=5 years and 62% had a PhD/MD.

Results: Over 90% of industry, agency, and CRO respondents routinely refer to Good Publication Practice (GPP2) and the International Committee of Medical Journal Editors' Uniform Requirements. Most respondents (78% industry, 79% agency) received mandatory training on ethical publication practices. Over 90% of respondents' companies had publication guidelines or policies and required medical writing support to be acknowledged in publications (96% industry, 99% agency). Many industry respondents used publication management tools to monitor compliance with company guidelines and about half (46%) stated that their company had formal publication audits. Fewer agencies audited adherence to guidelines but 20% of agency respondents reported audits of employees and 6% audits of freelancers. Of concern, 37% of agency respondents reported requests from authors or sponsors that they believed were unethical, although 93% of these requests were withdrawn after respondents explained the need for compliance with guidelines. Most respondents'

departments (63% industry, 58% agency, 60% CRO) had been involved in publishing studies with negative or inconclusive results.

Conclusions: Within this survey sample, publication professionals working in or for industry were aware of, and applied, major publication guidelines. However, the survey also identified specific areas where education and promotion of guidelines is needed to ensure ethical publication practices.

Article summary

Strengths of this study

- Large-scale, international survey of publication professionals (n=469)
- Focused on awareness and implementation of guidelines relating to responsible publication practice, providing insight into current industry practices
- Included publication professionals (e.g. writers, planners, and managers) working in pharmaceutical and medical device companies, medical communication agencies, contract research organizations, or as freelancers
- Survey allowed anonymous responses

Limitations of this study

- Limited response from freelancers (n=34), journal editors, publishers, and academics (n=38)
- Self-selection bias may mean that respondents were not representative of the total population if those with a particular interest in ethical publication practices were more likely to complete the survey than those with less knowledge or interest

INTRODUCTION

Misleading, inaccurate, or incomplete reporting of clinical trial findings can have serious consequences, since doctors and policy-makers rely on publications when developing treatment guidelines and making decisions affecting patients. The involvement of medical writers and other publication professionals, such as planners and managers, in developing peer-reviewed publications reporting clinical trials has been criticised by some,[1, 2] but defended by others.[3, 4] Similarly, while some studies have shown that publications funded by pharmaceutical companies are of equal or higher quality than publications from academia,[5-7] others have shown that they are more likely to be biased.[8, 9] Concern about irresponsible publication practices, from both within and outside the industry, has led to the creation and evolution of several guidelines.[4, 10-13] These guidelines seek to establish responsible publication practices, increase transparency, and prevent bias and commercial influence in reporting medical research. While many have welcomed such guidelines, critics of the pharmaceutical industry remain unconvinced, for example, commenting "Publicly, they insist that everything has changed…. But my concern is this. Having seen so many codes openly ignored and broken, it's hard to take any set of voluntary ideals seriously."[14] Given this concern about whether voluntary guidelines are effective, and because there was little evidence available to show whether continuing concerns about industry publication practices were justified, we sought to generate 'real world' evidence about current practices in the medical publications profession.

We therefore carried out a large-scale, international, survey (the Global Publication Survey) to obtain information about the ways in which medical writers and other publication professionals work and, in particular, their awareness of current publication guidelines. We also sought to learn about the processes adopted by pharmaceutical and communications

companies to encourage responsible practices and to implement published guidelines. The aim of this survey was to identify areas in which guidelines were understood and enforced, areas for improvement, and targets for education and training.

METHODS

The survey questionnaire (Appendix 1) was developed by an international team including professional writers and publication managers with experience of working in pharmaceutical and communications companies and in a freelance capacity. Several team members had been involved in developing publication guidelines (see the author list and acknowledgements for details). Question topics were based on results of a previous survey of members of the International Society for Medical Publication Professionals (ISMPP). Question and answer options were discussed, drafted, and refined by the team. Question types included multiple choice (check one/check all), matrix table, rating (1-5 scale), ranking (top 3), dropdown selection, and free text. Logic checks limited the number of questions respondents saw based on 'skip logic'(i.e. some questions only appeared if the respondent answered 'yes' to an earlier question). 'Not applicable', 'Don't know', and 'Other (specify)' responses were offered to capture the full range of possible responses.

The questionnaire was transcribed to an online data capture tool hosted by Qualtrics (www.qualtrics.com) survey technology. Pilot testing for question content, flow, and logic was performed by team members, and the survey was revised as necessary.

Respondents saw a different selection of questions depending on their work sector (categorised as: pharmaceutical or medical device company, agency, contract research organization [CRO], freelance, journal editor, publisher, or academic) and their previous

answers. Respondents answered, on average, about 40 questions. A response was required for each question before the next screen was displayed but users had the option to revisit previously completed questions. Optional questions were included at the end of the core survey allowing participants to offer additional comments.

The survey was announced on 28th November 2012 via email to all members of ISMPP (n=1105). A link included in the email provided individual access to the survey (so each recipient could respond only once and reminders could be sent to non-responders). ISMPP members were also encouraged to share an unrestricted link to the survey with individual colleagues or via their company intranet. The survey was also promoted via social media (LinkedIn and Twitter). Several organizations and companies (including the American Medical Writers Association, the European Medical Writers Association, the European Association of Science Editors, the Committee on Publication Ethics, McCann Complete Medical, and Excerpta Medica) publicised the survey to their members or on their websites through December 2012. The survey closed on 18th February 2012.

Respondents could complete the survey anonymously but, to encourage participation, had the option of supplying an email address to enter a draw for one of two iPad tablet computers. Participants were informed that their personal information would not be shared beyond those administering the survey. Respondent-level data was available only to TGaS Advisors who were responsible for all aspects of survey administration and data aggregation, and was not shared with the survey organizers or sponsors. Descriptive statistics using frequencies and percentages were used. Funding for the incentive prizes was provided by ISMPP. The team members who developed the questionnaire and executed the survey, interpreted the data, and

developed this publication, worked in their own time or during work time with permission from their various employers but without specific funding or payment.

Research Ethics Committee (Internal Review Board) approval was not required for this survey, as it did not relate to personal medical information, did not involve patients or healthcare professionals (other than in their role as journal editors), was not carried out by an academic institution, and participation was entirely voluntary.

RESULTS

Respondents

The survey reached the intended international target audience with responses from 23 countries. The largest responses came from the USA (44%) and UK (39%). Of the 490 who opened the survey invitation, 469 confirmed that they were involved in publishing industry-sponsored research in peer-reviewed medical journals and completed the survey (Table 1). Most respondents (92%), worked in pharmaceutical or medical device companies (termed 'industry' respondents; 31%), medical communications agencies (termed 'agency' respondents; 51%), or contract research organizations (CROs 3%) providing publication services to drug and device manufacturers, or as freelancers (7%). The survey was also completed by 5 journal editors, 17 publishers, 9 academics and 7 people working in other roles – results from these categories (total = 8%) are not reported in the text due to the low response rate and small numbers but may be viewed at QQQ. Because of the responsive design, the numbers answering each question varied – the full data tables are available at QQQ. Most respondents took 20-30 minutes to complete the survey.

Because of the methods used to promote the survey, it was not possible to calculate a response rate. However, the membership of ISMPP at the time of the survey was 1105 and the response rate from ISMPP members was 20% (i.e. 221 of the respondents responded via the individual links sent out to ISMPP members).

Most respondents were highly educated (56% had a doctorate) and experienced (79% had worked with medical publications for at least 5 years) (Table 1). Half of the respondents worked in departments that had been involved with over 30 manuscripts in the last year.

Table 1 Respondent characteristics

Characteristic	Number	Percentage
Workplace:		
industry[1]	144	31
agency or CRO[2]	238	51
CRO[3]	15	3
freelance	34	7
other	38	8
Experience of working with peer-reviewed publications:		
<2 years	36	8
2-4 years	66	14
5-9 years	111	24
10 years or more	256	55
Qualification:[4]		
Masters degree	111	24
Doctorate	263	56
MD / medical qualification	26	6
Other	26	6
Certified Medical Publication Professional (CMPP)	161	34

[1]Pharmaceutical, biotech or medical device company

[2] Communications company

[3] Contract research organization

[4] Respondents were asked to tick all that applied

Awareness of guidelines

Almost all industry and agency respondents were aware of international guidelines on responsible publication practices (Fig 1). Overall, 91% stated that they routinely referred to Good Publication Practice (GPP2) and 93% to the International Committee of Medical Journal Editors' Uniform Requirements for guidance on ethical practice. Other sources of guidance consulted routinely by respondents in all sectors included ISMPP (71%), medical writers associations (e.g. AMWA and EMWA: 39%), and the Committee on Publication Ethics (COPE: 34%).

Training

Regular training on ethical publication practices was compulsory for most respondents in industry and agencies. Mandatory training for employees was reported by 78% of industry, 79% of agency, and 93% of CRO respondents. In addition, 68% of agency respondents reported that their industry customers provided mandatory training for agency personnel. Training at least once a year was reported by 70%, 68% and 71% for industry, agency and CRO respondents respectively. Just over half the industry respondents (55%) reported that their companies provided training for agency staff or freelancers but only 17% of agency and 20% of CRO respondents reported that their organization provided training for freelancers (while 43% and 53% respectively didn't know if freelancers were trained). Similarly, 24% of the freelancers (5/21) reported that they received mandatory training from industry or agency customers.

Respondents kept up-to-date on current guidelines primarily via training provided by their organization (64%), from professional associations (68%), and monitoring the literature (70%).

Company codes of conduct and publication policies

In addition to their awareness of external guidelines on ethical publication practices (e.g., GPP2), most respondents were aware of internal guidelines governing publication practices. Overall, 78% of respondents worked in an organization that had a Code of Conduct governing ethical publication practices. Nearly all the industry (94%) and agency (94%) respondents and all the CRO respondents (15/15) stated that their company had guidelines or a policy on ethical publication practices (5 industry and 8 agency respondents stated their company did not have such a policy while 3 and 7, respectively, did not know) (Fig 1).

Most company guidelines and policies are not publicly available: only 38% of industry, 35% of agency, and 33% of CRO respondents reported that these documents were publicly accessible (e.g. posted online) (Figure 2).

Of the industry respondents, 67% stated that their company was committed to peer-reviewed publication of results of all studies in humans. Exceptions to this commitment were studies for which companies did not have control (e.g. investigator-initiated studies) (reported by 21) and Phase 1 studies (i.e. early-phase drug development) (reported by 14).

Public disclosure of trial results was reported, by those working within the industry, to be fulfilled by: posting results on a public register (92%), publishing in a peer-reviewed journal (73%), publishing a conference abstract (51%), posting results on a company website (28%), or a combination of these. When asked about the timing of journal publications, most industry respondents reported that their company policy was to submit a manuscript within 12 or 18 months of study completion (last subject, last visit) (43% and 18% respectively).

Nevertheless, 24% of industry respondents reported that their company did not have a target deadline for submitting a manuscript after trial completion (Figure 2).

Similar proportions of industry and agency respondents (80% and 81% respectively) reported that authorship obligations were set out in formal agreements before manuscript development (Fig 1). Almost all industry (96%) and agency (99%) respondents, and 100% of CRO respondents, reported that their department ensured that authors acknowledge professional medical writing support in every publication (Fig 1). Only one respondent from each of the industry and agency groups answered no to this question. However, 11% of respondents from both industry and agency, and 13% from CROs, were aware of academic authors initially refusing to acknowledge professional writing support in the last 12 months.

Compliance with codes

Respondents from industry, and to a lesser extent from agencies, had their publication practices subjected to compliance checks. Of the industry respondents, 61% stated that their company had a formal process for monitoring adherence to company standards and 66 of these (46% of the total) carried out publication audits. A very similar response was obtained from those working in CROs (60% and 47% respectively). However, of the agency respondents, 44% reported that their company had formal compliance monitoring for internal standards and only 20% carried out publication audits. In addition, about half the industry respondents (47%) reported that their company had a formal process for monitoring third-party providers' adherence with company standards and 75% of these reported that this involved an audit. Agency and CRO respondents stated that some (43%, 47% respectively), most (19%, 0%), or none (6%, 13%) of their customers had formal, regular processes such as knowledge tests or audits for monitoring suppliers' adherence to the customer's standards,

while 27% of agency and 40% of CRO respondents did not know if their customers did this. Agency and CRO respondents also reported that their customers used publication management tools to assess compliance (only 6% and 13% respectively reported that no customers did this).

Of the industry respondents, 52% worked in a company operating under a US Government 'Corporate Integrity Agreement' (CIA: see https://oig.hhs.gov/compliance/corporate-integrity-agreements/index.asp), which typically requires formal compliance checking.

Organization of publication activities

Publication activities were primarily governed by medical departments; publications were rarely funded, or approved, by commercial departments (Fig 1). According to the industry respondents, the budget for peer-reviewed publications was usually held by the medical affairs (72%) or clinical development (24%) departments. Nevertheless, seven respondents (5%) stated that the publications budget was held by a commercial department (e.g. sales or marketing) (Fig 2). Involvement of members of commercial departments in developing publications varied, with industry respondents stating that they were: not involved (27%), provided with information only (48%), members of the publication team (44%), allowed to suggest target journals for author consideration (22%), involved in reviewing manuscripts for accuracy (19%), or part of a formal approval process (5%).

Agency response to requests for perceived unethical practices

Respondents were often, but not always, successful in preventing publication practices they considered unethical. Of the agency respondents, 38% were aware, in the past 12 months, of their company being asked by an author or a sponsor to do something that they believed

contravened ethical practices (10% once and 28% more than once) while 2/15 CRO respondents (13%) reported such requests. Respondents reported that their agency's response was to explain the need for compliance, resulting in the request being withdrawn or amended (92% and both CRO cases), or to refuse to accept the work (1%); however, 3% (3/90) stated that the agency ultimately complied with the request.

Although a slightly higher proportion of freelancers (17/34, 50%) reported requests which they believed constituted unethical practices, this should not be over-interpreted due to the small group size; 12% (2/17) of freelancers accepted such work.

Information provided to authors

Authors were routinely provided with various documents and data sources to facilitate manuscript preparation. These documents included (for agency and industry respondents respectively): clinical study report (81%, 79%), study protocol (79%, 83%), summarized data (67%, 66%), statistical report (58%, 62%), manuscript outline (58%, 56%), statistical analysis plan (42%, 54%), and raw data/data tables (42%, 42%).

Enforcement of authorship criteria

Respondents actively enforced compliance with authorship criteria (Table 2).

Table 2

Responses to the question "In the last 12 months, to your knowledge, how often has your department recommended to the lead author the removal of a co-author from a manuscript or abstract that was in development?"

	Never	Once	More than once	Other	Don't know
Industry (n=144)	44% (64)	10% (15)	22% (32)	2% (3)	21% (30)
Agency (n=238)	24% (58)	11% (26)	35% (84)	3% (6)	27% (64)
CRO* (n=15)	27% (4)	33% (5)	7% (1)	7% (1)	27% (4)
Freelance (n=34)	74% (25)	9% (3)	15% (5)	3% (1)	0

*Contract Research Organization

Of the industry respondents, 33% were aware of an author being removed from a manuscript within the last 12 months and 94% stated that this was due to the individual not meeting authorship criteria. Other reasons for recommending removal of an author included individuals leaving the company (28%) or not agreeing to adhere to ethical publication practices (13%) (respondents could select more than one reason). Three respondents from industry and two from agencies reported authors being removed because they disagreed with

the interpretation of the data. Eight freelancers reported recommending the removal of an author, in all cases because the individual did not meet authorship criteria.

Publishing negative findings

Most industry respondents' companies attempted to publish negative or inconclusive results. Of the industry respondents, 63% reported that their department had supported the publication of a study with negative or inconclusive results (17% stated that this had not happened and 19% did not know). Only six respondents (4%) were aware of a negative or inconclusive study for which publication was not planned, in three cases this was due to the discontinuation of product development. Reponses were similar in the agency (and CRO) groups, with 58% (60%) aware of the publication of negative findings and 6% (13%) being aware of negative findings for which publication was not planned. Of the freelancers, 38% had been involved with the publication of negative findings in the last 12 months.

Freelance responses

Only 34 freelance publication professionals responded to the survey and some of these did not answer all questions, therefore the results may not be representative and should not be over-interpreted. However, the following findings were noteworthy: 12/34 (35%) did not know whether their customers had publication guidelines; 15/21 (71%) stated that they did not receive mandatory training; and 21/34 (62%) stated that their clients did not have formal, regular processes to monitor their adherence to standards. However, freelancers reported routinely consulting published guidelines (100% for ICMJE, 91% for GPP2) on ethical issues.

DISCUSSION

This is one of the largest, international surveys designed to capture information about current knowledge and implementation of publication guidelines within the pharmaceutical, medical device, and medical communications industries. Our survey showed high levels of knowledge of the various publication guidelines among publication professionals, with over 90% of respondents stating that they routinely referred to them. Although these published guidelines (such as GPP2) are not generally enforced by legislation, most companies have codes of conduct, policies, or internal guidelines that reflect and enforce them. Similarly, most companies (industry and agencies) provide mandatory training to internal staff, while many pharmaceutical and medical device companies also train agency personnel who develop publications on their behalf. The relatively low rates of training and auditing of freelancers suggested in this survey (albeit from a small number of respondents), however, may represent a problem that companies, agencies, and authors who work with freelancers should address.

Many pharmaceutical companies in the USA currently operate under Corporate Integrity Agreements (CIAs). For such companies, many aspects of good publication practice are legally enforced. An analysis of 12 such agreements issued from 2009 to mid-2012 showed that they included requirements for author agreements, publication plans, and the posting of study results.[15] The CIA requirements were consistent with GPP2 and the ICMJE guidelines and also mandated training and reporting. CIA requirements apply not only to the pharmaceutical company but also to their management of any third-party suppliers, therefore, they will also affect many agencies, freelancers, and CROs. Similarly, even companies without a CIA often require suppliers to follow their policies. Therefore, for many agencies and freelancers, failure to follow a customer's policy could mean loss of future business, thus the underlying guidelines are viewed as compulsory rather than optional.

The importance with which guidelines are viewed is reflected in the effort (and therefore time and money) companies invest in monitoring compliance. Our survey found that many pharmaceutical and device companies have formal monitoring processes including publication audits. Since our survey may have included several respondents from the same company, the results cannot indicate precisely what proportion of companies have such processes but it is probably well over half. The fact that fewer agencies appear to audit to their own internal standards is not surprising, since many reported being regularly audited by their customers. However, rates of training and auditing of freelancers (by pharmaceutical companies and agencies) is less reassuring and suggests room for improvement.

Many companies use specialist publication planning software (such as Datavision™ or PubSTRAT™). Our survey shows that such tools are used not only for publication project management but also to monitor and demonstrate compliance with company procedures, for example, by ensuring that all authors have approved a manuscript outline, drafts, and the final version.

Lack of transparency surrounding company involvement, non-disclosure of competing interests, and misleading authorship have been causes for concern in industry-sponsored publications in the past.[16] In particular, the occurrence of 'ghost-writing' (i.e. unacknowledged use of medical writers) and guest or honorary authorship (i.e. named authors not fulfilling journal authorship criteria) were spurs for the development of both general and specific guidelines.[3, 4, 11, 17] It is therefore encouraging that 96-100% of respondents (working in pharmaceutical and medical device companies, agencies, and CROs) stated that their department ensured that medical writers were acknowledged (thus preventing the

medical writers from being 'ghost writers'). Of concern, however, is the fact that some academic authors apparently continue to be reluctant to acknowledge writing support. Although publication professionals can alert authors about the need for disclosure, academic institutions clearly have an educational role to play.

The ICMJE authorship criteria (which are widely endorsed by medical journals and which were revised after the survey) state that listed authors should have made substantial contributions to both the research and its publication. Therefore authorship cannot be determined until a publication is developed. Individuals involved with the research being reported may be invited to become authors, but will not qualify unless they also take an active role in the publication. It is therefore encouraging that our survey found that not only industry sponsors of research, but also publication agencies and freelancers working for them, actively enforce authorship criteria by suggesting that individuals should be removed from author listings if they fail to meet the ICMJE or other agreed criteria (see Table 2). It can take considerable courage for a freelancer or agency employee to suggest that a proposed author has not contributed sufficiently to merit being listed, especially if that person is a senior academic or well-known expert. Being the one to identify a guest author carries the risk of damaging relationships and possibly work prospects. However, arguably there is an even greater and more serious risk of damaged relations, reputations, and work prospects if a publication professional fails to raise authorship concerns which are later raised by a journal. Early clarification of authorship obligations should reduce the risk of guest authorship and it was encouraging that most respondents reported that authorship agreements were confirmed before manuscript preparation started.

As we cannot tell how often proposed authors fail to contribute to publications, our survey cannot show how often this is overlooked, but the fact that almost one-third of industry respondents were aware of instances of authors being removed because they did not meet authorship criteria suggests that guidelines are being enforced. However, this question also revealed that three industry (2%) and two agency (0.8%) respondents were aware of authors being removed from publications because they disagreed with the interpretation of the findings. We cannot tell how many cases these represent, since several respondents may have reported the same case, nor can we tell whether the disagreements about interpretation were with the sponsor (which would be concerning) or between co-authors, but this issue needs further scrutiny.

The difficulties of interpreting the ICMJE authorship criteria in some situations have been examined in a study coordinated by the Medical Publishing Insights and Practices (MPIP) Initiative.[18] Using vignettes presenting 'challenging real-world authorship scenarios' this study found that journal editors, clinical investigators, medical writers, and publication planners had different views about who qualified for authorship and suggested that additional guidance might be helpful.

Limitations

We had originally hoped to compare or confirm responses from publication professionals with those from journal editors and academic investigators, however, we were less successful in promoting the survey among these groups than among publication professionals and consider the response from these sectors too small to be reliable. The number of responses from freelance publication professionals was also disappointing and it is therefore important not to over-interpret the findings from this group. Care should also be taken in extrapolating

proportions of respondents to proportions of companies or agencies, since we had no way of measuring the numbers of respondents per company.

We also recognise that our survey, like many others, carried the risk of self-selection bias. Our survey was promoted mainly via professional organizations such as ISMPP and AMWA/EMWA which promote ethical publication practices. Those choosing to respond to a survey supported by these associations may be more likely to follow and report ethical publication practices. Our respondents therefore may not be representative of all publication professionals and may be better informed about the topics covered by this survey and more aware of guidelines (e.g. from attending professional meetings or taking part in educational activities). We also acknowledge that our respondents came primarily from higher-income countries. Our findings may not be applicable to publication practices in lower-income countries, particularly given the significant influence of country income on publication practices. [5, 19]

Comparison with other surveys

Journal editors' awareness of various guidelines was measured in 2007 in an international survey to which 111 editors of biomedical journals responded.[20] This survey noted that "awareness and use of guidelines and other resources on publication ethics was generally low". Over half the editors (55%) reported being unaware of the ICMJE Uniform Requirements and two-thirds (67%) were unaware of the GPP guidelines, while the proportion of editors reporting that they had used these guidelines were just 24% and 9% respectively. This represents a marked contrast to the publication professionals responding to our survey, over 90% of whom reported that they routinely referred to these two guidelines.

Another survey of 183 editors of high-impact medical journals in 2009 found that, although 76% had received training in medical editing, they performed poorly when answering questions about: authorship (only 30% gave 'correct' answers, i.e. consistent with commonly cited guidelines), plagiarism (17% correct), peer review (16% correct), and conflicts of interest (15% correct).[21]

A 2012 survey of 294 healthcare professionals found that 42% were unaware of the GPP guidelines.[22] This survey also found that the doctors (69% of whom were authors on peer-reviewed articles) were unfamiliar with, or disagreed with, the ICMJE authorship criteria, since a considerable proportion considered that data collection (51%) or general supervision of a laboratory (33%) alone were criteria for authorship. Nevertheless, 66% of respondents in the healthcare practitioners survey stated that they would be concerned about 'the involvement of pharmaceutical employees as authors or reviewers of a draft manuscript'. A smaller survey of surgeons in Croatia (in 2011) found that only 54% (31/57) were aware of the ICMJE guidelines although 74% (43/58) of the respondents had worked on at least 2 manuscripts for publication in the last 2 years.[23]

A large-scale, repeated survey of medical writers (who were nearly all members of AMWA or EMWA),[24] which attracted 746 responses in 2005, and 662 in 2008, found lower levels of familiarity with guidelines than the current survey (carried out in 2012) but showed that awareness had risen between 2005 and 2008. For example, the proportion of respondents claiming to be familiar with ICMJE guidelines rose from 54% in 2005 to 75% in 2008. The figures for GPP were 43% and 58%, and for the EMWA guidelines (published in 2005) 27% and 46% respectively in 2005 and 2008. The AMWA/EMWA survey also asked writers about their experience of being involved with unacknowledged writing work (i.e.

ghostwriting). In 2005, 39% stated that this practice had decreased in the last 5 years (52% stated that it was unchanged and 8% that it had increased). In 2008, 63% considered that ghostwriting had decreased, 30% stated that it was unchanged and 6% that it had increased in the last 5 years. The proportion of professional writers reporting that they always requested acknowledgement for a substantial contribution to a manuscript also rose from 25% in 2005 to 43% in 2008. The survey was repeated in 2011 (with 620 respondents)[25] and responses showed a clear decrease in the proportion of manuscripts (not necessarily all for peer-reviewed journals) with undisclosed contributions (i.e. ghostwriting) which fell from 62% in 2005, to 42% in 2008, and 33% in 2011.

Ghostwriting of review articles commissioned by pharmaceutical companies was a particular concern when the first GPP guidelines were developed.[26] A survey of authors published in six, high impact general medical journals found a decline in ghost authorship between 1996 and 2008, and a significant decrease (from 26% to 15%) in honorary authorship (which often accompanies ghostwriting) for review articles and editorials (although not for other types of article).[27]

Our survey did not get sufficient response from academics to draw any conclusions about their understanding of their role as authors of medical publications. We hope that the full report of the MPIP authorship project will cast more light on this.[18]

RECOMMENDATIONS

While many of our findings are heartening (Fig 1), some indicate a need for further action (Fig 2). We hope that the professional organizations who were involved with this survey (in particular, ISMPP, AMWA, and EMWA) along with pharmaceutical and medical device

companies will use the findings to identify topics for future training or discussion. We suggest they might focus on the following areas.

- Although many companies and agencies had publication policies, it is disappointing that so few of these policies were made public. We encourage companies to post their publication policies on their websites. Companies might also consider publishing the results of publication audits to indicate how closely they comply with guidelines (for example, what proportion of clinical trials are published) and to help identify obstacles to compliance.
- While our survey suggests that most pharmaceutical companies and agencies have a code of conduct and provide mandatory training on responsible publication practices to relevant staff, this is not always the case, and there is room for improvement, especially for those that sub-contract work to freelancers. We therefore recommend that companies, agencies, and professional groups (such as ISMPP, EMWA, and AMWA) put renewed effort into ensuring that all publication professionals receive effective training. Freelancers should be accountable for their own training, or ensure they receive sufficient training from their customers. We also recommend that individuals involved less directly in publications should be made aware of the relevant guidelines.
- Although pharmaceutical companies generally provide invited authors with study reports and protocols, this was not universal. Named authors should always have access to study results to ensure they can understand and interpret the findings.
- The reported requests from authors or companies for agency staff to do something that the publication professionals considered unethical warrants further investigation. Our survey did not ask about reporting mechanisms for perceived unethical practices, or how strongly these are communicated and used. We encourage agencies to develop

systems for handling such situations. Further education of authors and industry staff, particularly those who are not familiar with the stringency of current guidelines, should help reduce such requests.

- The number of freelancers responding to the survey was small (<50), but some of their responses suggested differences from publication professionals working in companies. We therefore hope a similar survey might be undertaken focusing on the needs of this community and their publication practices to better understand areas where they may need support.

These suggested actions focus primarily on pharmaceutical companies and communications agencies. However, clinical trials and their publication involve many players, and other surveys suggest that both healthcare professionals (investigators and academics) and journal editors would benefit from greater knowledge of published guidelines and may, in fact, be less familiar with such guidelines than publication professionals. Given the financial and human resources required to ensure timely, accurate, and complete reporting of research results,[28] it is likely that the demand for, and use of, publication professionals will increase. Our survey findings indicate that further involvement of knowledgeable and experienced medical publication professionals, who are familiar with guidelines on reporting clinical trials and publication ethics, should be viewed as a positive step in achieving timely and reliable reporting. Our survey findings also complement evidence which shows that manuscripts prepared with professional writing or editing support are more likely to comply with reporting requirements,[29] less likely to be retracted for misconduct,[5] and are accepted for publication more quickly,[30] than those prepared without such support.

Authorship of research publications is not straightforward and the ICMJE criteria have recently been revised. Our survey did not examine views on existing criteria or problems with their implementation, although others have done so.[31, 32] We are aware of current initiatives aimed at deepening understanding and developing consensus around authorship and the transparency of contributions and we welcome these. We would also welcome surveys that test how well non-industry authors and editors comply with voluntary guidelines issued by their professional associations and how such compliance is checked.

CONCLUSIONS

Despite criticism that most publication guidelines are voluntary, our survey suggests that the major guidelines are widely known and implemented by publication professionals working in pharmaceutical and medical device companies, communication agencies, CROs, and as freelancers. Many companies enforce these guidelines through policies, codes of conduct, standard operating procedures, and audits. For companies operating under a CIA, many of the GPP and ICMJE recommendations are mandated and audited by the Office of the Inspector General via independent auditors. When the GPP guidelines were first developed (in the late 1990s), publication audits were unheard of, yet many companies now regularly audit their practices against guidelines such as GPP2, and CIAs mean that many of the GPP recommendations are now legally enforced and monitored.

While there is no room for complacency, and we make no claim that all problems with the publication of industry-funded research have disappeared, this survey, taken together with others showing improved acknowledgement of medical writers, and reductions in guest authorship, suggest that guidelines such as GPP (published in 2003) and GPP2 (2010) have

had a definite, positive effect on publication practices and that most companies and individual publication professionals are striving to do the right thing.

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Contributions

All authors were involved in developing the questionnaire and analysing or interpreting the data. All authors reviewed the manuscript and discussed it critically over several revisions, and agreed to submit it for publication. In addition, EW wrote the first draft of the paper, JF was responsible for data management and analysis, and KW presented initial findings at the 2013 ISMPP meeting and prepared the figures.

Competing interests

EW is an author of the original GPP guidelines, the anti-ghostwriting checklist, the EMWA guidelines on the role of medical writers in publications, and several COPE guidelines. She works as a freelance publications consultant and has provided training to many pharmaceutical companies and communication agencies and receives fees and expenses for talks and workshops on publication guidelines.

KW conducts and publishes research on ethical medical writing practices. She is actively involved in not-for-profit associations that advocate for ethical publication practices. She is paid to provide ethical medical writing training courses and services for not-for-profit and for-profit clients, particularly in the Asia-Pacific region.

AC has served on the ISMPP Certification Board of Trustees.

ST is the chair of the ISMPP Advocacy and Outreach Committee.

AC, VA and ST are employed by a medical communications company that provides publications services to authors and industry sponsors.

JG is on the Board of Trustees of ISMPP and is a steering committee member of the MPIP (Medical Publications Insights and Practices) Initiative.

JG and TG are employees of AstraZeneca and own shares in the company.

JF is an employee of TGaS Advisors, a division of the KnowledgePoint360 Group.

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Data sharing statement
The full questionnaire is available at QQQ. Data aggregated by sector (industry, agency, freelance) is available at XXX.

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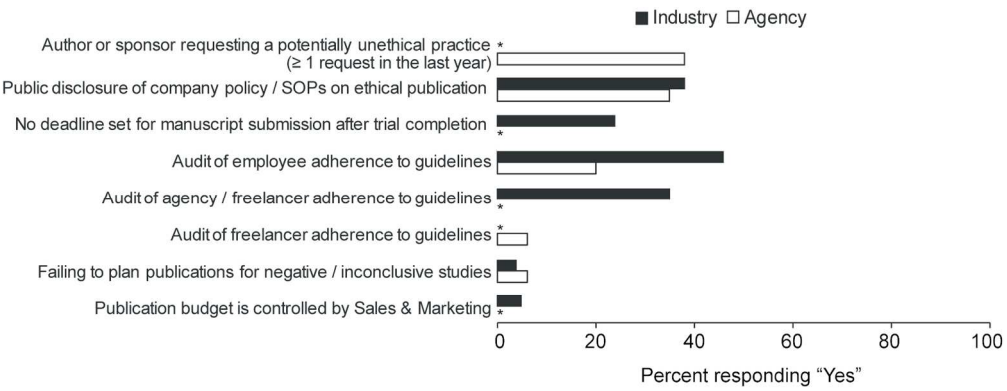

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The Global Publications Survey – Questionnaire Final Draft

MISSION

To identify educational needs in ethical medical publication practices and recommend how these should be addressed to advance the professions that support these practices, and to enhance transparency around peer-reviewed medical publications.

CONTENT

Privacy Notice

In completing this survey you will be providing TGaS Advisors with some of your personal information. TGaS Advisors, based in the United States, is part of the KnowledgePoint360 Group LLC, which is a Safe Harbor Certified company. Your personal information will be used only for the purposes of administering the survey, and to allow stratification and analysis of the data. Your personal information will not be shared with any third parties who are not involved in the administration or analysis of the data. Any shared reports or publications arising from the survey will include only aggregated anonymized data.

Section 1 – DEMOGRAPHICS and CORE QUESTIONS

- [Q1] Does your role include or involve medical publications, defined in this survey as publishing research in peer-reviewed medical journals?
  - Yes
  - No (If no, it is not appropriate for you to complete this Survey. Thank you for your interest.)

- [Q2] How long have you been involved with peer-reviewed medical publications?
  - <2 years
  - 2 to <5 years
  - 5 to <10 years
  - ≥10 years

- [Q3] What academic qualifications do you hold (tick all that apply)?
  - Bachelors degree
  - Masters degree
  - PhD/PharmD or other doctoral degree
  - MD or other medical qualification
  - Other (please specify)

- [Q4] Are you a Certified Medical Publication Professional (CMPP)? Yes/No
  - If no, please describe why you have chosen not to undertake this certification? (tick all that apply)
    - Not relevant to my role
    - Not supported by my senior managers
    - Not sufficiently recognized
    - Not required by my clients
    - Cost is prohibitive
    - Not aware of CMPP
    - I have other professional certifications (please specify)
    - Other (please specify)

- [Q5] Where do you or your organization routinely go for current information on guidelines for ethical medical publication practises? (tick all that apply)
  - Good Publication Practice 2 (GPP2)
  - ICMJE uniform requirements
  - Enhancing the QUAlity and Transparency Of health Research (EQUATOR)
  - Experts in-house (or external advisors)
  - International Society for Medical Publications Professionals (ISMPP)
  - Professional Medical Writers Association (eg. AMWA/EMWA)
  - Committee on Publication Ethics (COPE)
  - Council of Science Editors (CSE)
  - Association of Clinical Researchers and Educators (ACRE)
  - Medical Publishing Insights and Practices (MPIP)

- Social media/networking groups (please specify)
- Other (please specify)

- [Q6] How do you educate yourself on current guidelines and best practises? (tick all that apply)
  - Provided by the organization that I work for
  - Through industry/professional associations
  - Monitoring of the literature
  - Member of social networking groups
  - Undertaking professional qualifications
  - Informal interactions with colleagues
  - Other (please specify)

- [Q7] In your opinion, how informed are each of the following professional groups with regard to guidelines for ethical publication practises e.g. GPP2 (using a scale of '1' to '5', where 1 = not well informed; 5 = very well informed; or 'Don't know)
  - Medical publications professionals in industry
  - Medical publication professionals in agency
  - Medical publications professionals in CRO
  - Freelancer/ independent medical publications professionals
  - Journal editors
  - Publishers
  - Academic researchers
  - Clinical investigators
  - R&D in industry

- [Q8]. Is there a Code of Conduct governing ethical peer-reviewed medical publication practises in your organization? Yes/ No/ Don't know/Not relevant
  - If yes, please indicate if this code is:
    - internal to your organization
    - external to your organization
  - If no, would having a global Code of Conduct enhance adherence to current peer-reviewed medical publication standards? (i.e. a code that includes a formal process to enable complaints to be reviewed and disciplinary action to be taken against individuals or organizations that do not comply with the Code)?
    - Yes
    - No
    - Don't know

- [Q9] Please indicate what types of professional association(s) you are a member of (tick all that apply)
  - A medical professional association
  - An association linked to the pharmaceutical/medical device industry
  - An association for medical writers

- An association for academic researchers/scientists
- An association for clinical researchers
- An association for medical journal editors or publishers
- Other (please specify)
- Not a member of any professional associations

- [Q10] What type of organization do you currently work for? (tick one)
  - Pharmaceutical/biotech/medical device/diagnostics industry [TGaS: Go to Section 2]
  - Agency involved in peer-reviewed medical publications [TGaS: Go to Section 3]
  - CRO involved in peer-reviewed medical publications [TGaS: Go to Section 4]
  - Freelancer/independent medical publications professional involved in peer-reviewed medical publications [TGaS: Go to Section 5]
  - Medical journal [TGaS: Go to Section 6]
  - Publishing company involved in medical publications [TGaS: Go to Section 7]
  - Academic and/or medical institution or association [TGaS: Go to Section 8]
  - Other (please specify) [TGaS: Go to final questions]

Section 2 – INDUSTRY (Pharmaceutical, Biotech, Medical Devices, Diagnostics)

(Unless otherwise directed, please respond as a member of a department within a company, rather than your parent company)

- [Q1-IND] Please select the category that best describes the geographic remit of your role
  - Global HQ
  - Regional HQ
    - Please specify which region
  - National
    - Please specify which country [TGAS – please insert drop down list of countries]
  - Other (please specify)

- [Q2-IND] Please select the category that best describes your role in industry
  - Executive/Department or Function Head
  - Director/Team Leader
  - Publications Manager
  - Researcher (preclinical, clinical or medical)
  - Medical Writer/Editor
  - Other (please specify)

- [Q3-IND] Please indicate the primary focus of the company for which you work
  - Pharmaceutical
  - Biotech
  - Devices/diagnostics
  - Other (please specify)

- [Q4-1ND] To your knowledge, approximately how many peer-reviewed manuscripts has <u>your department</u> supported in the last 12 months?
  - None
    - If none, do you expect your department to support manuscripts in the next 12 months? Yes/No/Don't know
  - <10
  - 10 to <30
  - 30 to <100
  - ≥100
  - Don't know

- [Q5-IND] Is <u>your department</u> operating according to the requirements of a U.S. government Corporate Integrity Agreement (CIA), even if not located in the U.S.? Yes/No/Don't know

- [Q6-IND] Does your company have guidelines/SOP/policy or equivalent that drives ethical, peer-reviewed medical publications practises? Yes/No/Don't know
  - If yes

- Are these global standards? Yes/No/Don't know
- Are any of these publicly disclosed? Yes/No/Don't know
- Is mandatory training provided to the medical publications professionals in your company? Yes/ No/ Don't know
  - If yes, are training updates mandated at least annually? Yes/No/Don't know
- Is mandatory training provided to other employees involved in peer-reviewed medical publications, even if these are not the main focus of their role (e.g. an internal researcher who will be an author on a paper)? Yes/No/Don't know

- [Q6a-IND] Is there a formal, regular process to monitor internal adherence to your standards? Yes/No/Don't know
  - If yes (tick all that apply)
    - Testing knowledge, at least annually
    - Audits
    - Reports from publication management tools
    - Other (please specify)
    - Don't know

- [Q6b-IND] Is training provided to third-party service providers involved in peer-reviewed medical publications (e.g. Agency and Freelancers/independent publications professionals)? Yes/No/Don't know
  - If yes, how frequently? (tick all that apply)
    - At least annually
    - At instigation of the relationship
    - *Ad hoc* updates provided as guidelines change
    - Other (please specify)
    - Don't know

- [Q6c-IND] Is there a formal, regular process to monitor third-party service providers' adherence to your standards? Yes/No/Don't know
  - If yes (tick all that apply)
    - Testing knowledge, at least annually
    - Audits
    - Reports from publication management tools
    - Other (please specify)
    - Don't know

- [Q7-IND] In your department, what public disclosure of clinical trial results is required to fulfil obligations of data transparency? (tick all that apply)
  - Posting summary results on public trial database/registry
  - Abstract publication
  - Peer-reviewed manuscript publication
  - Posting summary results on company website

- Posting full clinical study report (e.g. on company website)
- Other (please specify)
- Don't know

- [Q8-IND] Does your department commit to peer-reviewed publication of results of all studies in humans)? Yes/No/Don't know
  - If yes, within what timeframe do you commit to submit manuscripts for peer review?
    - Within 12 months of last subject, last visit
    - Within 18 months of last subject, last visit
    - No timeframe mandated
    - Other (please specify)
    - Don't know
  - If no, what are the exceptions? (tick all that apply)
    - Phase I studies (in healthy volunteers and/or patients)
    - Studies for which the company does not have control
      - Studies controlled by development partners
      - Investigator Initiated Studies
    - Other (please specify)
    - Don't know

- [Q9-IND] In the last 12 months, approximately what percentage of the peer-reviewed manuscripts that your department has supported were published in open access journals?
  - None
  - <5%
  - 5 to <10%
  - 10 to <20%
  - ≥20%
  - Don't know

  - [Q9a-IND] In your opinion, how do you think the level of open access publications that your department will support will change over the next 2 years?
    - Increase
    - Stay the same
    - Decrease
    - Don't know

  - [Q9b-IND] From the list below, please rate the following reasons to publish in open access journals (using a scale of '1' to '5', where 1 = weak rationale; 5 = strong rationale)
    - Wider access to data
    - Increased speed of publication
    - Copyright retained with authors or company
    - It's mandatory in my organization
    - Other (please specify)

- Don't know

- [Q10-IND] In what circumstances does your department support review articles? (tick all that apply)
  - We do not support review articles
  - Where a scientific/medical or educational need has been identified
  - If proposed by a journal editor/publisher
  - If proposed by external authors
  - If it is a systematic review
  - If it is a narrative review
  - Other (please specify)
  - Don't know

  - [Q10a-IND] If your department supports review articles, please outline in what capacity? (tick all that apply)
    - Company author
    - Review for scientific accuracy
    - Providing data
    - Financial support for professional medical writing/editing, statistical analysis or other assistance
    - Other (please specify)

- [Q11-IND] In your company, which department directly manages the budget for peer-reviewed medical publications? (tick all that apply)
  - Medical Affairs
  - Clinical Development
  - Commercial (e.g. Sales and Marketing)
  - Other (please specify)
  - Don't know

- [Q12-IND] How are Commercial (e.g. Sales and Marketing) colleagues involved in peer-reviewed medical publications? (tick all that apply)
  - They are not involved
  - They are provided with information only
  - They are members of the Publication Planning Team
  - They can suggest publications/journals for author consideration
  - They can review draft manuscripts for accuracy
  - They are part of the formal approval process
  - Other (please specify)
  - Don't know

- [Q13-IND] Thinking about phase III studies in particular, has your department organized/implemented publication steering committees or plan to implement such a committee within the next 6 months? Yes/No/Don't know
  - If yes, how often is this happening compared with 2 years ago?

- More often
- About the same
- Less often
- Don't know

- [Q14-IND] In your department, what data are routinely shared with authors for development of peer-reviewed medical publications? (tick all that apply)
  - Study protocol
  - Statistical analysis plan
  - Statistical reports
  - Raw data/data tables
  - Clinical Study Report (CSR)
  - Summarized data
  - An outline or draft manuscript
  - Other (please specify)
  - Don't know

- [Q15-IND] In the last 12 months, to your knowledge, how often has your department recommended to the lead author the removal of a co-author from a manuscript or abstract that was in development?
  - Never
  - Once
  - More than once
  - Other, please specify
  - Don't know

  - [15a-IND] If once or more, please state reasons (tick all that apply)
    - Author did not meet authorship criteria
    - Author did not agree to adhere to ethical publication practises
    - Author did not agree to disclose medical writing support
    - Author disagreed with the interpretation of the data
    - Author disagreed with the order of authorship
    - Internal author left the organization
    - Other (please specify)
    - Don't know

- [Q16-IND] In your department, are authorship obligations covered under formal agreements prior to each manuscript development? Yes/No/Don't know

- [Q17-IND] In your opinion, who should take responsibility for educating authors on ethical peer-reviewed publication practises? (rank top 3, where 1=primary responsibility)
  - Industry and its professional associations
  - Third party service providers
  - Medical professional associations
  - Academic institutions (universities or hospitals)

- Journal Editors and their professional associations
- Medical writing and publication professionals associations
- Government
- Other (please specify)
- Don't know

- [Q18-IND] Does your department receive assistance from third party service providers in the development of publication plans? (tick all that apply)
  - No third party assistance
  - Agencies
  - CROs
  - Self-employed/ independent publications professionals
  - Other (please specify)
  - Don't know

- [Q19IND] In your opinion, what percentage of peer-reviewed medical publications in your publication plan are provided with some level of support from professional medical writers?
  - <25%
  - 25 to <50%
  - ≥50%
  - Don't know

- [Q20-IND] In your department, over the past 12 months, how often has an author refused an offer of professional medical writing support for their manuscript?
  - Never
  - Once
  - More than once
  - Don't know
    - [Q20a-IND]In your opinion, is refusal happening more or less frequently than 2 years ago?
      - More frequently
      - About the same
      - Less frequently
      - Don't know

- [Q21-IND] Does your department ensure that authors acknowledge professional medical writing support within a peer-reviewed publication according to current guidelines? Yes/No/Don't know
  - [Q21a-IND] In the last 12 months, have you had an author refuse to acknowledge professional writing support? Yes/No/Don't know
    - If yes, how frequently has this occurred in the last 12 months?
      - Once
      - More than once
      - Don't know

- [Q21b-IND] In your opinion, is refusal happening more or less frequently than 2 years ago?
  - More frequently
  - About the same
  - Less frequently
  - Don't know

- [Q22-IND] In the last 12 months, how frequently has your department made a specific payment to external authors for their time and commitment writing and reviewing a manuscript?
  - Never
  - Once
  - More than once
  - Don't know

  - [Q22a-IND] If payment has been made please describe the circumstances (tick all that apply)
    - For statistical review
    - For developing clinical manuscripts
    - For developing review papers
    - Other (please specify)
    - Don't know

- [Q23-IND] In the past 12 months, how often do you think your department has experienced a journal rejecting a manuscript from a robust, well-designed clinical trial, on the grounds that it was associated with the pharmaceutical industry?
  - Never
  - Once
  - More than once
    - If once or more, please indicate which journal(s)
  - Don't know

- [Q24-IND] In the peer-reviewed medical publications that your department has supported over the past 12 months, how often has a journal required a professional medical writer to be included as an author?
  - Never
  - Once
  - More than once
    - If once or more, please indicate which journal(s)
  - Don't know

- [Q25-IND] In the past 12 months, to your knowledge, has your department supported development of a peer-reviewed publication for a study (or studies) that did not meet the primary endpoint or could otherwise be construed as inconclusive or negative? Yes/No/Don't know

- If yes, has the paper(s) been accepted or published in a peer-reviewed journal? Yes/No/Don't know
  - If no (tick all that apply)
    - The paper(s) has not yet been submitted for peer review
    - The paper(s) was rejected
    - The paper(s) was published, but not in a peer-reviewed journal
    - Other (please specify)
    - Don't know

- [Q26-IND] In the past 12 months, are you aware of any results from your company's study (or studies) that did not meet the primary endpoint or could otherwise be construed as inconclusive or negative for which publication is not planned? Yes/No/Don't know
  - If yes, what reason is given for non-publication? (tick all that apply)
    - Study did not meet primary endpoint
    - Study was not conducted in humans
    - Drug development has been discontinued
    - Study was not well designed
    - Study did not complete
    - Additional studies are required to verify the findings
    - Company does not like the results
    - Other (please specify)
    - Don't know

Section 3 – AGENCY

(Unless otherwise directed, please respond as an employee of an Agency, or a single division of a larger Agency network, rather than the parent company)

- [Q1-AG] Please select the category that best describes the geographic remit of your role
  - Global HQ
  - Regional
    - Please specify which region
  - National
    - Please specify which country *[TGAS – please insert drop down list of countries]*
  - Other (please specify)

- [Q2-AG] Please select the category that best describes your role in the Agency
  - Executive/Department or Function Head
  - Director/Team leader
  - Medical Writer/Editor
  - Account Manager/Client Services
  - Other (please specify)

- [Q3-AG] To you knowledge, approximately how many peer-reviewed manuscripts has your Agency supported in the last 12 months?
  - None
    - If none, do you expect your Agency to support manuscripts in the next 12 months? Yes/No/Don't know
  - <10
  - 10 to <30
  - 30 to <100
  - ≥100
  - Don't know

- [Q4-AG] What proportion of your Agency's business revenues were related to peer-reviewed medical publications in the last 12 months?
  - None
  - <10%
  - 10 to <25%
  - 25 to <50%
  - 50 to <75%
  - ≥75%
  - Don't know

- [Q5-AG] Does your Agency have guidelines/SOP/policy or equivalent that drives ethical peer-reviewed medical publications practises? Yes/No/Don't know
  - If yes

- Are these global standards? Yes/No/Don't know
- Are any of these publicly disclosed? Yes/No/Don't know
- Is mandatory training provided to the medical publications professionals in your company? Yes/No/Don't know
    - If yes, are training updates mandated at least annually? Yes/No/Don't know

- [Q5a-AG] Is there a formal, regular process to monitor internal adherence to your standards? Yes/No/Don't know
    - If yes (tick all that apply)
        - Testing knowledge, at least annually
        - Audits
        - Reports from publication management tools
        - Other (please specify)
        - Don't know

- [Q5b-AG] Is training provided to Freelancers (independent publications professionals) that work with your Agency? Yes/No/Don't know
    - If yes, How frequently does your agency provide training to freelancers?(tick all that apply)
        - At least annually
        - At instigation of the relationship
        - *Ad hoc* updates provided as guidelines change
        - Other (please specify)
        - Don't know
        - Not applicable

- [Q5c-AG] Is there a formal, regular process to monitor Freelancers' adherence to your standards? Yes/No/Don't know
    - If yes (tick all that apply)
        - Testing knowledge, at least annually
        - Audits
        - Reports from publication management tools
        - Other (please specify)
        - Don't know
        - Not applicable

- [Q6-AG] What proportion of your client companies have their own guidelines/SOPs/policies or equivalent that drive ethical peer-reviewed medical publications practises?
    - None
    - <10%
    - 10 to <50%
    - 50 to <90%
    - ≥90%
    - Don't know

- [Q6a-AG] If clients do have guidelines/SOPs/policy:
  - Are these global standards? Most / Some / None / Don't know
  - If most or some, are any of these publically disclosed? Most / Some / None / Don't know
  - Is mandatory training provided to your Agency? Yes/No/Don't know
    - If yes, how frequently (tick all that apply)?
      - At least annually
      - At instigation of the relationship
      - *Ad hoc* updates provided as guidelines change
      - Other (please specify)
      - Don't know

- [Q6b-AG] Do any of your clients have a formal, regular process to monitor Agency adherence to their standards? Most/some /None / Don't know
  - If yes, indicate what proportion of your clients use the following (where 0=none; 1=<50%; 2=50-99%; 3=100%)
    - Testing knowledge, at least annually
    - Audits
    - Reports from publication management tools
    - Don't know

- [Q7-AG] What role(s) does your Agency play in peer-reviewed publications? (tick all that apply)?
  - Strategic services e.g. gap analyses to identify unmet educational needs?
  - Publication plan management, tracking all manuscripts within database systems
  - Medical writing services for authors
  - Editorial services for authors
  - Authorship, when criteria are met
  - Other, please specify
  - Don't know

- [Q8-AG] In the last 12 months, approximately what percentage of peer-reviewed manuscripts that your Agency has supported were published in open access journals?
  - None
  - <5%
  - 5 to <10%
  - 10 to <20%
  - ≥20%
  - Don't know

  - [Q8a-AG] In your opinion, how do you think the level of open access publications that your Agency will support will change over the next 2 years?
    - Increase
    - Stay the same
    - Decrease

- Don't know

- [Q8b-AG] From the list below, please rate each of the following reasons to publish in open access journals (using a scale of '1' to '5', where 1 = weak rationale ; 5 = strong rationale)
  - Wider access to data
  - Increased speed of publication
  - Copyright retained with authors or company
  - It's mandatory in the organizations with which we work
  - Don't know

- [Q9-AG] What data do your clients routinely share with authors for development of peer-reviewed medical publications? (tick all that apply)
  - Study protocol
  - Statistical analysis plan
  - Statistical reports
  - Raw data/data tables
  - Clinical Study Report (CSR)
  - Summarized data
  - An outline or draft manuscript
  - Other (please specify)
  - Don't know

- [Q10-AG] In the last 12 months, to your knowledge, how often has your Agency recommended to the lead author the removal of a co-author from a manuscript or abstract that was in development?
  - Never
  - Once
  - More than once
  - Other (please specify)
  - Don't know

  - [Q10a-AG] If once or more, please state reasons (tick all that apply)
    - Author did not meet authorship criteria
    - Author did not agree to adhere to ethical publication practises
    - Author did not agree to disclose medical writing support
    - Author disagreed with the interpretation of the data
    - Author disagreed with the order of authorship
    - Internal author left the client organization
    - Other (please specify)
    - Don't know

- [Q11-AG] In your Agency, are authorship obligations covered under formal agreements between authors and client companies prior to each manuscript development? Yes/No/Don't know

- [Q12-AG] In your opinion, who should take responsibility for educating authors on ethical peer-reviewed publication practises? (rank top 3, where 1=primary responsibility)
    - Industry and its professional associations
    - Third party service providers (such as agencies and independent publication professionals)
    - Medical professional associations
    - Academic institutions (universities or hospitals)
    - Journal Editors and their professional associations
    - Medical writing and publication professionals associations
    - Government
    - Other (please specify)
    - Don't know

- [Q13-AG] In your Agency, over the past 12 months, how often has an author refused an offer of professional medical writing support for their manuscript?
    - Never
    - Once
    - More than once
    - Don't know
        - [Q13a-AG] In your opinion, is refusal happening more or less frequently than 2 years ago?
            - More frequently
            - About the same
            - Less frequently
            - Don't know

- [Q14-AG] Does your Agency ensure that authors acknowledge professional medical writing support within a peer-reviewed publication according to current guidelines? Yes/No/Don't know
    - [Q14a-AG] in the last 12 months, have you had an author refuse to acknowledge professional writing support? Yes/No/Don't know
        - If yes, how frequently has this occurred in the last 12 months?
            - Once
            - More than once
            - Don't know
    - [Q14b-AG] In your opinion, is refusal happening more or less frequently than 2 years ago?
        - More frequently
        - About the same
        - Less frequently
        - Don't know

- [Q15-AG] In the past 12 months, how often do you believe a journal has rejected a manuscript (from robust, well-designed clinical trials) that your Agency was involved with on the grounds that it was associated with the pharmaceutical industry?
    - Never
    - Once
    - More than once
        - If once or more, please indicate which journal(s)
    - Don't know

- [Q16-AG] In the peer-reviewed medical publications that your Agency has supported over the past 12 months, how often has a journal requested a professional medical writer to be included as an author?
    - Never
    - Once
    - More than once
        - If once or more, please indicate which journal(s)
    - Don't know

- [Q17-AG] In the past 12 months, to your knowledge, how frequently has your Agency been asked by a member of a client team or author to undertake a task that you understood may contravene ethical peer-reviewed publications practises?
    - Never
    - Once
    - More than once
    - Don't know

    - [Q17a-AG] If one or more times, how did your Agency respond?
        - Refused to accept the work
        - Explained the need for compliance, such that the request was withdrawn/amended appropriately
        - Accepted the work, even though it was not amended after discussion about compliance
        - Other (please specify)
        - Don't know

- [Q18-AG] In the past 12 months, to your knowledge, has your Agency been involved in the development of a peer-reviewed publication for a study (or studies) that did not meet the primary endpoint or could otherwise be construed as inconclusive or negative? Yes/No/Don't know
    - If yes, has the paper(s) been accepted or published in a peer-reviewed journal? Yes/No/Don't know
        - If no (tick all that apply)
            - The paper(s) has not yet been submitted for peer review
            - The paper(s) was rejected
            - The paper(s) was published, but not in a peer-reviewed journal

- Other (please specify)
- Don't know

- [Q19-AG] In the past 12 months, are you aware of any results from a client study (or studies) that did not meet the primary endpoint, or could otherwise be construed as inconclusive or negative, for which publication is not planned? Yes/No/Don't know
  - If yes, what reason is given for non-publication? (tick all that apply)
    - Study did not meet primary endpoint
    - Study was not conducted in humans
    - Drug development has been discontinued
    - Study was not well designed
    - Study did not complete
    - Additional studies are required to verify the findings
    - Company did not like the results
    - Other (please specify)
    - Don't know

- [Q20-AG] What proportion of your Agency's medical publications work is outsourced to freelancers (independent medical publications professionals)?
  - None
  - <5%
  - 5 to <10%
  - 10 to <20%
  - ≥20%

- [Q21-AG]If not "None" to Q20-AG When freelancers work with your Agency, do they? (tick all that apply)
  - Support development and/or management of publication plans?
  - Provide medical writing assistance in support of peer-reviewed publications?
  - Provide editorial assistance in support of peer-reviewed publications?
  - Manage publications databases
  - Other (please specify)

- [Q22-AG] If not "None" to Q20-AG Does your Agency draw up a formal contract with every freelancer prior to assigning any work? Yes/No/Don't know

Section 4 – CRO

(Unless otherwise directed, please respond as an employee of a department within a CRO, rather than the parent company)

- [Q1-CRO] Please select the category that best describes the geographic remit of your role
  - Global HQ
  - Regional
    - Please specify which region
  - National
    - Please specify which country [TGAS – please insert drop down list of countries]
  - Other (please specify)

- [Q2-CRO] Please select the category that best describes your role in the CRO
  - Executive/Department or Function Head
  - Director/Team Leader
  - Medical Writer/Editor
  - Account Manager/Client Services
  - Other (please specify)

- [Q3-CRO] To you knowledge, approximately how many manuscripts has your department supported during the last 12 months?
  - None
    - If none, do you expect your department to support manuscripts in the next 12 months? Yes/No/Don't know
  - <10
  - 10 to <30
  - 30 to <100
  - ≥100
  - Don't know

- [Q4-CRO] What proportion of your department's business revenues were related to peer-reviewed medical publications in the last 12 months?
  - None
  - <10%
  - 10 to <25%
  - 25 to <50%
  - 50 to <75%
  - ≥75%
  - Don't know

- [Q5-CRO] Does your department have guidelines/SOP/policy or equivalent that drives ethical peer-reviewed medical publications practises? Yes/No/Don't know
  - If yes

- Are these global standards? Yes/No/Don't know
- Are any of these publicly disclosed? Yes/No/Don't know
- Is mandatory training provided to the medical publications professionals in your company? Yes/No/Don't know
    - If yes, are training updates mandated at least annually? Yes/No/Don't know

- [Q5a-CRO] Is there a formal, regular process to monitor internal adherence to your standards? Yes/No/Don't know
    - If yes (tick all that apply)
        - Testing knowledge, at least annually
        - Audits
        - Reports from publication management tools
        - Other (please specify)
        - Don't Know

- [Q5b-CRO] Is training provided to freelancers (independent medical publications professionals) who work with your company? Yes/No/Don't know
    - If yes, how frequently? (tick all that apply)
        - At least annually
        - At instigation of the relationship
        - *Ad hoc* updates provided as guidelines change
        - Other (please specify)
        - Don't know

- [Q5c-CRO]Is there a formal, regular process to monitor freelancers' adherence to your standards? Yes/No/Don't know
    - If yes (tick all that apply)
        - Testing knowledge, at least annually
        - Audits
        - Reports from publication management tools
        - Other (please specify)
        - Don't know

- [Q6-CRO] What proportion of your client companies have their own guidelines/SOPs/policies or equivalent that drive ethical peer-reviewed medical publications practises?
    - None
    - <10%
    - 10 to <50%
    - 50 to <90%
    - ≥90%
    - Don't know

    - [Q6a-CRO] If clients do have guidelines/SOPs/policy

- Are these global standards? Most / Some / None / Don't know
- Are any of these publically disclosed? Most / Some / None /Don't know
- Is mandatory training provided to your department? Yes/No/Don't know
  - If yes, how frequently? (tick all that apply)
    - At least annually
    - At instigation of the relationship
    - *Ad hoc* updates provided as guidelines change
    - Other (please specify)
    - Don't know

- [Q6b-CRO] Do any of your clients have a formal, regular process to monitor your adherence to their standards? Most / Some / None / Don't know
  - If Most / Some, indicate what proportion of your clients use the following (where 0=none; 1=<50%; 2=50-99%; 3=100%)
    - Testing knowledge, at least annually
    - Audits
    - Reports from publication management tools
    - Don't know

- [Q7-CRO] What role(s) does your department play in peer-reviewed publications? (tick all that apply)
  - Strategic services e.g. gap analyses to identify unmet educational needs
  - Publication plan management, tracking all manuscripts within database systems
  - Medical writing assistance for authors
  - Editorial service for authors
  - Authorship, when criteria are met
  - Other (please specify)
  - Don't know

- [Q8-CRO] What data do your clients routinely share with authors for development of peer-reviewed publications? (tick all that apply)
  - Study protocol
  - Statistical analysis plan
  - Statistical reports
  - Raw data/data tables
  - Clinical Study Report (CSR)
  - Summarized data
  - An outline or draft manuscript
  - Other (please specify)
  - Don't know

- [Q9-CRO] In the last 12 months, to your knowledge, how often has your department recommended to the lead author the removal of a co-author from a manuscript or abstract that was in development?

- Never
- Once
- More than once
- Other (please specify)
- Don't know

- [Q9a-CRO] If once or more, please state reasons (tick all that apply)
  - Author did not meet authorship criteria
  - Author did not agree to adhere to ethical publication practises
  - Author did not agree to disclose medical writing support
  - Author disagreed with the interpretation of the data
  - Author disagreed with the order of authorship
  - Internal author left the client organization
  - Other (please specify)
  - Don't know

- [Q10-CRO] In your department, are authorship obligations covered under formal agreements between authors and client companies prior to each manuscript development? Yes/No/Don't know

- [Q11-CRO] In your opinion, who should take responsibility for educating authors on ethical peer-reviewed publication practises? (rank top 3, where 1=primary responsibility)
  - Industry and its professional associations
  - Third party service providers (such as agencies, CROs and independent medical publication professionals)
  - Medical professional associations
  - Academic institutions (universities or hospitals)
  - Journal Editors and their professional associations
  - Medical writing and publication professionals associations
  - Government
  - Other (please specify)

- [Q12-CRO] In your department, over the past 12 months, how often has an author refused an offer of professional medical writing support for their manuscript?
  - Never
  - Once
  - More than once
  - Don't know

  - [Q12a-CRO] In your opinion, is refusal happening more or less frequently than 2 years ago?
    - More frequently
    - About the same
    - Less frequently
    - Don't know

- [Q13-CRO] Does your department ensure that authors acknowledge professional medical writing support within a peer-reviewed publication according to current guidelines? Yes/No/Don't know
    - [Q13a-CRO] In the last 12 months, have you had an author refuse to acknowledge professional medical writing support? Yes/No/Don't know
        - If yes, how frequently has this occurred in the last 12 months?
            - Never
            - Once
            - More than once
            - Don't know
    - [Q13b-CRO] In your opinion, is refusal happening more or less frequently than 2 years ago?
        - More frequently
        - About the same
        - Less frequently
        - Don't know

- [Q14-CRO] In the past 12 months, how often do you believe a journal has rejected a manuscript (from robust, well-designed clinical trials) that your department was involved with on the grounds that it was associated with the pharmaceutical industry?
    - Never
    - Once
    - More than once
        - If once or more, please indicate which journal(s)
    - Don't know

- [Q15-CRO] In the peer-reviewed medical publications that your department has supported over the past 12 months, how often has a journal requested a professional medical writer to be included as an author?
    - Never
    - Once
    - More than once
        - If once or more, please indicate which journal(s)
    - Don't know

- [Q16-CRO] In the past 12 months, to your knowledge, how frequently has your department been asked by a member of a client team or author to undertake a task which you understood may contravene ethical peer-reviewed publications practises?
    - Never
    - Once
    - More than once
    - Don't know

- [Q16a-CRO] If one or more times, how did your department respond? (tick all that apply)
  - Refused to accept the work
  - Explained the need for compliance, such that the request was withdrawn/amended appropriately
  - Accepted the work even though it was not amended after discussion about compliance
  - Other (please specify)
  - Don't know

- [Q17-CRO] In the past 12 months, to your knowledge, has your department been involved with the development of a peer-reviewed publication for a study (or studies) that did not meet the primary endpoint or could otherwise be construed as inconclusive or negative? Yes/No/Don't know
  - If yes, has the paper(s) been accepted or published in a peer-reviewed journal? Yes/No/Don't know
    - If no (tick all that apply)
      - The paper(s) has not yet been submitted for peer review
      - The paper(s) was rejected
      - The paper(s) was published, but not in a per-reviewed journal
      - Other (please specify)
      - Don't know

- [Q18-CRO] In the past 12 months, are you aware of any results from a client study (or studies) that did not meet the primary endpoint, or could otherwise be construed as inconclusive or negative, for which publication is not planned? Yes/No/Don't know
  - If yes, what reason is given for non-publication? (tick all that apply)
    - Study did not meet primary endpoint
    - Study was not conducted in humans
    - Drug development has been discontinued
    - Study was not well designed
    - Study did not complete
    - Additional studies are required to verify the findings
    - Company did not like the results
    - Other (please specify)
    - Don't know

- [Q19-CRO] What proportion of your department's medical publications work is outsourced to freelancers (independent medical publications professionals)?
  - None
  - <5%
  - 5 to <10%
  - 10 to <20%
  - ≥20%

- [Q20-CRO] When freelancers work with your department, do they? (tick all that apply)
  - Support development and/or management of publication plans?
  - Provide medical writing assistance in support of peer-reviewed publications?
  - Provide editorial assistance in support of peer-reviewed publications?
  - Manage publications databases
  - Other (please specify)

- [Q21-CRO] Does your department draw up a formal contract with every freelancer prior to assigning any work? Yes/No/Don't know

Section 5 – FREELANCER (independent medical publications professional)

- [Q1-FL] How long have you worked in medical publications in a freelance (independent) capacity?
  - <2 years
  - 2 to <5 years
  - 5 to <10 years
  - ≥10 years

  - [Q1a-FL] If >5 years, in your opinion, how does freelance writers' adherence to ethical peer-reviewed publication practise today compare with 5 years ago?
    - Today writers are more aware of good publication practice and follow it stringently (1=strongly disagree to 5=strongly agree)

- [Q2-FL] Please rank which of the following most strongly influences your adherence to ethical peer-reviewed publication practise (1= least influential to 6 = most influential)?
  - Author(s)
  - Client (Industry)
  - Client (Agency)
  - Peer network
  - Medical publication associations
  - Self-regulated, based on keeping up-to-date with guidelines

- [Q3-FL] What role(s) do you play in peer-reviewed publications? (tick all that apply)
  - Strategic services e.g. gap analyses to identify unmet educational needs
  - Publication plan management, tracking all manuscripts within database systems
  - Medical writing assistance for authors
  - Editorial services for authors
  - Authorship, when criteria are met
  - Other (please specify)

- [Q4-FL] What proportion of your client companies have their own guidelines/SOPs/policies or equivalent that drive ethical peer-reviewed medical publications practises?
  - None
  - <10%
  - 10 to<50%
  - 50 to<90%
  - ≥90%
  - Don't know

  - [Q4a-FL] If clients do have guidelines/SOPs/policy
    - Are these global standards? Most / Some / None /Don't know
    - Are any of these publicly disclosed? Most / Some / None/Don't know
    - Is mandatory training provided to you? Yes/No/Don't know
      - If yes, how frequently? (tick all that apply)

- At least annually
- At instigation of the relationship
- *Ad hoc* updates provided as guidelines change
- Other (please specify)
- Don't know

- [Q4b-FL] Do any of your clients have a formal, regular process to monitor your adherence to their standards? Yes/No/Don't know
  - If yes, indicate what proportion of your clients use the following (where 0=none; 1=<50%; 2=50-99%; 3=100%)
    - Testing knowledge, at least annually
    - Audits
    - Reports from publication management tools
    - Don't know

- [Q5-FL] In the past 12 months, how frequently have you been asked by a member of a client team to undertake a task that you understood may contravene ethical peer-reviewed publications practises?
  - Never
  - Once
  - More than once
  - Don't know

  - [Q5a-FL] If one or more times, how did you respond? (tick all that apply)
    - Refused to accept the work
    - Explained the need for compliance, such that the request was withdrawn/amended appropriately
    - Accepted the work even though it was not amended after discussion about compliance
    - Other (please specify)
    - Don't know

- [Q6-FL] In your opinion, what level of independent support is available to you when dealing with client or author issues related to ethical peer-reviewed publication practises? None/insufficient/sufficient/plenty
  - If none or insufficient, in your opinion, how should this counsel be provided?
    - Professional association to provide compliance support services
    - Peer network
    - Social media
    - Other (please specify)

- [Q7-FL] In the last 12 months, how often have you recommended to the lead author the removal of a co-author from a manuscript or abstract that was in development?
  - Never
  - Once

- More than once
- Other (please specify)
- Don't know

- [Q7a-FL] If once or more, please state reasons (tick all that apply)
  - Author did not meet authorship criteria
  - Author did not agree to adhere to ethical publication practises
  - Author did not agree to disclose medical writing support
  - Author disagreed with the interpretation of the data
  - Author disagreed with the order of authorship
  - Internal author left the client organization
  - Other (please specify)
  - Don't know

- [Q8-FL] In your opinion, who should take responsibility for educating authors on ethical peer-reviewed publication practises? (rank top 3, where 1=primary responsibility)
  - Industry and its professional associations
  - Third party service providers (such as agencies and independent medical publication professionals)
  - Medical professional associations
  - Academic institutions (universities or hospitals)
  - Journal Editors and their professional associations
  - Medical writing and publication professionals associations
  - Government
  - Other (please specify)

- [Q9-FL] In the past 12 months, how have you had an author refuse an offer of professional medical writing support for their manuscript?
  - Never
  - Once
  - More than once
  - Don't know

  - [Q9a-FL] In your opinion, is refusal happening more or less frequently than 2 years ago?
    - More frequently
    - About the same
    - Less frequently
    - Don't know

- [Q10-FL] Do you feel that you are appropriately acknowledged for medical writing support that you provide?
  - Always
  - Sometimes
  - Never

- Don't know

- [Q11-FL] In the peer-reviewed medical publications that you have supported over the past 12 months, has a journal requested that you be included as an author?
  - Never
  - Once
  - More than once.
  - Don't Know

  - [Q11a-FL]If once or more, please indicate which journal(s)

- [Q12-FL] Over the past 12 months, how often do you believe a journal has rejected a manuscript (from robust, well-designed clinical trials) that you were involved with on the grounds that it was associated with the pharmaceutical industry?
  - Never
  - Once
  - More than once
    - If once or more, please indicate which journal(s)
  - Don't know

- [Q13-FL] In the past 12 months, have you been involved with the development of a peer-reviewed publication for a study (or studies) that did not meet the primary endpoint or could otherwise be construed as inconclusive or negative? Yes/No/Don't know
  - If yes, has the paper(s) been accepted or published in a peer-reviewed journal? Yes/No/Don't know
    - If no, tick all that apply
      - The paper(s) has not yet been submitted for peer review
      - The paper(s) was rejected
      - The paper(s) was published, but not in a peer-reviewed journal
      - Other (please specify)
      - Don't know

- [Q14-FL] In the past 12 months, are you aware of any results from a client study (or studies) that did not meet the primary endpoint, or could be construed as inconclusive or negative, for which publication is <u>not</u> planned? Yes/No/Don't know
  - If yes, what reason is given for non-publication? (tick all that apply)
    - Study did not meet primary endpoint
    - Study was not conducted in humans
    - Drug development has been discontinued
    - Study was not well designed
    - Study did not complete
    - Additional studies are required to verify the findings
    - Company did not like the results
    - Other (please specify)
    - Don't know

Section 6 – JOURNAL EDITOR – Please respond thinking of one Primary Healthcare journal you are responsible for

- [Q1-JE] Please select the category that best describes the geographic remit of your role
  - Global HQ
  - Regional HQ
    - Please specify which region
  - National
    - Please specify which country [TGAS – please insert drop down list of countries]
  - Other, please specify…

- [Q2-JE] Please select the category that best describes your role at the journal
  - Journal Editor
  - Managing Editor
  - Associate Editor
  - Administrative role
  - Other (please specify)

- [Q3-JE] Please describe the key elements of your role (tick all that apply)
  - Screening all submissions prior to peer-review
  - Selecting journal review panel
  - Writing editorials on key papers
  - Developing author guidelines
  - Soliciting content for the journal
  - Developing themed issues
  - Handling queries on manuscripts
  - Determining manuscripts for enhanced content
  - Handling disputes/retractions
  - Other (please specify)

- [Q4-JE] What medium does your journal publish in?
  - Print only
  - Online only
  - Both

- [Q5-JE] Please describe the importance of the following to your journal
  - Open Access content:
    - Very
    - Somewhat
    - Not relevant
    - Don't know
  - Enhanced content such as MOAs, videos, supplemental information:
    - Very
    - Somewhat

- Not relevant
- Don't know

- [Q5a-JE] If very or somewhat, do you charge a fee for these enhancements?
  - Yes
  - No
  - Don't know

- [Q6-JE] Is your journal considered to be a general or specialty journal?
  - General medical
  - Speciality medical
  - Health economics
  - Epidemiology
  - Primary care
  - Other (please specify)

- [Q7-JE] In the course of a 12-month period, roughly what proportion of accepted papers in your journal covers negative studies (i.e. studies that have not met the primary endpoint or are statistically non-significant/neutral/inconclusive)?
  - None
  - <10%
  - 10 to <25%
  - 25 to <50%
  - 50 to <75%
  - ≥75%
  - Don't know

- [Q8-JE] In the past 12 months, has your journal had to print a retraction as a result of misconduct?
  - Yes
  - No
  - Don't know

  - [Q8a-JE] If yes, please specify if the research was
    - Industry-sponsored
    - Academic research
    - Other (please specify)
    - Don't know

- [Q9-JE] Do you publicly name your peer-review panel on your website?
  - Yes
  - No
  - Other, please specify
  - Don't know

- [Q9b-JE] Do you disclose which reviewers participated in the peer-review for individual papers?
  - Yes
  - No
  - Other, please specify
  - Don't know

- [Q10-JE] When sending manuscripts out for peer-review, is this conducted in a blinded or open fashion?
  - We anonymize submissions prior to peer review
  - We do not anonymize submissions prior to peer review
  - Other (please specify)
  - Don't know

- [Q11-JE] What authorship criteria does your journal apply?
  - ICMJE guidelines
  - Specific journal criteria (modified ICMJE)
  - Specific journal criteria
  - Contributor model
  - Other (please specify)
  - Don't know

- [Q12-JE] In the last 12 months, has your journal refused to accept an author on a manuscript or abstract because he/she has not fulfilled your specified authorship criteria?
  - No
  - Yes
    - Was this as a result of your own review? Yes/No
    - Was this as a result of concerns raised by others? Yes/No
  - We don't check authorship criteria – authors are responsible for their own submissions
  - Other (please specify)
  - Don't know

- [Q13-JE]: What conflict of interest guidelines are used at your journal?
  - ICMJE
  - Journal's own
  - Other (please specify)
  - Don't know

    - [Q13a-JE] Over what duration of time does your journal require authors to disclose COI information over?
      - Current relationships and activities

- Activities within the last 2 years
- Activities within the last 4 years
- Activities within the last 5 years
- More than 5 years

- [Q13b-JE] Do you require disclosures on
  - Solely in relation to drugs/devices that are the subject of the manuscript
  - All industry COI regardless of whether they are discussed in the manuscript

- [Q14-JE] What is your journal's position on professional medical writing support? (tick all that apply)
  - Medical writers are acceptable as long as their contribution is appropriately acknowledged and they are authors if they fulfil the criteria for authorship
  - All medical writers involved in drafting a manuscript should be authors
  - We follow a contributor model
  - Only where the authors need help for language and grammar
  - We do not accept manuscripts that have had professional medical writing support
  - Other (please specify)
  - Don't know

- [Q15-JE]. Do professional medical writers improve the quality of a manuscript?
  - Yes
  - Sometimes,
  - No,
  - Don't know

- [Q16-JE]Do you ensure authors acknowledge medical writing support according to your journal's current guidelines?
  - Yes, in our guidance for authors, we provide relevant information (such as a checklist) on acknowledging contributions and support
  - No, this is the responsibility of the authors.
  - Don't know
  - Other (please specify)

- [Q17-JE]Does your journal always publish the full acknowledgments submitted by the authors?
  - Yes – both online and in print
  - Yes – in print only
  - Yes – online only
  - No
  - Other (please specify)
  - Don't know

- [Q18-JE] In the past 12 months, how often have you heard of an author refusing to acknowledge professional medical writing support on a manuscript they submitted to your journal?
    - Never
    - Once
    - More than once
    - Don't know

    - [Q18a-JE] In your opinion, is refusal happening more or less frequently than 2 years ago?
        - More frequently
        - About the same
        - Less frequently
        - Don't know

- [Q19-JE] What is your journal's policy on review articles? (tick all that apply)
    - We review all submissions on merit, provided all appropriate acknowledgments and COIs are disclosed and journal guidelines are met
    - We only accept review articles from academia
    - We do not publish review articles
    - Other (please specify)
    - Don't know

- [Q20 – JE] What is your journal's philosophy and/or policy on publishing pharmaceutical industry sponsored research? (tick all that apply)
    - We consider all well-conducted research regardless of the funding source
    - We accept industry sponsored research only if they allow full access to the original data
    - We accept industry sponsored research if they allow analysis of the data to be conducted by an independent academic statistician
    - We do a more rigorous review of industry sponsored research
    - We don't accept publications on industry sponsored research
    - Other (please specify)
    - Don't know

- [Q21-JE] In the past 12 months, has your journal rejected a paper primarily because of you believed the content was biased because it was associated with the pharmaceutical industry?
    - No
    - We don't publish industry sponsored research
    - Yes, once
    - Yes, more than once
    - Don't know

- [Q22-JE] Does your journal accept advertising from industry?

- Yes
- No
- Don't know
  - If yes, do you have an in-house or affiliated sales department that contacts industry regarding potential advertising?
    - Yes
    - No
    - Don't know

- [Q23-JE] Does your journal sell reprints of individual papers?
  - Yes
  - No
  - Don't know
    - If yes, do you have an in-house or affiliated sales department that contacts industry regarding potential reprints?
      - Yes
      - No
      - Don't know

Section 7 – PUBLISHING COMPANY

- [Q1-PC] Please select the category that best describes the geographic remit of your role
  - Global HQ
  - Regional
    - Please specify which region
  - National
    - Please specify which country [TGAS – please insert drop down list of countries]
  - Other (please specify)

- [Q2-PC] Please select the category that best describes your role in the journal
  - Executive
  - Journal Publisher
  - Managing Publisher
  - Associate Publisher
  - Business / Sales role
  - Administrative role
  - Other (please specify)

- [Q3-PC] Please describe the key elements of your role (tick all that apply)
  - Developing new publication channels applicable to medical publications
  - Determining manuscripts for enhanced content
  - Handling disputes/retractions
  - Managing journal production
  - Commissioning content
  - Other (please specify)

- [Q4-PC] What proportion of your company is focused on medical publishing?
  - <10%
  - 10 to <50%
  - 50 to <75%
  - ≥75%

- [Q5-PC] What proportion of your medical journals are supported by online content
  - None
  - 10 to <50%
  - 50 to <75%
  - ≥75%

- [Q6-PC] What is the primary business model for your medical journals? (tick all that apply)
  - Journal subscriptions
  - Advertising revenue
  - Open access fees
  - Other (please specify)

- Don't know

- [Q7-PC] Please describe the importance of the following to your medical journals
  - Open access content
    - Very
    - Somewhat
    - Not relevant
    - Don't know
  - Enhanced content such as MOAs, videos, supplemental information
    - Very
    - Somewhat
    - Not relevant
    - Don't know

    - [Q7a-PC]If very or somewhat, do you charge a fee for these enhancements?
      - Yes
      - No
      - Don't know

    - [Q7b-PC] Who pays for enhanced content in your journals?
      - There is no charge
      - Either the industry or academic sponsor linked to that paper
      - Paid for by unrestricted educational grants
      - Paid for from the advertising budget
      - Other (please specify)

- [Q8-PC] Are your medical journals primarily considered to be general or specialty journals? Please tick all that apply
  - General medical
  - Speciality medical
  - Health economics
  - Epidemiology
  - Primary care
  - Other (please specify)

- [Q9-PC] In the course of a 12-month period, roughly what proportion of accepted papers in your medical journals cover negative studies (i.e. studies that have not met the primary endpoint or are statistically non-significant/neutral/inconclusive)?
  - None
  - <10%
  - 10 to <25%
  - 25 to <50%
  - 50 to <75%
  - ≥75%

- Don't know

- [Q10-PC] In the past 12 months, have any of your medical journals had to print a retraction as a result of misconduct?
  - Yes
  - No
  - Don't Know

  - [Q10a-PC] If yes, please specify if the research was
    - Industry-sponsored
    - Academic research only
    - Other (please specify – including if there was more than one retraction relating to your journals)
    - Don't know

- [Q11-PC] What authorship criteria do your medical journals apply?
  - ICMJE guidelines
  - Specific journal criteria (modified ICMJE)
  - Specific journal criteria
  - Contributor model
  - Other (please specify)
  - Don't know

- [Q12-PC] In the last 12 months, have any of your medical journals refused to accept an author on a manuscript or abstract because he/she has not fulfilled your specified authorship criteria?
  - No
  - Yes
    - Was this as a result of your own review? Yes/No
    - Was this as a result of concerns raised by others? Yes/No
  - We don't check authorship criteria – authors are responsible for their own submissions
  - Other (please specify)
  - Don't know

- [Q13-PC]: What conflict of interest guidelines are used at your medical journals?
  - ICMJE
  - Journal's own
  - Other (please specify)
  - Don't know

  - [Q13a-PC] Over what duration of time do your journals require authors to disclose COI information?
    - Current relationships and activities

- Activities within the last 2 years
- Activities within the last 4 years
- Activities within the last 5 years
- More than 5 years

- [Q13b-PC] Do you require disclosures on
  - Solely in relation to drugs/devices that are the subject of the manuscript (Y/N)
  - All industry COI regardless of whether they are discussed in the manuscript (Y/N)

- [Q14-PC] What is your journals' position on professional medical writing support? (tick all that apply)
  - Medical writers are acceptable as long as their contribution is appropriately acknowledged and they are authors if they fulfil the criteria for authorship.
  - All medical writers involved in drafting a manuscript should be authors
  - We follow a contributor model
  - Only where the authors need help for language and grammar
  - We do not accept manuscripts that have had professional medical writing support
  - Other (please specify)
  - Don't know

- [Q15-PC]. Do professional medical writers improve the quality of a manuscript?
  - Yes
  - Sometimes
  - No
  - Don't know

- [Q16-PC] Do you ensure authors acknowledge medical writing support according to your journal's current guidelines?
  - Yes - In our guidance for authors, we provide relevant information (such as a checklist) on acknowledging contributions and support
  - No, This is the responsibility of the authors.
  - Don't know
  - Other (please specify)

- [Q17-PC]Do your medical journals always publish the full acknowledgments submitted by the authors?
  - Yes – both online and in print
  - Yes – in print only
  - Yes – online only
  - No
  - Other (please specify)

- Don't know

- [Q18-PC] In the past 12 months, how often have you heard of an author refusing to acknowledge professional writing support on a manuscript they submitted to your journal?
  - Never
  - Once
  - More than once
  - Don't know

    - [Q18a-PC] In your opinion, is refusal happening more or less frequently than 2 years ago?
      - More frequently
      - About the same
      - Less frequently
      - Don't know

- [Q19-PC] What are your medical journal's policies on review articles? (tick all that apply)
  - We review all submissions on merit provided all appropriate acknowledgements and COIs are disclosed and journal guidelines are met
  - We only accept review articles from academia
  - We do not publish review articles
  - Other (please specify)
  - Don't know

- [Q20 – PC] What is your philosophy and/or policy on publishing pharmaceutical industry sponsored research? (tick all that apply)
  - We consider all well-conducted research regardless of the funding source
  - We accept industry sponsored research only if they allow full access to the original data
  - We accept industry sponsored research if they allow analysis of the data to be conducted by an independent academic statistician
  - We do a more rigorous review of industry sponsored research
  - We don't accept publications on industry sponsored research
  - Other (please specify)
  - Don't know

- [Q21-PC] In the past 12 months, has your journal rejected a paper primarily because you believed the content was biased because it was associated with the pharmaceutical industry?
  - No
  - No, we don't publish industry sponsored research
  - Yes, once
  - Yes, more than once.
  - Don't know

- [Q22-PC] Do your journals accept advertising from industry?
  - Yes
  - No
  - Don't know
    - If yes, do you have an in-house or affiliated sales department that contacts industry regarding potential advertising?
      - Yes
      - No
      - Don't know

- [Q23-PC] Do your journals sell reprints of individual papers?
  - Yes
  - No
  - Don't know
    - If yes, do you have an in-house or affiliated sales department that contacts industry regarding potential reprints?
      - Yes
      - No
      - Don't know

Section 8 – ACADEMIC, RESEARCH and/or MEDICAL Institution or Association

- [Q1-ARM] Please select the category that best describes the geographic remit of your role
  - Global
  - Regional
    - Please specify which region
  - National
    - Please specify which country [TGaS to add drop down list of countries]
  - Other (please specify)

- [Q2-ARM] Please select the category that best describes your role in the institution/association
  - Executive/Department or Function Head
  - Director/Team Leader
  - Researcher
  - Educator
  - Other (please specify)

- [Q3-ARM] Does your institution/association have a role in publication of medical research in peer-reviewed journals? (tick all that apply)
  - Yes – we conduct and publish our own research
  - Yes – we conduct and publish research in collaboration with academic partners
  - Yes – we conduct and publish medical research in collaboration with pharmaceutical/Biotechnology/Devices industry partners
  - No – we do not publish medical research papers
  - Don't know

- [Q4-ARM] As there are guidelines in place to publish all medical research regardless of outcome, how do you address the challenge of publishing everything? (tick all that apply)
  - Our academics author all of the papers themselves
  - We have dedicated writing resource at our institution
  - We contract with freelancers to support development of the publications
  - Our industry partners fund professional medical writing support for us
  - We prioritise publications of most relevance and interest to the field
  - We don't publish all of the studies that we conduct
  - Don't know

- [Q5-ARM] Do you work with professional medical writers (Check all that apply)?
  - Yes
    - If yes are they
      - Independent freelancers? Y/N
      - Agency professionals? Y/N
      - In-house writing team? Y/N
  - No
  - Don't know

- [Q6-ARM] If yes to Q5 Who pays for professional medical writing support for your academics?
  - Our institution pays
  - Industry partners pay
  - We don't use paid medical writing support
  - Other (please specify)
  - Don't know

- [Q7-ARM] How do you ensure that you have acknowledged professional medical writing support according to the current/journal guidelines? (tick all that apply)
  - We expect authors to follow the specific journal requirements
  - We provide training to all of our researchers regarding publication of medical research in journals
  - We leave this up to the journals to determine
  - It is up to the medical writers to ensure they are appropriately acknowledged
  - Other (please specify)
  - Don't know

- [Q8-ARM] What are your institution policies on review articles?
  - We don't have a policy on this
  - Review articles are allowable
  - We follow journal guidelines on review articles
  - We only support systematic reviews papers
  - Other (please specify)
  - Don't know

  - [Q8a-ARM] If you support review articles, do you work with industry collaborators?
    - We don't work with industry on review papers
    - Yes
      - They pay for the research to be done
      - They pay for a medical writer to support development of the paper once the research has been done
      - They provide an unrestricted grant and have no input into the paper at all
    - Don't know

- [Q9-ARM] What are your institution policies on industry sponsored research? That is, are you able to collaborate with industry in relation to clinical research projects, able to author papers with industry authors, able to accept the support of medical publication professionals etc?
  - [Free text]

- [Q10-ARM] Who provides you with advice regarding proper disclosure of potential conflicts of interest when publishing medical research?
    - Our institution provides guidance
    - My colleagues
    - Journal requirements
    - Medical writers
    - Industry personnel
    - We don't get advice
    - Other (please specify)
    - Don't know

- [Q11-ARM] What guidelines do you follow for conflict of interest disclosures?
    - My institution's
    - The journal's
    - Depends on who's guidelines are strongest
    - Other (please specify)
    - Don't know

- [Q12-ARM]Please outline your perceptions and attitudes towards pharmaceutical industry involvement in medical publications
    - I think there is a role for industry as authors and collaborators in medical publications as they have internal research and development departments and relevant expertise
    - I think there is a role for industry in supporting medical publications, but not as authors
    - I think industry should hand over the research and allow academia to analyse the data
    - I'm not sure what role industry should have in medical publications
    - Other (please specify)
    - Don't know

- [Q13-ARM] In the last 12 months, have you been refused authorship on a manuscript or abstract because you did not fulfil authorship criteria?
    - Never
    - Once
    - More than once

    - [Q13a-ARM] If once or more, please indicate why you were refused authorship.
        - Disagreed with the interpretation of the data
        - Disagreed with the order of authorship
        - Left the organisation where I did the work
        - Did not meet authorship criteria
        - Did not agree to adhere to ethical publication practises
        - Did not agree to disclose medical writing support

- Other (please specify)
- Don't know

- [Q14-ARM] In the past 12 months, have you refused professional writing support based on concerns about the perception of 'ghost-writing'?
  - No
  - Yes – I prefer to do all my own writing
  - Yes – my institution does not allow the use of any medical writers
  - Yes, but I did not understand the role of the professional medical writer and accepted their support once I understood how this would be disclosed

- [Q15-ARM] In the last 12 months have you used unacknowledged, professional medical writing support?
  - No
  - Yes (please explain)

- [Q16-ARM] Do you feel that the pharmaceutical industry influences the content of industry sponsored publications?
  - No
  - Yes - inappropriately influences the selection of data for inclusion, discussion and conclusions
  - Yes - provides appropriate contributions that are acknowledged
  - Yes - provides appropriate contributions that are unacknowledged
  - Other (please specify)
  - Don't know

- [Q17-ARM] When you are working on a paper relating to an industry sponsored study, do you have full access to the relevant data if you request it?
  - Yes
  - Yes, but I rarely look at the raw data
  - No
  - I have never asked
  - Other (please specify)
  - Don't know

- [Q18-ARM] When developing a paper with industry partners and other authors, how much input do you have on the choice of journal?
  - The authors decide as a team
  - The lead author usually decides
  - Industry partners decide
  - The agency decides
  - Don't know
  - Other

- [Q19-ARM] In the past 12 months, to your knowledge, has your department been involved in the development of a peer-reviewed publication for a study (or studies) that did not meet the

primary endpoint or could otherwise be construed as inconclusive or negative? Yes/No/Don't know

- If yes, has the paper(s) been accepted or published in a peer-reviewed journal? Yes/No/Don't know
  - If no (tick all that apply)
    - The paper(s) has not yet been submitted for peer review
    - The paper(s) was rejected
    - The paper(s) was published, but not in a peer-reviewed journal
    - Other (please specify)
    - Don't know

- [Q20-AG] In the past 12 months, are you aware of any results from a study (or studies) that did not meet the primary endpoint, or could otherwise be construed as inconclusive or negative, for which publication is not planned? Yes/No/Don't know
  - If yes, what reason is given for non-publication? (tick all that apply)
    - Study did not meet primary endpoint
    - Study was not conducted in humans
    - Drug development has been discontinued
    - Study was not well designed
    - Study did not complete
    - Additional studies are required to verify the findings
    - Company did not like the results
    - Other (please specify)
    - Don't know

- [Q21-ARM] Is number of academic publications a requirement for progression in your department?
  - Yes – they are very important
  - Yes – they are very important, but only if listed as lead or last author
  - Somewhat important
  - Not really
  - Other (please specify)
  - Don't know

- [Q22-ARM] Who do you think should provide training about ethical medical publication practises and standards to academia?
  - Our institution
  - The journals
  - Industry
  - Professional associations
  - Training during qualifications
  - Other (please specify)
  - Don't know

- [Q23-ARM] What method do you use most when looking for up-to-date information in peer-reviewed publications?
    - PubMed
    - Google
    - Google scholar
    - My institution's library
    - Open access journals only
    - Print journals delivered to me
    - Online journals only
    - Other (please specify)

OPTIONAL QUESTIONS AND CLOSING COMMENTS

Email address to opt-in for receiving results

- Please state where you obtained the link to this survey
    - Email from an association that I am a member of
    - From my organization
    - GPS LinkedIn site
    - From a colleague
    - Other (please specify)

  Please provide your email address if you would like to receive the summary results once available

IF you have time we would welcome any additional thoughts around:

- What educational needs remain regarding ethical publication practices? (free text)
- How best might these be addressed? (free text)
- Are there any additional questions you think would be useful to ask in future surveys? (free text)

BMJ Open

Awareness and enforcement of guidelines for publishing industry-sponsored medical research among publication professionals: the Global Publication Survey

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Awareness and enforcement of guidelines for publishing industry-sponsored medical research among publication professionals: the Global Publication Survey

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Abstract

Objectives: To gather information about current practices and implementation of publication guidelines among publication professionals working in or for the pharmaceutical industry.

Design/ Setting: Web-based survey publicised via email and social media to members of the International Society for Medical Publication Professionals (ISMPP) and other organizations November 2012 to February 2013.

Participants: 469 individuals involved in publishing industry-sponsored research in peer-reviewed journals, mainly working in pharmaceutical or device companies ('industry', n=144), communication agencies ('agency', n=238), contract research organizations (CRO, n=15), or as freelancers (n=34). Most respondents (78%) had worked on medical publications for >=5 years and 62% had a PhD/MD.

Results: Over 90% of industry, agency, and CRO respondents routinely refer to Good Publication Practice (GPP2) and the International Committee of Medical Journal Editors' Uniform Requirements. Most respondents (78% industry, 79% agency) received mandatory training on ethical publication practices. Over 90% of respondents' companies had publication guidelines or policies and required medical writing support to be acknowledged in publications (96% industry, 99% agency). Many industry respondents used publication management tools to monitor compliance with company guidelines and about half (46%) stated that their company had formal publication audits. Fewer agencies audited adherence to guidelines but 20% of agency respondents reported audits of employees and 6% audits of freelancers. Of concern, 37% of agency respondents reported requests from authors or sponsors that they believed were unethical, although 93% of these requests were withdrawn after respondents explained the need for compliance with guidelines. Most respondents'

departments (63% industry, 58% agency, 60% CRO) had been involved in publishing studies with negative or inconclusive results.

Conclusions: Within this sample, most publication professionals working in or for industry were aware of, and applying, major publication guidelines. However, the survey also identified specific areas where education and promotion of guidelines is needed to ensure ethical publication practices.

Article summary

Strengths of this study

- Large-scale, international survey of publication professionals (n=469)
- Focused on awareness and implementation of guidelines relating to responsible publication practice, providing insight into current industry practices
- Included publication professionals (e.g. writers, planners, and managers) working in pharmaceutical and medical device companies, medical communication agencies, contract research organizations, or as freelancers
- Survey allowed anonymous responses

Limitations of this study

- Limited response from freelancers (n=34), journal editors, publishers, and academics (n=38)
- Self-selection bias may mean that respondents were not representative of the total population if those with a particular interest in, or concerns about, ethical publication practices were more likely to complete the survey than those with less knowledge, interest or concerns
- Methods used for publicising the survey (via websites, social media, etc.) meant it was impossible to calculate a precise response rate.

INTRODUCTION

Misleading, inaccurate, or incomplete reporting of clinical trial findings can have serious consequences, since doctors and policy-makers rely on publications when developing treatment guidelines and making decisions affecting patients. The involvement of medical writers and other publication professionals, such as planners and managers, in developing peer-reviewed publications reporting clinical trials has been criticised by some,[1, 2] but defended by others.[3, 4] Similarly, while some studies have shown that publications funded by pharmaceutical companies are of equal or higher quality than publications from academia,[5-7] others have shown that they are more likely to be biased.[8, 9] Concern about irresponsible publication practices, from both within and outside the industry, has led to the creation and evolution of several guidelines.[4, 10-13] These guidelines seek to establish responsible publication practices, increase transparency, and prevent bias and commercial influence in reporting medical research. While many have welcomed such guidelines, critics of the pharmaceutical industry remain unconvinced, for example, commenting "Publicly, they insist that everything has changed…. But my concern is this. Having seen so many codes openly ignored and broken, it's hard to take any set of voluntary ideals seriously."[14] Given this concern about whether voluntary guidelines are effective, and because there was little evidence available to show whether continuing concerns about industry publication practices were justified, we sought to generate 'real world' evidence about current practices in the medical publications profession.

We therefore carried out a large-scale, international, survey (the Global Publication Survey) to obtain information about the ways in which medical writers and other publication professionals work and, in particular, their awareness of current publication guidelines. We also sought to learn about the processes adopted by pharmaceutical and communications

companies to encourage responsible practices and to implement published guidelines. The aim of this survey was to identify areas in which guidelines were understood and enforced, areas for improvement, and targets for education and training.

METHODS

The survey questionnaire (Appendix 1) was developed by an international team including professional writers and publication managers with experience of working in pharmaceutical and communications companies and in a freelance capacity. Several team members had been involved in developing publication guidelines (see the author list and acknowledgements for details). Question topics were based on results of a previous survey of members of the International Society for Medical Publication Professionals (ISMPP). Question and answer options were discussed, drafted, and refined by the team. Question types included multiple choice (check one/check all), matrix table, rating (1-5 scale), ranking (top 3), dropdown selection, and free text. Logic checks limited the number of questions respondents saw based on 'skip logic'(i.e. some questions only appeared if the respondent answered 'yes' to an earlier question). 'Not applicable', 'Don't know', and 'Other (specify)' responses were offered to capture the full range of possible responses.

The questionnaire was transcribed to an online data capture tool hosted by Qualtrics (www.qualtrics.com) survey technology. Pilot testing for question content, flow, and logic was performed by team members, and the survey was revised as necessary.

Respondents saw a different selection of questions depending on their work sector (categorised as: pharmaceutical or medical device company, agency, contract research organization [CRO], freelance, journal editor, publisher, or academic) and their previous

answers. A response was required for each question before the next screen was displayed but users had the option to revisit previously completed questions. Optional questions were included at the end of the core survey allowing participants to offer additional comments.

The survey was announced on 28th November 2012 via email to all members of ISMPP (n=1105). A link included in the email provided individual access to the survey (so each recipient could respond only once and reminders could be sent to non-responders). ISMPP members were also encouraged to share an unrestricted link to the survey with individual colleagues or via their company intranet. The survey was also promoted via social media (LinkedIn and Twitter). Several organizations and companies (including the American Medical Writers Association, the European Medical Writers Association, the European Association of Science Editors, the Committee on Publication Ethics, McCann Complete Medical, and Excerpta Medica) publicised the survey to their members or on their websites through December 2012. The survey closed on 18th February 2012.

Respondents could complete the survey anonymously but, to encourage participation, had the option of supplying an email address to enter a draw for one of two iPad tablet computers. Participants were informed that their personal information would not be shared beyond those administering the survey. Respondent-level data was available only to TGaS Advisors (the company responsible for all aspects of survey administration and data aggregation), and was not shared with the survey organizers or sponsors. Descriptive statistics using frequencies and percentages were used. Funding for the incentive prizes was provided by ISMPP. The team members who developed the questionnaire and executed the survey, interpreted the data, and developed this publication, worked in their own time or during work time with permission from their various employers but without specific funding or payment.

Research Ethics Committee (Internal Review Board) approval was not required for this survey, as it did not relate to personal medical information, did not involve patients or healthcare professionals (other than in their role as journal editors), was not carried out by an academic institution, and participation was entirely voluntary. Participants were given the option of supplying an email address if they wanted to enter a prize draw, but could remain completely anonymous if they preferred. We considered that provision of an email address does not necessarily identify an individual (since email addresses do not necessarily indicate name or workplace) and participants were assured that only two people would be contacted to supply the incentive prize. Email details were stored securely by TGas Advisors and were not revealed to anybody else involved with the survey. Following the guidelines of University College London (although this study was entirely independent of any academic institution) and of the National Research Ethics Service of the UK, such a questionnaire is exempt from requiring Research Ethics Committee approval.

RESULTS

Respondents

The survey reached the intended international target audience with responses from 23 countries. The largest responses came from the USA (44%) and UK (39%). Of the 490 who opened the survey invitation, 469 confirmed that they were involved in publishing industry-sponsored research in peer-reviewed medical journals and completed the survey (Table 1). Most respondents (92%), worked in pharmaceutical or medical device companies (termed 'industry' respondents; 31%), medical communications agencies (termed 'agency' respondents; 51%), or contract research organizations (CROs 3%) providing publication services to drug and device manufacturers, or as freelancers (7%). The survey was also

completed by 5 journal editors, 17 publishers, 9 academics and 7 people working in other roles – results from these categories (total = 8%) are not reported in the text due to the low response rate and small numbers but may be viewed at http://www.ismpp.org/gps-raw-data. Because of the responsive design, the numbers answering each question varied but respondents generally answered about 40 questions. Most respondents took 20-30 minutes to complete the survey.The full data tables are available at http://www.ismpp.org/gps-raw-data.

Because of the methods used to promote the survey (including websites and social media), it was not possible to calculate a precise response rate or assess differences between respondents and non-respondents. However, the membership of ISMPP at the time of the survey was 1105 and the response rate from ISMPP members was 20% (i.e. 221 of the respondents responded via the individual links sent out to ISMPP members).

Most respondents were highly educated (56% had a doctorate) and experienced (79% had worked with medical publications for at least 5 years) (Table 1). Half of the respondents worked in departments that had been involved with over 30 manuscripts in the last year.

Table 1 Respondent characteristics

Characteristic	Number	Percentage
Workplace:		
industry[1]	144	31
agency or CRO[2]	238	51
CRO[3]	15	3
freelance	34	7
other	38	8
Experience of working with peer-reviewed publications:		
<2 years	36	8
2-4 years	66	14
5-9 years	111	24
10 years or more	256	55
Qualification:[4]		
Masters degree	111	24
Doctorate	263	56
MD / medical qualification	26	6
Other	26	6
Certified Medical Publication Professional (CMPP)	161	34

[1]Pharmaceutical, biotech or medical device company

[2] Communications company

[3] Contract research organization

[4] Respondents were asked to tick all that applied

Awareness of guidelines

Almost all industry and agency respondents reported being aware of international guidelines on responsible publication practices (Fig 1). Overall, 91% stated that they routinely referred to Good Publication Practice (GPP2) and 93% to the International Committee of Medical Journal Editors' Uniform Requirements for guidance on ethical practice. Other sources of guidance consulted routinely by respondents in all sectors included ISMPP (71%), medical writers associations (e.g. AMWA and EMWA: 39%), and the Committee on Publication Ethics (COPE: 34%).

Training

Regular training on ethical publication practices was compulsory for most respondents in industry and agencies. Mandatory training for employees was reported by 78% of industry, 79% of agency, and 93% of CRO respondents. In addition, 68% of agency respondents reported that their industry customers provided mandatory training for agency personnel. Training at least once a year was reported by 70%, 68% and 71% for industry, agency and CRO respondents respectively. Just over half the industry respondents (55%) reported that their companies provided training for agency staff or freelancers but only 17% of agency and 20% of CRO respondents reported that their organization provided training for freelancers (while 43% and 53% respectively didn't know if freelancers were trained). Similarly, 24% of the freelancers (5/21) reported that they received mandatory training from industry or agency customers.

Respondents kept up-to-date on current guidelines primarily via training provided by their organization (64%), from professional associations (68%), and monitoring the literature (70%).

Company codes of conduct and publication policies

In addition to their awareness of external guidelines on ethical publication practices (e.g., GPP2), most respondents reported being aware of internal guidelines governing publication practices. Overall, 78% of respondents worked in an organization that had a Code of Conduct governing ethical publication practices. Nearly all the industry (94%) and agency (94%) respondents and all the CRO respondents (15/15) stated that their company had guidelines or a policy on ethical publication practices (5 industry and 8 agency respondents stated their company did not have such a policy while 3 and 7, respectively, did not know) (Fig 1).

Most company guidelines and policies are not publicly available: only 38% of industry, 35% of agency, and 33% of CRO respondents reported that these documents were publicly accessible (e.g. posted online) (Figure 2).

Of the industry respondents, 67% stated that their company was committed to peer-reviewed publication of results of all studies in humans. Exceptions to this commitment were studies for which companies did not have control (e.g. investigator-initiated studies) (reported by 21) and Phase 1 studies (i.e. early-phase drug development) (reported by 14).

Public disclosure of trial results was reported, by those working within the industry, to be fulfilled by: posting results on a public register (92%), publishing in a peer-reviewed journal (73%), publishing a conference abstract (51%), posting results on a company website (28%), or a combination of these. When asked about the timing of journal publications, most industry respondents reported that their company policy was to submit a manuscript within 12 or 18 months of study completion (last subject, last visit) (43% and 18% respectively).

Nevertheless, 24% of industry respondents reported that their company did not have a target deadline for submitting a manuscript after trial completion (Figure 2).

Similar proportions of industry and agency respondents (80% and 81% respectively) reported that authorship obligations were set out in formal agreements before manuscript development (Fig 1). Almost all industry (96%) and agency (99%) respondents, and 100% of CRO respondents, reported that their department ensured that authors acknowledge professional medical writing support in every publication (Fig 1). Only one respondent from each of the industry and agency groups answered no to this question. However, 11% of respondents from both industry and agency, and 13% from CROs, were aware of academic authors initially refusing to acknowledge professional writing support in the last 12 months.

Compliance with codes

Respondents from industry, and to a lesser extent from agencies, reported that their publication practices were subjected to compliance checks. Of the industry respondents, 61% stated that their company had a formal process for monitoring adherence to company standards and 66 of these (46% of the total) carried out publication audits. A very similar response was obtained from those working in CROs (60% and 47% respectively). However, of the agency respondents, 44% reported that their company had formal compliance monitoring for internal standards and only 20% carried out publication audits. In addition, about half the industry respondents (47%) reported that their company had a formal process for monitoring third-party providers' adherence with company standards and 75% of these reported that this involved an audit. Agency and CRO respondents stated that some (43%, 47% respectively), most (19%, 0%), or none (6%, 13%) of their customers had formal, regular processes such as knowledge tests or audits for monitoring suppliers' adherence to the

customer's standards, while 27% of agency and 40% of CRO respondents did not know if their customers did this. Agency and CRO respondents also reported that their customers used publication management tools to assess compliance (only 6% and 13% respectively reported that no customers did this).

Of the industry respondents, 52% worked in a company operating under a US Government 'Corporate Integrity Agreement' (CIA: see https://oig.hhs.gov/compliance/corporate-integrity-agreements/index.asp), which typically requires formal compliance checking.

Organization of publication activities

Publication activities were primarily governed by medical departments; publications were rarely funded, or approved, by commercial departments (Fig 1). According to the industry respondents, the budget for peer-reviewed publications was usually held by the medical affairs (72%) or clinical development (24%) departments. Nevertheless, seven respondents (5%) stated that the publications budget was held by a commercial department (e.g. sales or marketing) (Fig 2). Involvement of members of commercial departments in developing publications varied, with industry respondents stating that they were: not involved (27%), provided with information only (48%), members of the publication team (44%), allowed to suggest target journals for author consideration (22%), involved in reviewing manuscripts for accuracy (19%), or part of a formal approval process (5%).

Agency response to requests for perceived unethical practices

Respondents were often, but not always, successful in preventing publication practices they considered unethical. Of the agency respondents, 38% were aware, in the past 12 months, of their company being asked by an author or a sponsor to do something that they believed

contravened ethical practices (10% once and 28% more than once) while 2/15 CRO respondents (13%) reported such requests. Respondents reported that their agency's response was to explain the need for compliance, resulting in the request being withdrawn or amended (92% and both CRO cases), or to refuse to accept the work (1%); however, 3% (3/90) stated that the agency ultimately complied with the request.

Although a slightly higher proportion of freelancers (17/34, 50%) reported requests which they believed constituted unethical practices, this should not be over-interpreted due to the small group size; 12% (2/17) of freelancers accepted such work.

Information provided to authors

Authors were routinely provided with various documents and data sources to facilitate manuscript preparation. These documents included (for agency and industry respondents respectively): clinical study report (81%, 79%), study protocol (79%, 83%), summarized data (67%, 66%), statistical report (58%, 62%), manuscript outline (58%, 56%), statistical analysis plan (42%, 54%), and raw data/data tables (42%, 42%).

Enforcement of authorship criteria

Respondents actively enforced compliance with authorship criteria (Table 2).

Table 2

Responses to the question "In the last 12 months, to your knowledge, how often has your department recommended to the lead author the removal of a co-author from a manuscript or abstract that was in development?"

	Never	Once	More than once	Other	Don't know
Industry (n=144)	44% (64)	10% (15)	22% (32)	2% (3)	21% (30)
Agency (n=238)	24% (58)	11% (26)	35% (84)	3% (6)	27% (64)
CRO* (n=15)	27% (4)	33% (5)	7% (1)	7% (1)	27% (4)
Freelance (n=34)	74% (25)	9% (3)	15% (5)	3% (1)	0

*Contract Research Organization

Of the industry respondents, 33% were aware of an author being removed from a manuscript within the last 12 months and 94% stated that this was due to the individual not meeting authorship criteria. Other reasons for recommending removal of an author included individuals leaving the company (28%) or not agreeing to adhere to ethical publication practices (13%) (respondents could select more than one reason). Three respondents from industry and two from agencies reported authors being removed because they disagreed with

the interpretation of the data. Eight freelancers reported recommending the removal of an author, in all cases because the individual did not meet authorship criteria.

Publishing negative findings

Most industry respondents' companies attempted to publish negative or inconclusive results. Of the industry respondents, 63% reported that their department had supported the publication of a study with negative or inconclusive results (17% stated that this had not happened and 19% did not know). Only six respondents (4%) were aware of a negative or inconclusive study for which publication was not planned, in three cases this was due to the discontinuation of product development. Reponses were similar in the agency (and CRO) groups, with 58% (60%) aware of the publication of negative findings and 6% (13%) being aware of negative findings for which publication was not planned. Of the freelancers, 38% had been involved with the publication of negative findings in the last 12 months.

Freelance responses

Only 34 freelance publication professionals responded to the survey and some of these did not answer all questions, therefore the results may not be representative and should not be over-interpreted. However, the following findings were noteworthy: 12/34 (35%) did not know whether their customers had publication guidelines; 15/21 (71%) stated that they did not receive mandatory training; and 21/34 (62%) stated that their clients did not have formal, regular processes to monitor their adherence to standards. However, freelancers reported routinely consulting published guidelines (100% for ICMJE, 91% for GPP2) on ethical issues.

DISCUSSION

This is one of the largest, international surveys designed to capture information about current knowledge and implementation of publication guidelines within the pharmaceutical, medical device, and medical communications industries. Our survey showed high reported levels of knowledge of the various publication guidelines among publication professionals, with over 90% of respondents stating that they routinely referred to them. Although these published guidelines (such as GPP2) are not generally enforced by legislation, according to our survey most companies have codes of conduct, policies, or internal guidelines that reflect and enforce them. Similarly, most companies (industry and agencies) provide mandatory training to internal staff, while many pharmaceutical and medical device companies also train agency personnel who develop publications on their behalf. The relatively low rates of training and auditing of freelancers suggested in this survey (albeit from a small number of respondents), however, may represent a problem that companies, agencies, and authors who work with freelancers should address.

Many pharmaceutical companies in the USA currently operate under Corporate Integrity Agreements (CIAs). For such companies, many aspects of good publication practice are legally enforced. An analysis of 12 such agreements issued from 2009 to mid-2012 showed that they included requirements for author agreements, publication plans, and the posting of study results.[15] The CIA requirements were consistent with GPP2 and the ICMJE guidelines and also mandated training and reporting. CIA requirements apply not only to the pharmaceutical company but also to their management of any third-party suppliers, therefore, they will also affect many agencies, freelancers, and CROs. Similarly, even companies without a CIA often require suppliers to follow their policies. Therefore, for many agencies

and freelancers, failure to follow a customer's policy could mean loss of future business, thus the underlying guidelines are viewed as compulsory rather than optional.

The importance with which guidelines are viewed is reflected in the effort (and therefore time and money) companies invest in monitoring compliance. Our survey found that many pharmaceutical and device companies have formal monitoring processes including publication audits. Since our survey may have included several respondents from the same company, the results cannot indicate precisely what proportion of companies have such processes but it is probably well over half. The fact that fewer agencies appear to audit to their own internal standards is not surprising, since many reported being regularly audited by their customers. However, rates of training and auditing of freelancers (by pharmaceutical companies and agencies) is less reassuring and suggests room for improvement.

Many companies use specialist publication planning software (such as Datavision™ or PubSTRAT™). Our survey shows that such tools are used not only for publication project management but also to monitor and demonstrate compliance with company procedures, for example, by ensuring that all authors have approved a manuscript outline, drafts, and the final version.

Lack of transparency surrounding company involvement, non-disclosure of competing interests, and misleading authorship have been causes for concern in industry-sponsored publications in the past.[16] In particular, the occurrence of 'ghost-writing' (i.e. unacknowledged use of medical writers) and guest or honorary authorship (i.e. named authors not fulfilling journal authorship criteria) were spurs for the development of both general and specific guidelines.[3, 4, 11, 17] It is therefore encouraging that 96-100% of respondents

(working in pharmaceutical and medical device companies, agencies, and CROs) stated that their department ensured that medical writers were acknowledged (thus preventing the medical writers from being 'ghost writers'). Of concern, however, is the fact that some academic authors apparently continue to be reluctant to acknowledge writing support. Although publication professionals can alert authors about the need for disclosure, academic institutions clearly have an educational role to play.

The ICMJE authorship criteria (which are widely endorsed by medical journals and which were revised after the survey) state that listed authors should have made substantial contributions to both the research and its publication. Therefore authorship cannot be determined until a publication is developed. Individuals involved with the research being reported may be invited to become authors, but will not qualify unless they also take an active role in the publication. It is therefore encouraging that our survey found that not only industry sponsors of research, but also publication agencies and freelancers working for them, actively enforce authorship criteria by suggesting that individuals should be removed from author listings if they fail to meet the ICMJE or other agreed criteria (see Table 2). It can take considerable courage for a freelancer or agency employee to suggest that a proposed author has not contributed sufficiently to merit being listed, especially if that person is a senior academic or well-known expert. Being the one to identify a guest author carries the risk of damaging relationships and possibly work prospects. However, arguably there is an even greater and more serious risk of damaged relations, reputations, and work prospects if a publication professional fails to raise authorship concerns which are later raised by a journal. Early clarification of authorship obligations should reduce the risk of guest authorship and it was encouraging that most respondents reported that authorship agreements were confirmed before manuscript preparation started.

As we cannot tell how often proposed authors fail to contribute to publications, our survey cannot show how often this is overlooked, but the fact that almost one-third of industry respondents were aware of instances of authors being removed because they did not meet authorship criteria suggests that guidelines are being enforced. However, this question also revealed that three industry (2%) and two agency (0.8%) respondents were aware of authors being removed from publications because they disagreed with the interpretation of the findings. We cannot tell how many cases these represent, since several respondents may have reported the same case, nor can we tell whether the disagreements about interpretation were with the sponsor (which would be concerning) or between co-authors, but this issue needs further scrutiny.

The difficulties of interpreting the ICMJE authorship criteria in some situations have been examined in a study coordinated by the Medical Publishing Insights and Practices (MPIP) Initiative.[18] Using vignettes presenting 'challenging real-world authorship scenarios' this study found that journal editors, clinical investigators, medical writers, and publication planners had different views about who qualified for authorship and suggested that additional guidance might be helpful.

Limitations

We had originally hoped to compare or confirm responses from publication professionals with those from journal editors and academic investigators, however, we were less successful in promoting the survey among these groups than among publication professionals and consider the response from these sectors too small to be reliable. The number of responses from freelance publication professionals was also disappointing and it is therefore important

not to over-interpret the findings from this group. Care should also be taken in extrapolating proportions of respondents to proportions of companies or agencies, since we had no way of measuring the numbers of respondents per company.

We also recognise that our survey, like many others, carried the risk of self-selection bias. Our survey was promoted mainly via professional organizations such as ISMPP and AMWA/EMWA which promote ethical publication practices. Those choosing to respond to a survey supported by these associations may be more likely to follow and report ethical publication practices. Also, those who chose to complete the survey may have had a special interest in, or concerns about, the issues covered. Our respondents therefore may not be representative of all publication professionals and may be better informed about the topics covered by this survey and more aware of guidelines (e.g. from attending professional meetings or taking part in educational activities). However, due to the methods used to publicise the survey (including websites and social media rather than to a clearly defined population) it was not possible to compare characteristics of respondents and non-respondents. We also acknowledge that our respondents came primarily from higher-income countries. Our findings may not be applicable to publication practices in lower-income countries, particularly given the significant influence of country income on publication practices. [5, 19]

Another problem with any survey is if respondents give 'socially desirable' rather than truthful answers. One reason we have confidence in our findings is that responses were not uniform, e.g. only 34% reported referring to the COPE guidelines compared with 91% for the ICMJE guidelines. The fact that the survey highlighted weaknesses as well as strengths (e.g. the proportion of freelancers who receive training) also suggests that responses were factual.

Comparison with other surveys

Journal editors' awareness of various guidelines was measured in 2007 in an international survey to which 111 editors of biomedical journals responded.[20] This survey noted that "awareness and use of guidelines and other resources on publication ethics was generally low". Over half the editors (55%) reported being unaware of the ICMJE Uniform Requirements and two-thirds (67%) were unaware of the GPP guidelines, while the proportion of editors reporting that they had used these guidelines were just 24% and 9% respectively. This represents a marked contrast to the publication professionals responding to our survey, over 90% of whom reported that they routinely referred to these two guidelines.

Another survey of 183 editors of high-impact medical journals in 2009 found that, although 76% had received training in medical editing, they performed poorly when answering questions about: authorship (only 30% gave 'correct' answers, i.e. consistent with commonly cited guidelines), plagiarism (17% correct), peer review (16% correct), and conflicts of interest (15% correct).[21]

A 2012 survey of 294 healthcare professionals found that 42% were unaware of the GPP guidelines.[22] This survey also found that the doctors (69% of whom were authors on peer-reviewed articles) were unfamiliar with, or disagreed with, the ICMJE authorship criteria, since a considerable proportion considered that data collection (51%) or general supervision of a laboratory (33%) alone were criteria for authorship. Nevertheless, 66% of respondents in the healthcare practitioners survey stated that they would be concerned about 'the involvement of pharmaceutical employees as authors or reviewers of a draft manuscript'. A smaller survey of surgeons in Croatia (in 2011) found that only 54% (31/57) were aware of

the ICMJE guidelines although 74% (43/58) of the respondents had worked on at least 2 manuscripts for publication in the last 2 years.[23]

A large-scale, repeated survey of medical writers (who were nearly all members of AMWA or EMWA),[24] which attracted 746 responses in 2005, and 662 in 2008, found lower levels of familiarity with guidelines than the current survey (carried out in 2012) but showed that awareness had risen between 2005 and 2008. For example, the proportion of respondents claiming to be familiar with ICMJE guidelines rose from 54% in 2005 to 75% in 2008. The figures for GPP were 43% and 58%, and for the EMWA guidelines (published in 2005) 27% and 46% respectively in 2005 and 2008. The AMWA/EMWA survey also asked writers about their experience of being involved with unacknowledged writing work (i.e. ghostwriting). In 2005, 39% stated that this practice had decreased in the last 5 years (52% stated that it was unchanged and 8% that it had increased). In 2008, 63% considered that ghostwriting had decreased, 30% stated that it was unchanged and 6% that it had increased in the last 5 years. The proportion of professional writers reporting that they always requested acknowledgement for a substantial contribution to a manuscript also rose from 25% in 2005 to 43% in 2008. The survey was repeated in 2011 (with 620 respondents)[25] and responses showed a clear decrease in the proportion of manuscripts (not necessarily all for peer-reviewed journals) with undisclosed contributions (i.e. ghostwriting) which fell from 62% in 2005, to 42% in 2008, and 33% in 2011.

Ghostwriting of review articles commissioned by pharmaceutical companies was a particular concern when the first GPP guidelines were developed.[26] A survey of authors published in six, high impact general medical journals found a decline in ghost authorship between 1996 and 2008, and a significant decrease (from 26% to 15%) in honorary authorship (which often

accompanies ghostwriting) for review articles and editorials (although not for other types of article).[27]

Our survey did not get sufficient response from academics to draw any conclusions about their understanding of their role as authors of medical publications. We hope that the full report of the MPIP authorship project will cast more light on this.[18]

RECOMMENDATIONS

While many of our findings are heartening (Fig 1), some indicate a need for further action (Fig 2). We hope that the professional organizations who were involved with this survey (in particular, ISMPP, AMWA, and EMWA) along with pharmaceutical and medical device companies will use the findings to identify topics for future training or discussion. We suggest they might focus on the following areas.

- Although many companies and agencies had publication policies, it is disappointing that so few of these policies were made public. We encourage companies to post their publication policies on their websites. Companies might also consider publishing the results of publication audits to indicate how closely they comply with guidelines (for example, what proportion of clinical trials are published) and to help identify obstacles to compliance.
- While our survey suggests that most pharmaceutical companies and agencies have a code of conduct and provide mandatory training on responsible publication practices to relevant staff, this is not always the case, and there is room for improvement, especially for those that sub-contract work to freelancers. We therefore recommend that companies, agencies, and professional groups (such as ISMPP, EMWA, and AMWA) put renewed effort into ensuring that all publication professionals receive

effective training. Freelancers should be accountable for their own training, or ensure they receive sufficient training from their customers. We also recommend that individuals involved less directly in publications should be made aware of the relevant guidelines.

- Although pharmaceutical companies generally provide invited authors with study reports and protocols, this was not universal. Named authors should always have access to study results to ensure they can understand and interpret the findings.
- The reported requests from authors or companies for agency staff to do something that the publication professionals considered unethical warrants further investigation. Our survey did not ask about reporting mechanisms for perceived unethical practices, or how strongly these are communicated and used. We encourage agencies to develop systems for handling such situations. Further education of authors and industry staff, particularly those who are not familiar with the stringency of current guidelines, should help reduce such requests.
- The number of freelancers responding to the survey was small (<50), but some of their responses suggested differences from publication professionals working in companies. We therefore hope a similar survey might be undertaken focusing on the needs of this community and their publication practices to better understand areas where they may need support.

These suggested actions focus primarily on pharmaceutical companies and communications agencies. However, clinical trials and their publication involve many players, and other surveys suggest that both healthcare professionals (investigators and academics) and journal editors would benefit from greater knowledge of published guidelines and may, in fact, be less familiar with such guidelines than publication professionals. Given the financial and

human resources required to ensure timely, accurate, and complete reporting of research results,[28] it is likely that the demand for, and use of, publication professionals will increase. Our survey findings indicate that further involvement of knowledgeable and experienced medical publication professionals, who are familiar with guidelines on reporting clinical trials and publication ethics, should be viewed as a positive step in achieving timely and reliable reporting. Our survey findings also complement evidence which shows that manuscripts prepared with professional writing or editing support are more likely to comply with reporting requirements,[29] less likely to be retracted for misconduct,[5] and are accepted for publication more quickly,[30] than those prepared without such support.

Authorship of research publications is not straightforward and the ICMJE criteria have recently been revised. Our survey did not examine views on existing criteria or problems with their implementation, although others have done so.[31, 32] We are aware of current initiatives aimed at deepening understanding and developing consensus around authorship and the transparency of contributions and we welcome these. We would also welcome surveys that test how well non-industry authors and editors comply with voluntary guidelines issued by their professional associations and how such compliance is checked.

CONCLUSIONS

Despite criticism that most publication guidelines are voluntary, our survey suggests that the major guidelines are widely known and implemented by publication professionals working in pharmaceutical and medical device companies, communication agencies, CROs, and as freelancers. Many companies enforce these guidelines through policies, codes of conduct, standard operating procedures, and audits. For companies operating under a CIA, many of the GPP and ICMJE recommendations are mandated and audited by the Office of the Inspector

General via independent auditors. When the GPP guidelines were first developed (in the late 1990s), publication audits were unheard of, yet many companies now regularly audit their practices against guidelines such as GPP2, and CIAs mean that many of the GPP recommendations are now legally enforced and monitored.

While there is no room for complacency, and we make no claim that all problems with the publication of industry-funded research have disappeared, this survey, taken together with others showing improved acknowledgement of medical writers, and reductions in guest authorship, suggest that guidelines such as GPP (published in 2003) and GPP2 (2010) have had a definite, positive effect on publication practices and that most companies and individual publication professionals are striving to do the right thing.

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Contributions

All authors were involved in developing the questionnaire and analysing or interpreting the data. All authors reviewed the manuscript and discussed it critically over several revisions, and agreed to submit it for publication. In addition, EW wrote the first draft of the paper, JF was responsible for data management and analysis, and KW presented initial findings at the 2013 ISMPP meeting and prepared the figures.

Competing interests

EW is an author of the original GPP guidelines, the anti-ghostwriting checklist, the EMWA guidelines on the role of medical writers in publications, and several COPE guidelines. She works as a freelance publications consultant and has provided training to many pharmaceutical companies and communication agencies and receives fees and expenses for talks and workshops on publication guidelines.

KW conducts and publishes research on ethical medical writing practices. She is actively involved in not-for-profit associations that advocate for ethical publication practices. She is paid to provide ethical medical writing training courses and services for not-for-profit and for-profit clients, particularly in the Asia-Pacific region.

AC has served on the ISMPP Certification Board of Trustees.

ST is the chair of the ISMPP Advocacy and Outreach Committee.

AC, VA, TG and ST are employed by medical communications companies that provide publications services to authors and industry sponsors.

JG is on the Board of Trustees of ISMPP and is a steering committee member of the MPIP (Medical Publications Insights and Practices) Initiative.

JG and TG are/were employees of AstraZeneca and own shares in the company.

JF is an employee of TGaS Advisors, a division of the KnowledgePoint360 Group.

All authors (except JF) are members of ISMPP. None of the authors received any specific remuneration for working on this project.

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Data sharing statement

The full questionnaire and raw data aggregated by sector (industry, agency, freelance) are available at http://www.ismpp.org/gps-raw-data

Figure legends

Fig 1. Percentage of survey respondents from industry and agency groups responding 'yes' to selected questions.

Fig 2. Percentage of survey respondents from industry and agency groups responding 'yes' to selected questions. (Asterisks indicate that question was only relevant to one group.)

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Awareness and enforcement of guidelines for publishing industry-sponsored medical research among publication professionals: the Global Publication Survey

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Abstract

Objectives: To gather information about current practices and implementation of publication guidelines among publication professionals working in or for the pharmaceutical industry.

Design/ Setting: Web-based survey publicised via email and social media to members of the International Society for Medical Publication Professionals (ISMPP) and other ~~relevant~~ organizations , ~~–~~November 2012 to February 2013.

Participants: 469 individuals involved in publishing industry-sponsored research in peer-reviewed journals, mainly working in pharmaceutical or device companies ('industry', n=144), communication agencies ('agency', n=238), ~~or~~ contract research organizations (CRO, n=15), or as freelancers (n=34). Most respondents (78%) had worked on medical publications for >=5 years and 62% had a PhD/MD.

Results: Over 90% of industry, agency, and CRO respondents routinely refer to Good Publication Practice (GPP2) and the International Committee of Medical Journal Editors' Uniform Requirements. Most respondents (78% industry, 79% agency) received mandatory training on ethical publication practices. Over 90% of respondents' companies had publication guidelines or policies and required medical writing support to be acknowledged in publications (96% industry, 99% agency). Many industry respondents used publication management tools to monitor compliance with company guidelines and about half (46%) stated that their company had formal publication audits. Fewer agencies audited adherence to guidelines but 20% of agency respondents reported audits of employees and 6% audits of freelancers. Of concern, 37% of agency respondents reported requests from authors or sponsors that they believed were unethical, although 93% of these requests were withdrawn after respondents explained the need for compliance with guidelines. Most respondents'

departments (63% industry, 58% agency, 60% CRO) had been involved in publishing studies with negative or inconclusive results.

Conclusions: Within this ~~survey~~ sample, most publication professionals working in or for industry were aware of, and applying~~ied~~, major publication guidelines. However, the survey also identified specific areas where education and promotion of guidelines is needed to ensure ethical publication practices.

Article summary

Strengths of this study

- Large-scale, international survey of publication professionals (n=469)
- Focused on awareness and implementation of guidelines relating to responsible publication practice, providing insight into current industry practices
- Included publication professionals (e.g. writers, planners, and managers) working in pharmaceutical and medical device companies, medical communication agencies, contract research organizations, or as freelancers
- Survey allowed anonymous responses

Limitations of this study

- Limited response from freelancers (n=34), journal editors, publishers, and academics (n=38)
- Self-selection bias may mean that respondents were not representative of the total population if those with a particular interest in, or concerns about, ethical publication practices were more likely to complete the survey than those with less knowledge, ~~or~~ interest or concerns
- Methods used for publicising the survey (via websites, social media, etc.) meant it was impossible to calculate a precise response rate.

INTRODUCTION

Misleading, inaccurate, or incomplete reporting of clinical trial findings can have serious consequences, since doctors and policy-makers rely on publications when developing treatment guidelines and making decisions affecting patients. The involvement of medical writers and other publication professionals, such as planners and managers, in developing peer-reviewed publications reporting clinical trials has been criticised by some,[1, 2] but defended by others.[3, 4] Similarly, while some studies have shown that publications funded by pharmaceutical companies are of equal or higher quality than publications from academia,[5-7] others have shown that they are more likely to be biased.[8, 9] Concern about irresponsible publication practices, from both within and outside the industry, has led to the creation and evolution of several guidelines.[4, 10-13] These guidelines seek to establish responsible publication practices, increase transparency, and prevent bias and commercial influence in reporting medical research. While many have welcomed such guidelines, critics of the pharmaceutical industry remain unconvinced, for example, commenting "Publicly, they insist that everything has changed…. But my concern is this. Having seen so many codes openly ignored and broken, it's hard to take any set of voluntary ideals seriously."[14] Given this concern about whether voluntary guidelines are effective, and because there was little evidence available to show whether continuing concerns about industry publication practices were justified, we sought to generate 'real world' evidence about current practices in the medical publications profession.

We therefore carried out a large-scale, international, survey (the Global Publication Survey) to obtain information about the ways in which medical writers and other publication professionals work and, in particular, their awareness of current publication guidelines. We also sought to learn about the processes adopted by pharmaceutical and communications

companies to encourage responsible practices and to implement published guidelines. The aim of this survey was to identify areas in which guidelines were understood and enforced, areas for improvement, and targets for education and training.

METHODS

The survey questionnaire (Appendix 1) was developed by an international team including professional writers and publication managers with experience of working in pharmaceutical and communications companies and in a freelance capacity. Several team members had been involved in developing publication guidelines (see the author list and acknowledgements for details). Question topics were based on results of a previous survey of members of the International Society for Medical Publication Professionals (ISMPP). Question and answer options were discussed, drafted, and refined by the team. Question types included multiple choice (check one/check all), matrix table, rating (1-5 scale), ranking (top 3), dropdown selection, and free text. Logic checks limited the number of questions respondents saw based on 'skip logic'(i.e. some questions only appeared if the respondent answered 'yes' to an earlier question). 'Not applicable', 'Don't know', and 'Other (specify)' responses were offered to capture the full range of possible responses.

The questionnaire was transcribed to an online data capture tool hosted by Qualtrics (www.qualtrics.com) survey technology. Pilot testing for question content, flow, and logic was performed by team members, and the survey was revised as necessary.

Respondents saw a different selection of questions depending on their work sector (categorised as: pharmaceutical or medical device company, agency, contract research organization [CRO], freelance, journal editor, publisher, or academic) and their previous

answers. ~~Respondents answered, on average, about 40 questions.~~ A response was required for each question before the next screen was displayed but users had the option to revisit previously completed questions. Optional questions were included at the end of the core survey allowing participants to offer additional comments.

The survey was announced on 28th November 2012 via email to all members of ISMPP (n=1105). A link included in the email provided individual access to the survey (so each recipient could respond only once and reminders could be sent to non-responders). ISMPP members were also encouraged to share an unrestricted link to the survey with individual colleagues or via their company intranet. The survey was also promoted via social media (LinkedIn and Twitter). Several organizations and companies (including the American Medical Writers Association, the European Medical Writers Association, the European Association of Science Editors, the Committee on Publication Ethics, McCann Complete Medical, and Excerpta Medica) publicised the survey to their members or on their websites through December 2012. The survey closed on 18th February 2012.

Respondents could complete the survey anonymously but, to encourage participation, had the option of supplying an email address to enter a draw for one of two iPad tablet computers. Participants were informed that their personal information would not be shared beyond those administering the survey. Respondent-level data was available only to TGaS Advisors (the company~~who were~~ responsible for all aspects of survey administration and data aggregation), and was not shared with the survey organizers or sponsors. Descriptive statistics using frequencies and percentages were used. Funding for the incentive prizes was provided by ISMPP. The team members who developed the questionnaire and executed the survey,

interpreted the data, and developed this publication, worked in their own time or during work time with permission from their various employers but without specific funding or payment.

Research Ethics Committee (Internal Review Board) approval was not required for this survey, as it did not relate to personal medical information, did not involve patients or healthcare professionals (other than in their role as journal editors), was not carried out by an academic institution, and participation was entirely voluntary. Participants were given the option of supplying an email address if they wanted to enter a prize draw, but could remain completely anonymous if they preferred. We considered that provision of an email address does not necessarily identify an individual (since email addresses do not necessarily indicate name or workplace) and participants were assured that only two people would be contacted to supply the incentive prize. Email details were stored securely by TGas Advisors and were not revealed to anybody else involved with the survey. Following the guidelines of University College London (although this study was entirely independent of any academic institution) and of the National Research Ethics Service of the UK, such a questionnaire is exempt from requiring Research Ethics Committee approval.

RESULTS

Respondents

The survey reached the intended international target audience with responses from 23 countries. The largest responses came from the USA (44%) and UK (39%). Of the 490 who opened the survey invitation, 469 confirmed that they were involved in publishing industry-sponsored research in peer-reviewed medical journals and completed the survey (Table 1). Most respondents (92%), worked in pharmaceutical or medical device companies (termed 'industry' respondents; 31%), medical communications agencies (termed 'agency'

respondents; 51%), or contract research organizations (CROs 3%) providing publication services to drug and device manufacturers, or as freelancers (7%). The survey was also completed by 5 journal editors, 17 publishers, 9 academics and 7 people working in other roles – results from these categories (total = 8%) are not reported in the text due to the low response rate and small numbers but may be viewed at http://www.ismpp.org/gps-raw-dataQQQ. Because of the responsive design, the numbers answering each question varied but respondents generally answered about 40 questions. – Most respondents took 20-30 minutes to complete the survey. tThe full data tables are available at http://www.ismpp.org/gps-raw-dataQQQ. ~~Most respondents took 20-30 minutes to complete the survey.~~

Because of the methods used to promote the survey (including websites and social media), it was not possible to calculate a precise response rate or assess differences between respondents and non-respondents. However, the membership of ISMPP at the time of the survey was 1105 and the response rate from ISMPP members was 20% (i.e. 221 of the respondents responded via the individual links sent out to ISMPP members).

Most respondents were highly educated (56% had a doctorate) and experienced (79% had worked with medical publications for at least 5 years) (Table 1). Half of the respondents worked in departments that had been involved with over 30 manuscripts in the last year.

Table 1 Respondent characteristics

Characteristic	Number	Percentage
Workplace:		
industry[1]	144	31
agency or CRO[2]	238	51
CRO[3]	15	3
freelance	34	7
other	38	8
Experience of working with peer-reviewed publications:		
<2 years	36	8
2-4 years	66	14
5-9 years	111	24
10 years or more	256	55
Qualification:[4]		
Masters degree	111	24
Doctorate	263	56
MD / medical qualification	26	6
Other	26	6
Certified Medical Publication Professional (CMPP)	161	34

[1]Pharmaceutical, biotech or medical device company

[2] Communications company

[3] Contract research organization

[4] Respondents were asked to tick all that applied

Awareness of guidelines

Almost all industry and agency respondents reported being ~~were~~ aware of international guidelines on responsible publication practices (Fig 1). Overall, 91% stated that they routinely referred to Good Publication Practice (GPP2) and 93% to the International Committee of Medical Journal Editors' Uniform Requirements for guidance on ethical practice. Other sources of guidance consulted routinely by respondents in all sectors included ISMPP (71%), medical writers associations (e.g. AMWA and EMWA: 39%), and the Committee on Publication Ethics (COPE: 34%).

Training

Regular training on ethical publication practices was compulsory for most respondents in industry and agencies. Mandatory training for employees was reported by 78% of industry, 79% of agency, and 93% of CRO respondents. In addition, 68% of agency respondents reported that their industry customers provided mandatory training for agency personnel. Training at least once a year was reported by 70%, 68% and 71% for industry, agency and CRO respondents respectively. Just over half the industry respondents (55%) reported that their companies provided training for agency staff or freelancers but only 17% of agency and 20% of CRO respondents reported that their organization provided training for freelancers (while 43% and 53% respectively didn't know if freelancers were trained). Similarly, 24% of the freelancers (5/21) reported that they received mandatory training from industry or agency customers.

Respondents kept up-to-date on current guidelines primarily via training provided by their organization (64%), from professional associations (68%), and monitoring the literature (70%).

Company codes of conduct and publication policies

In addition to their awareness of external guidelines on ethical publication practices (e.g., GPP2), most respondents reported being ~~were~~ aware of internal guidelines governing publication practices. Overall, 78% of respondents worked in an organization that had a Code of Conduct governing ethical publication practices. Nearly all the industry (94%) and agency (94%) respondents and all the CRO respondents (15/15) stated that their company had guidelines or a policy on ethical publication practices (5 industry and 8 agency respondents stated their company did not have such a policy while 3 and 7, respectively, did not know) (Fig 1).

Most company guidelines and policies are not publicly available: only 38% of industry, 35% of agency, and 33% of CRO respondents reported that these documents were publicly accessible (e.g. posted online) (Figure 2).

Of the industry respondents, 67% stated that their company was committed to peer-reviewed publication of results of all studies in humans. Exceptions to this commitment were studies for which companies did not have control (e.g. investigator-initiated studies) (reported by 21) and Phase 1 studies (i.e. early-phase drug development) (reported by 14).

Public disclosure of trial results was reported, by those working within the industry, to be fulfilled by: posting results on a public register (92%), publishing in a peer-reviewed journal (73%), publishing a conference abstract (51%), posting results on a company website (28%), or a combination of these. When asked about the timing of journal publications, most industry respondents reported that their company policy was to submit a manuscript within

12 or 18 months of study completion (last subject, last visit) (43% and 18% respectively). Nevertheless, 24% of industry respondents reported that their company did not have a target deadline for submitting a manuscript after trial completion (Figure 2).

Similar proportions of industry and agency respondents (80% and 81% respectively) reported that authorship obligations were set out in formal agreements before manuscript development (Fig 1). Almost all industry (96%) and agency (99%) respondents, and 100% of CRO respondents, reported that their department ensured that authors acknowledge professional medical writing support in every publication (Fig 1). Only one respondent from each of the industry and agency groups answered no to this question. However, 11% of respondents from both industry and agency, and 13% from CROs, were aware of academic authors initially refusing to acknowledge professional writing support in the last 12 months.

Compliance with codes

Respondents from industry, and to a lesser extent from agencies, reported that ~~had~~ their publication practices were subjected to compliance checks. Of the industry respondents, 61% stated that their company had a formal process for monitoring adherence to company standards and 66 of these (46% of the total) carried out publication audits. A very similar response was obtained from those working in CROs (60% and 47% respectively). However, of the agency respondents, 44% reported that their company had formal compliance monitoring for internal standards and only 20% carried out publication audits. In addition, about half the industry respondents (47%) reported that their company had a formal process for monitoring third-party providers' adherence with company standards and 75% of these reported that this involved an audit. Agency and CRO respondents stated that some (43%, 47% respectively), most (19%, 0%), or none (6%, 13%) of their customers had formal,

regular processes such as knowledge tests or audits for monitoring suppliers' adherence to the customer's standards, while 27% of agency and 40% of CRO respondents did not know if their customers did this. Agency and CRO respondents also reported that their customers used publication management tools to assess compliance (only 6% and 13% respectively reported that no customers did this).

Of the industry respondents, 52% worked in a company operating under a US Government 'Corporate Integrity Agreement' (CIA: see https://oig.hhs.gov/compliance/corporate-integrity-agreements/index.asp), which typically requires formal compliance checking.

Organization of publication activities

Publication activities were primarily governed by medical departments; publications were rarely funded, or approved, by commercial departments (Fig 1). According to the industry respondents, the budget for peer-reviewed publications was usually held by the medical affairs (72%) or clinical development (24%) departments. Nevertheless, seven respondents (5%) stated that the publications budget was held by a commercial department (e.g. sales or marketing) (Fig 2). Involvement of members of commercial departments in developing publications varied, with industry respondents stating that they were: not involved (27%), provided with information only (48%), members of the publication team (44%), allowed to suggest target journals for author consideration (22%), involved in reviewing manuscripts for accuracy (19%), or part of a formal approval process (5%).

Agency response to requests for perceived unethical practices

Respondents were often, but not always, successful in preventing publication practices they considered unethical. Of the agency respondents, 38% were aware, in the past 12 months, of

their company being asked by an author or a sponsor to do something that they believed contravened ethical practices (10% once and 28% more than once) while 2/15 CRO respondents (13%) reported such requests. Respondents reported that their agency's response was to explain the need for compliance, resulting in the request being withdrawn or amended (92% and both CRO cases), or to refuse to accept the work (1%); however, 3% (3/90) stated that the agency ultimately complied with the request.

Although a slightly higher proportion of freelancers (17/34, 50%) reported requests which they believed constituted unethical practices, this should not be over-interpreted due to the small group size; 12% (2/17) of freelancers accepted such work.

Information provided to authors

Authors were routinely provided with various documents and data sources to facilitate manuscript preparation. These documents included (for agency and industry respondents respectively): clinical study report (81%, 79%), study protocol (79%, 83%), summarized data (67%, 66%), statistical report (58%, 62%), manuscript outline (58%, 56%), statistical analysis plan (42%, 54%), and raw data/data tables (42%, 42%).

Enforcement of authorship criteria

Respondents actively enforced compliance with authorship criteria (Table 2).

Table 2

Responses to the question "In the last 12 months, to your knowledge, how often has your department recommended to the lead author the removal of a co-author from a manuscript or abstract that was in development?"

	Never	Once	More than once	Other	Don't know
Industry (n=144)	44% (64)	10% (15)	22% (32)	2% (3)	21% (30)
Agency (n=238)	24% (58)	11% (26)	35% (84)	3% (6)	27% (64)
CRO* (n=15)	27% (4)	33% (5)	7% (1)	7% (1)	27% (4)
Freelance (n=34)	74% (25)	9% (3)	15% (5)	3% (1)	0

*Contract Research Organization

Of the industry respondents, 33% were aware of an author being removed from a manuscript within the last 12 months and 94% stated that this was due to the individual not meeting authorship criteria. Other reasons for recommending removal of an author included individuals leaving the company (28%) or not agreeing to adhere to ethical publication practices (13%) (respondents could select more than one reason). Three respondents from industry and two from agencies reported authors being removed because they disagreed with

the interpretation of the data. Eight freelancers reported recommending the removal of an author, in all cases because the individual did not meet authorship criteria.

Publishing negative findings

Most industry respondents' companies attempted to publish negative or inconclusive results. Of the industry respondents, 63% reported that their department had supported the publication of a study with negative or inconclusive results (17% stated that this had not happened and 19% did not know). Only six respondents (4%) were aware of a negative or inconclusive study for which publication was not planned, in three cases this was due to the discontinuation of product development. Reponses were similar in the agency (and CRO) groups, with 58% (60%) aware of the publication of negative findings and 6% (13%) being aware of negative findings for which publication was not planned. Of the freelancers, 38% had been involved with the publication of negative findings in the last 12 months.

Freelance responses

Only 34 freelance publication professionals responded to the survey and some of these did not answer all questions, therefore the results may not be representative and should not be over-interpreted. However, the following findings were noteworthy: 12/34 (35%) did not know whether their customers had publication guidelines; 15/21 (71%) stated that they did not receive mandatory training; and 21/34 (62%) stated that their clients did not have formal, regular processes to monitor their adherence to standards. However, freelancers reported routinely consulting published guidelines (100% for ICMJE, 91% for GPP2) on ethical issues.

DISCUSSION

This is one of the largest, international surveys designed to capture information about current knowledge and implementation of publication guidelines within the pharmaceutical, medical device, and medical communications industries. Our survey showed high reported levels of knowledge of the various publication guidelines among publication professionals, with over 90% of respondents stating that they routinely referred to them. Although these published guidelines (such as GPP2) are not generally enforced by legislation, according to our survey most companies have codes of conduct, policies, or internal guidelines that reflect and enforce them. Similarly, most companies (industry and agencies) provide mandatory training to internal staff, while many pharmaceutical and medical device companies also train agency personnel who develop publications on their behalf. The relatively low rates of training and auditing of freelancers suggested in this survey (albeit from a small number of respondents), however, may represent a problem that companies, agencies, and authors who work with freelancers should address.

Many pharmaceutical companies in the USA currently operate under Corporate Integrity Agreements (CIAs). For such companies, many aspects of good publication practice are legally enforced. An analysis of 12 such agreements issued from 2009 to mid-2012 showed that they included requirements for author agreements, publication plans, and the posting of study results.[15] The CIA requirements were consistent with GPP2 and the ICMJE guidelines and also mandated training and reporting. CIA requirements apply not only to the pharmaceutical company but also to their management of any third-party suppliers, therefore, they will also affect many agencies, freelancers, and CROs. Similarly, even companies without a CIA often require suppliers to follow their policies. Therefore, for many agencies

and freelancers, failure to follow a customer's policy could mean loss of future business, thus the underlying guidelines are viewed as compulsory rather than optional.

The importance with which guidelines are viewed is reflected in the effort (and therefore time and money) companies invest in monitoring compliance. Our survey found that many pharmaceutical and device companies have formal monitoring processes including publication audits. Since our survey may have included several respondents from the same company, the results cannot indicate precisely what proportion of companies have such processes but it is probably well over half. The fact that fewer agencies appear to audit to their own internal standards is not surprising, since many reported being regularly audited by their customers. However, rates of training and auditing of freelancers (by pharmaceutical companies and agencies) is less reassuring and suggests room for improvement.

Many companies use specialist publication planning software (such as Datavision™ or PubSTRAT™). Our survey shows that such tools are used not only for publication project management but also to monitor and demonstrate compliance with company procedures, for example, by ensuring that all authors have approved a manuscript outline, drafts, and the final version.

Lack of transparency surrounding company involvement, non-disclosure of competing interests, and misleading authorship have been causes for concern in industry-sponsored publications in the past.[16] In particular, the occurrence of 'ghost-writing' (i.e. unacknowledged use of medical writers) and guest or honorary authorship (i.e. named authors not fulfilling journal authorship criteria) were spurs for the development of both general and specific guidelines.[3, 4, 11, 17] It is therefore encouraging that 96-100% of respondents

(working in pharmaceutical and medical device companies, agencies, and CROs) stated that their department ensured that medical writers were acknowledged (thus preventing the medical writers from being 'ghost writers'). Of concern, however, is the fact that some academic authors apparently continue to be reluctant to acknowledge writing support. Although publication professionals can alert authors about the need for disclosure, academic institutions clearly have an educational role to play.

The ICMJE authorship criteria (which are widely endorsed by medical journals and which were revised after the survey) state that listed authors should have made substantial contributions to both the research and its publication. Therefore authorship cannot be determined until a publication is developed. Individuals involved with the research being reported may be invited to become authors, but will not qualify unless they also take an active role in the publication. It is therefore encouraging that our survey found that not only industry sponsors of research, but also publication agencies and freelancers working for them, actively enforce authorship criteria by suggesting that individuals should be removed from author listings if they fail to meet the ICMJE or other agreed criteria (see Table 2). It can take considerable courage for a freelancer or agency employee to suggest that a proposed author has not contributed sufficiently to merit being listed, especially if that person is a senior academic or well-known expert. Being the one to identify a guest author carries the risk of damaging relationships and possibly work prospects. However, arguably there is an even greater and more serious risk of damaged relations, reputations, and work prospects if a publication professional fails to raise authorship concerns which are later raised by a journal. Early clarification of authorship obligations should reduce the risk of guest authorship and it was encouraging that most respondents reported that authorship agreements were confirmed before manuscript preparation started.

As we cannot tell how often proposed authors fail to contribute to publications, our survey cannot show how often this is overlooked, but the fact that almost one-third of industry respondents were aware of instances of authors being removed because they did not meet authorship criteria suggests that guidelines are being enforced. However, this question also revealed that three industry (2%) and two agency (0.8%) respondents were aware of authors being removed from publications because they disagreed with the interpretation of the findings. We cannot tell how many cases these represent, since several respondents may have reported the same case, nor can we tell whether the disagreements about interpretation were with the sponsor (which would be concerning) or between co-authors, but this issue needs further scrutiny.

The difficulties of interpreting the ICMJE authorship criteria in some situations have been examined in a study coordinated by the Medical Publishing Insights and Practices (MPIP) Initiative.[18] Using vignettes presenting 'challenging real-world authorship scenarios' this study found that journal editors, clinical investigators, medical writers, and publication planners had different views about who qualified for authorship and suggested that additional guidance might be helpful.

Limitations

We had originally hoped to compare or confirm responses from publication professionals with those from journal editors and academic investigators, however, we were less successful in promoting the survey among these groups than among publication professionals and consider the response from these sectors too small to be reliable. The number of responses from freelance publication professionals was also disappointing and it is therefore important

not to over-interpret the findings from this group. Care should also be taken in extrapolating proportions of respondents to proportions of companies or agencies, since we had no way of measuring the numbers of respondents per company.

We also recognise that our survey, like many others, carried the risk of self-selection bias. Our survey was promoted mainly via professional organizations such as ISMPP and AMWA/EMWA which promote ethical publication practices. Those choosing to respond to a survey supported by these associations may be more likely to follow and report ethical publication practices. Also, those who chose to complete the survey may have had a special interest in, or concerns about, the issues covered. Our respondents therefore may not be representative of all publication professionals and may be better informed about the topics covered by this survey and more aware of guidelines (e.g. from attending professional meetings or taking part in educational activities). However, due to the methods used to publicise the survey (including websites and social media rather than to a clearly defined population) it was not possible to compare characteristics of respondents and non-respondents. We also acknowledge that our respondents came primarily from higher-income countries. Our findings may not be applicable to publication practices in lower-income countries, particularly given the significant influence of country income on publication practices. [5, 19]

Another problem with any survey is if respondents give 'socially desirable' rather than truthful answers. One reason we have confidence in our findings is that responses were not uniform, e.g. only 34% reported referring to the COPE guidelines compared with 91% for the ICMJE guidelines. The fact that the survey highlighted weaknesses as well as strengths (e.g. the proportion of freelancers who receive training) also suggests that responses were factual.

Comparison with other surveys

Journal editors' awareness of various guidelines was measured in 2007 in an international survey to which 111 editors of biomedical journals responded.[20] This survey noted that "awareness and use of guidelines and other resources on publication ethics was generally low". Over half the editors (55%) reported being unaware of the ICMJE Uniform Requirements and two-thirds (67%) were unaware of the GPP guidelines, while the proportion of editors reporting that they had used these guidelines were just 24% and 9% respectively. This represents a marked contrast to the publication professionals responding to our survey, over 90% of whom reported that they routinely referred to these two guidelines.

Another survey of 183 editors of high-impact medical journals in 2009 found that, although 76% had received training in medical editing, they performed poorly when answering questions about: authorship (only 30% gave 'correct' answers, i.e. consistent with commonly cited guidelines), plagiarism (17% correct), peer review (16% correct), and conflicts of interest (15% correct).[21]

A 2012 survey of 294 healthcare professionals found that 42% were unaware of the GPP guidelines.[22] This survey also found that the doctors (69% of whom were authors on peer-reviewed articles) were unfamiliar with, or disagreed with, the ICMJE authorship criteria, since a considerable proportion considered that data collection (51%) or general supervision of a laboratory (33%) alone were criteria for authorship. Nevertheless, 66% of respondents in the healthcare practitioners survey stated that they would be concerned about 'the involvement of pharmaceutical employees as authors or reviewers of a draft manuscript'. A smaller survey of surgeons in Croatia (in 2011) found that only 54% (31/57) were aware of

the ICMJE guidelines although 74% (43/58) of the respondents had worked on at least 2 manuscripts for publication in the last 2 years.[23]

A large-scale, repeated survey of medical writers (who were nearly all members of AMWA or EMWA),[24] which attracted 746 responses in 2005, and 662 in 2008, found lower levels of familiarity with guidelines than the current survey (carried out in 2012) but showed that awareness had risen between 2005 and 2008. For example, the proportion of respondents claiming to be familiar with ICMJE guidelines rose from 54% in 2005 to 75% in 2008. The figures for GPP were 43% and 58%, and for the EMWA guidelines (published in 2005) 27% and 46% respectively in 2005 and 2008. The AMWA/EMWA survey also asked writers about their experience of being involved with unacknowledged writing work (i.e. ghostwriting). In 2005, 39% stated that this practice had decreased in the last 5 years (52% stated that it was unchanged and 8% that it had increased). In 2008, 63% considered that ghostwriting had decreased, 30% stated that it was unchanged and 6% that it had increased in the last 5 years. The proportion of professional writers reporting that they always requested acknowledgement for a substantial contribution to a manuscript also rose from 25% in 2005 to 43% in 2008. The survey was repeated in 2011 (with 620 respondents)[25] and responses showed a clear decrease in the proportion of manuscripts (not necessarily all for peer-reviewed journals) with undisclosed contributions (i.e. ghostwriting) which fell from 62% in 2005, to 42% in 2008, and 33% in 2011.

Ghostwriting of review articles commissioned by pharmaceutical companies was a particular concern when the first GPP guidelines were developed.[26] A survey of authors published in six, high impact general medical journals found a decline in ghost authorship between 1996 and 2008, and a significant decrease (from 26% to 15%) in honorary authorship (which often

accompanies ghostwriting) for review articles and editorials (although not for other types of article).[27]

Our survey did not get sufficient response from academics to draw any conclusions about their understanding of their role as authors of medical publications. We hope that the full report of the MPIP authorship project will cast more light on this.[18]

RECOMMENDATIONS

While many of our findings are heartening (Fig 1), some indicate a need for further action (Fig 2). We hope that the professional organizations who were involved with this survey (in particular, ISMPP, AMWA, and EMWA) along with pharmaceutical and medical device companies will use the findings to identify topics for future training or discussion. We suggest they might focus on the following areas.

- Although many companies and agencies had publication policies, it is disappointing that so few of these policies were made public. We encourage companies to post their publication policies on their websites. Companies might also consider publishing the results of publication audits to indicate how closely they comply with guidelines (for example, what proportion of clinical trials are published) and to help identify obstacles to compliance.
- While our survey suggests that most pharmaceutical companies and agencies have a code of conduct and provide mandatory training on responsible publication practices to relevant staff, this is not always the case, and there is room for improvement, especially for those that sub-contract work to freelancers. We therefore recommend that companies, agencies, and professional groups (such as ISMPP, EMWA, and AMWA) put renewed effort into ensuring that all publication professionals receive

effective training. Freelancers should be accountable for their own training, or ensure they receive sufficient training from their customers. We also recommend that individuals involved less directly in publications should be made aware of the relevant guidelines.

- Although pharmaceutical companies generally provide invited authors with study reports and protocols, this was not universal. Named authors should always have access to study results to ensure they can understand and interpret the findings.
- The reported requests from authors or companies for agency staff to do something that the publication professionals considered unethical warrants further investigation. Our survey did not ask about reporting mechanisms for perceived unethical practices, or how strongly these are communicated and used. We encourage agencies to develop systems for handling such situations. Further education of authors and industry staff, particularly those who are not familiar with the stringency of current guidelines, should help reduce such requests.
- The number of freelancers responding to the survey was small (<50), but some of their responses suggested differences from publication professionals working in companies. We therefore hope a similar survey might be undertaken focusing on the needs of this community and their publication practices to better understand areas where they may need support.

These suggested actions focus primarily on pharmaceutical companies and communications agencies. However, clinical trials and their publication involve many players, and other surveys suggest that both healthcare professionals (investigators and academics) and journal editors would benefit from greater knowledge of published guidelines and may, in fact, be less familiar with such guidelines than publication professionals. Given the financial and

human resources required to ensure timely, accurate, and complete reporting of research results,[28] it is likely that the demand for, and use of, publication professionals will increase. Our survey findings indicate that further involvement of knowledgeable and experienced medical publication professionals, who are familiar with guidelines on reporting clinical trials and publication ethics, should be viewed as a positive step in achieving timely and reliable reporting. Our survey findings also complement evidence which shows that manuscripts prepared with professional writing or editing support are more likely to comply with reporting requirements,[29] less likely to be retracted for misconduct,[5] and are accepted for publication more quickly,[30] than those prepared without such support.

Authorship of research publications is not straightforward and the ICMJE criteria have recently been revised. Our survey did not examine views on existing criteria or problems with their implementation, although others have done so.[31, 32] We are aware of current initiatives aimed at deepening understanding and developing consensus around authorship and the transparency of contributions and we welcome these. We would also welcome surveys that test how well non-industry authors and editors comply with voluntary guidelines issued by their professional associations and how such compliance is checked.

CONCLUSIONS

Despite criticism that most publication guidelines are voluntary, our survey suggests that the major guidelines are widely known and implemented by publication professionals working in pharmaceutical and medical device companies, communication agencies, CROs, and as freelancers. Many companies enforce these guidelines through policies, codes of conduct, standard operating procedures, and audits. For companies operating under a CIA, many of the GPP and ICMJE recommendations are mandated and audited by the Office of the Inspector

General via independent auditors. When the GPP guidelines were first developed (in the late 1990s), publication audits were unheard of, yet many companies now regularly audit their practices against guidelines such as GPP2, and CIAs mean that many of the GPP recommendations are now legally enforced and monitored.

While there is no room for complacency, and we make no claim that all problems with the publication of industry-funded research have disappeared, this survey, taken together with others showing improved acknowledgement of medical writers, and reductions in guest authorship, suggest that guidelines such as GPP (published in 2003) and GPP2 (2010) have had a definite, positive effect on publication practices and that most companies and individual publication professionals are striving to do the right thing.

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Contributions

All authors were involved in developing the questionnaire and analysing or interpreting the data. All authors reviewed the manuscript and discussed it critically over several revisions, and agreed to submit it for publication. In addition, EW wrote the first draft of the paper, JF was responsible for data management and analysis, and KW presented initial findings at the 2013 ISMPP meeting and prepared the figures.

Competing interests
EW is an author of the original GPP guidelines, the anti-ghostwriting checklist, the EMWA guidelines on the role of medical writers in publications, and several COPE guidelines. She works as a freelance publications consultant and has provided training to many pharmaceutical companies and communication agencies and receives fees and expenses for talks and workshops on publication guidelines.

KW conducts and publishes research on ethical medical writing practices. She is actively involved in not-for-profit associations that advocate for ethical publication practices. She is paid to provide ethical medical writing training courses and services for not-for-profit and for-profit clients, particularly in the Asia-Pacific region.

AC has served on the ISMPP Certification Board of Trustees.

ST is the chair of the ISMPP Advocacy and Outreach Committee.

AC, VA, TG and ST are employed by ~~a~~ medical communications companies~~y~~ that provide~~s~~ publications services to authors and industry sponsors.

JG is on the Board of Trustees of ISMPP and is a steering committee member of the MPIP (Medical Publications Insights and Practices) Initiative.

JG and TG are/were employees of AstraZeneca and own shares in the company.

JF is an employee of TGaS Advisors, a division of the KnowledgePoint360 Group.

All authors (except JF) are members of ISMPP. None of the authors received any specific remuneration for working on this project.

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Data sharing statement
The full questionnaire and raw ~~is available at QQQ. D~~ data aggregated by sector (industry, agency, freelance) ~~is~~are available at ~~XXX~~ http://www.ismpp.org/gps-raw-data

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Figure legends.

Fig 1. Percentage of survey respondents from industry and agency groups responding 'yes' to selected questions.

Fig 2. Percentage of survey respondents from industry and agency groups responding 'yes' to selected questions. (Asterisks indicate that question was only relevant to one group.)

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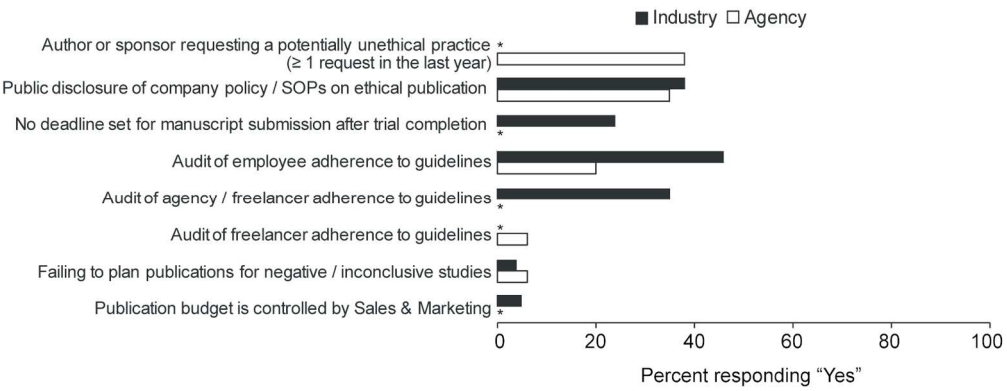

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