



Preface

Dear Colleagues:

The 7th Annual Meeting of the International Society for Medical Publication Professionals (ISMPP) is titled ***Anticipating Change in Medical Publications: Leading Now for the Future***. Those involved in the development of the program all agreed that although we know that change is coming, we cannot predict what it will look like, and more specifically how it will affect our roles as medical publication professionals.

What we all can agree on as medical publication professionals is that we must practice our profession with transparency, integrity, and ethics. We do this by following the standards and best practices that have been established by and for our profession, many of which have been developed and/or tested based on well-designed research.

This edition of CMRO marks our third collaborative journal publication effort, showcasing the research conducted over this past year by members of ISMPP. In this issue, you will find 26 abstracts submitted to the 7th

Annual Meeting of ISMPP and accepted for either oral or poster presentation. The outstanding quality of the research conducted by our membership speaks for itself, and demonstrates the degree to which our standards elevate with each passing year.

On behalf of ISMPP, we would like to express our sincere appreciation to the publishers of CMRO for their continued support of ISMPP's initiatives.

Sincerely,

Two handwritten signatures are shown side-by-side. The signature on the left is 'Rob Matheis' and the one on the right is 'Faith DiBiasi'.

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 Certified Medical Publication
 Professional
 President, ISMPP

Faith DiBiasi, MBA
 Certified Medical Publication
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Acknowledgment

Declaration of interest: Current Medical Research & Opinion (a Founding Corporate Supporter of the International Society for Medical Publication Professionals) is pleased to cooperate with ISMPP and the abstract authors in the preparation of this supplement. The selection and peer review of abstracts was carried out by ISMPP; they have not been peer reviewed by CMRO.

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***Oral presentation at the 7th annual meeting of ISMPP**

Editorial

ISMPP and advocacy for the medical publication profession

Jackie Marchington^a on behalf of the ISMPP Issues and Action Committee

On behalf of the ISMPP Issues and Action Committee

The International Society for Medical Publication Professionals (ISMPP) Issues & Actions Committee's advocacy activities are a priority for the ISMPP Executive Committee and the organization as a whole. ISMPP is striving to take a leadership position on behalf of the profession, so we can refute inaccurate or biased press and publications, correct related perceptions surrounding the role of publication professionals, and communicate that we act appropriately and are compliant with professional standards, thereby playing a significant role in ensuring the integrity of the medical literature. The advocacy program comprises three strategies: government affairs, professional coalitions and public relations.

ISMPP is an international organization committed to raising standards on a global basis in response to the discussion of publication conduct ongoing in many countries. In the US, as a result of the Minority Staff Report, Senate Committee on Finance¹ and discussion in the political arena, the government affairs sub-team has been focussing on US Congress as the target for their activities. To this end, the team has scheduled an advocacy day to coincide with the 2011 annual meeting on April 6, which will provide a structured opportunity to connect ISMPP members to their own legislators, enabling ISMPP to communicate its voice and opinions on relevant publication planning issues to US policy makers. The opportunity then exists to create a network of relationships on Capitol Hill and to establish ISMPP members as 'go-to' experts on relevant policy issues. Through these relationships we can then communicate the value of publication professionals to the quality of scientific literature. To achieve these aims, the government affairs sub-team has been working to schedule visits, organize pre-visit training, and develop leave-behind literature supporting the position papers that have been developed by the public relations sub-team.

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Another area where we believe we can build advocacy is with professional associations that have a focus or interest related to medical publishing, as well as medical institutions, which may not fully understand the role and contributions of medical publication professionals. The professional coalitions sub-team has developed a plan for ISMPP to build relationships with three target groups:

- Building collaboration with professional associations that have goals in common with ISMPP, such as AMWA/EMWA and the Council of Science Editors;
- Seeking common ground with associations that are also striving for high quality publications and transparency, such as ICMJE, medical journal editors, medical schools/institutions, and medical societies (e.g., American Society of Clinical Oncology);
- Providing education on medical publication professionals to important influencers, such as the Association of American Medical Colleges, Council of Medical Specialty Societies, American Society for Clinical Pharmacology and Therapeutics, and International Society for Pharmacoeconomics and Outcomes Research, to ensure that they understand and differentiate professional medical writing support from ghostwriting and other unethical activities.

The final strategy – public relations – is aimed not only at external audiences, but also is designed to assist ISMPP members to discuss media issues with due confidence. By creating position statements on key issues and developing a strategy and process for responding to professional medical publication issues, the public relations sub-team are creating the tools that will enable ISMPP to leverage its leadership position to speak on behalf of the profession. The first two position papers “‘Ghostwriting’ and the Professional Medical Writer”² and ‘Rationale and Value of Medical Publications’³ are currently available on the ISMPP website, with others in development. The team also generated a press release⁴ in response to the Minority Staff Report, Senate Committee on Finance¹ last summer, and is monitoring sources for issues of importance to ISMPP so we can respond reactively when appropriate and proactively when we see the opportunity for

media outreach. We plan to identify a number of ISMPP spokespersons for these opportunities, to widen the pool of individuals who liaise with the media.

We believe that these strategies will improve understanding and awareness of medical publication professionals and the positive contribution we make to the medical literature.

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Abstracts

Analyzing the landscape of author instructions for general medicine journals: past and present

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Objective: This analysis was performed to examine the relationship of medical journal impact factors (IF) and the adoption of transparency guidelines during the last 10 years.

Research design and methods: Journals of interest were selected from Thomson Reuters' Journal Citation Reports in the general medicine category, based on IF, publication language, and availability. Author instructions from 2000, 2005, and 2010 were gathered from nine journals organized by tiers (three journals each) relative to IF (high, middle, and low). Journal policies and practices regarding authorship requirements, conflict of interest statements, source(s) of funding, acknowledgment of writing assistance, and extent of uniformity with the International Committee of Medical Journal Editors (ICMJE) guidelines, among others, were reviewed.

Results: Across all years, the majority of the high- ($n=3$) and middle-tier ($n=2$) journals defined criteria for authorship and/or required that author contributions be specified, and mandated conflict of interest statements and source(s) of funding for manuscript submission. The number of high- and middle-tier journals requiring an acknowledgment of writing assistance increased from 2000 to 2010; however, no increase was noted in low-tier journals. Independent of IF, by 2010, nearly all journals ($n=8$) had author instructions that referenced aspects of ICMJE guidelines.

Conclusions: Overall, low-tier journals were slower to adopt policies and practices regarding authorship, conflict of interest, funding, and acknowledgment of writing assistance.

Assessment of good publication practice in medical communications companies' online descriptions of capabilities

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Objective: The continued scrutiny of industry-sponsored publications may come from a misunderstanding of the role of medical communications departments within pharmaceutical companies and their external partners in supporting authors in the development of a publication. This study compared the publicly available descriptions of publication planning capabilities/policies of medical communications companies with the standards set forth in Good Publication Practice 2 guidelines, along with those standards generally adopted as good practice in the industry.

Research design and methods: A representative sample of medical communication companies was compiled by Internet searches of keyword terms. The first 50 results from each term were investigated and descriptions of publication practices reachable in ≤ 4 clicks were included.

Results: Fifty companies were included in the study. Of these, 35 (70%) described practices that were in accordance with standard industry practice, 2 (4%) described practices that were partially in accordance, and 13 (26%) described practices that were not. Many of the descriptions not in accordance could be perceived as linking publications to the marketing of a drug or supporting ghostwriting. Redacted examples of each will be presented.

Conclusions: Most of the described practices of medical communication companies were in accordance with industry best practices. However, the descriptions of substandard practice by a few may contribute to the perception of bias associated with all industry-sponsored publications, regardless of actual practice. All medical communications professionals should review their descriptions of capabilities/policies to ensure consistency with best practices.

Characterization of awareness and application of publications guidelines among pharmaceutical professionals

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Objective: This survey assessed the level of awareness and application of publications guidelines and practices among pharmaceutical/biotechnology/device company professionals.

Research design and methods: A web-based survey of 5000 subscribers to *PharmaVOICE* was conducted in December 2010.

Results: A total of 79 responses were obtained, mainly from clinical (31%), commercial (24%), or medical affairs (23%); $<7\%$ were members of the International Society for Medical Publication Professionals. Overall, awareness of publications guidelines was low, and no single guideline was associated with a high level of awareness. The rank order of awareness (highest to lowest) of guidelines set forth by the following was: Food and Drug Administration Amendments Act, International Committee of Medical Journal Editors, Association of American Medical Colleges, Good Publication Practice 2, and Committee on Publication Ethics. According to respondents, medical literature and colleagues are common places to seek vital information, publication societies less so. Although variable, there appeared to be a greater awareness of publications guidelines among clinical versus commercial roles. Respondents indicated a high level of personal involvement in publications planning across roles. Additionally, the vast majority of companies have policies in place regarding a wide range of publications practices, from acknowledgment of medical writing support to author selection to final manuscript review/approval. Regarding review, there remains a high level of commercial involvement (67%) in content review despite heightened sensitivities. Also noteworthy, smaller companies (<500 employees) were more likely to engage authors later in manuscript development.

Conclusions: Significant opportunities exist for publications professionals and associated organizations to broaden awareness and application of critical publications principles.

Comparative effectiveness research in the United States: implications for publication planners

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Objective: Government-sponsored comparative effectiveness research (CER) is established in Europe and is gaining prominence in the United States (US), raising concern that CER might be used to restrict access to branded products. We analyzed CER summaries from the US Agency for Healthcare Research and Quality (AHRQ) to determine therapy areas of interest and implications for publication planning.

Research design and methods: CER summaries in the AHRQ database were categorized by therapeutic area. Summaries in the most frequent category were qualitatively analyzed.

Results: In all, 65 CER documents, including reports, protocols, and drafts, were available. The most common therapy areas were cardiovascular disease (CVD) (14 CERs, including drafts/protocols), hematology/oncology (8), psychiatry (8), rheumatology (6), and metabolics (5). The reports utilized publicly available data, emphasizing primary literature obtained through PubMed. Where available, data were meta-analyzed. The seven final CVD reports were analyzed qualitatively. An illustrative example compared angiotensin-converting enzyme (ACE) inhibitors (an antihypertensive class with many generic options) with angiotensin receptor blockers (ARBs) (an antihypertensive class with many branded members), concluding no difference in efficacy. A difference in adverse events of cough in favor of ARBs was acknowledged; relative cost was not explicitly mentioned.

Conclusions: AHRQ reports include comprehensive data summaries for many interventions and therapeutic classes. Although subtly conveyed, CER reports include arguments that support restricted access to newer or branded products. Publication planners should be aware of CERs in development and consider strategies to clarify data and provide context.

Comparison of results reporting on ClinicalTrials.gov by funding source

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Objective: In an effort to increase transparency, the Food and Drug Administration Amendments Act of 2007 (FDAAA) mandated clinical trial registration and results reporting. This study quantified the number of trials with results on ClinicalTrials.gov by funding source.

Research design and methods: All trial entries in ClinicalTrials.gov (downloaded on 10/31/2010; $N=98,833$) were sorted by funding source (government, industry, or academia) using the 'Funded By' option. FDA-approved drugs/devices were confirmed on FDA.gov.

Results: Only 2.5% (2488/98,833) of all trials in the registry have posted results. Of the industry-funded trials, 5.3% reported results, with academic and government-funded trials each reporting 0.6%. Limiting trials to those within the FDAAA-mandated time frame for results reporting gave marginal improvement, with results posted for 15% (1226/7991), 3.8% (77/2021), and 2.4% (161/6842) of trials funded by industry, government, and academia, respectively. Out of the phase IV trials that met the time frame for results reporting of trials on FDA-approved drugs or devices, only 28% (259/931), 7% (6/86), and 2.5% (18/716) of trials funded by industry, government, and academia, respectively, reported results. Interestingly, of the industry-funded trials, only 6% (16/259) of those with results shared sponsorship with a university/hospital/ research foundation, while 43% (286/672) of those without results did.

Conclusions: Despite FDAAA, the majority of clinical trials required to report results have not done so on ClinicalTrials.gov, though results could be posted and/or published elsewhere. Nevertheless, it appears that industry-funded trials are the most compliant with FDAAA regulations.

Correlating open access article views with citations using four databases

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Objective: The impact of articles on the medical and general literature can be gauged from citation indices. There is a considerable lag time from publication to citation and online views might be an earlier impact indicator. The hypothesis examined was that numbers of article views can be used to estimate the frequency an article would appear in four citation indices.

Research design and methods: Numbers of views for articles published in *PLoS Medicine* were compared with article citations using CrossRef, PubMed, Scopus, and Google Scholar, as these are freely available. The database included 43 research articles from 2005, 70 from 2007, and 35 from 2009.

Results: Correlations between article views and frequency of citations were poor (e.g., highest R^2 in 2005 was 0.35 for Google Scholar) regardless the citation index. Comparing citation indices, Google Scholar consistently had the highest numbers of citations (48.2/article; uses parsers software), followed by Scopus (33.6/article; publications with International Standard Serial Numbers). CrossRef (12.2/article; publications with digital object identifiers) and PubMed (7.9/article; restricted $\approx 5,000$ titles in medical literature) had considerably fewer citations and neither of these was consistently greater than the other.

Conclusions: Article views alone cannot be used as an indicator of subsequent impact of an article on the medical or general literature. Citation indices vary considerably in their purposes and coverage, with Google Scholar having the broadest (layman and medical literature) and PubMed the most focused (medical literature only) coverage.

Create a scientific publications guidance document to ensure continued awareness and compliance with industry best practices, regulations, guidances, and laws

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Objective: The purpose of this research was to provide guidance for publication leaders and teams to use for publication planning, processes, and daily tactical operations. Existing standard operating procedures were supplemented to include relevant provisions from Good Publication Practice 2 (GPP2) guidelines, industry best practices, current laws and/or regulations, including industry government investigative trends. Additional guidance was provided to publication leaders, teams, and agencies to continue to ensure consistency and compliance across publication teams.

Research design and methods: Publication department stakeholders and compliance and legal representatives provided guidance on relevant provisions of GPP2 guidelines, regulations, and laws. United States (US) and ex-US departmental employees also provided feedback to ensure global applicability of the guidance document.

Results: A comprehensive guidance document was created and endorsed by key company stakeholders that included: best practices provisions related to written authorship agreements, confidentiality agreements, author access to data, publication steering committees, authorship criteria and selection process, acknowledgments, disclosures and/or competing interests, author approvals, timelines, and local affiliate publication projects. Additionally, four written authorship agreement templates were created to cover various scenarios (agreements with external authors of primary and secondary publications and of review publications, and agreements with internal authors). A standard consulting agreement template was also created for poster presenters.

Conclusions: A comprehensive guidance document provides publication team standardization and is an example of an effective proactive compliance measure to help companies continue to navigate through ever-changing industry guidances and regulations.

Current and future publication practices: a survey of attendees at ISMP 2010

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Objective: This survey canvassed medical publication professionals for information and opinion regarding current and future publication practices. This information is essential in guiding planning and future communication initiatives.

Research design and methods: The 10-question survey was administered at the 2010 Annual Meeting of the International Society for Medical Publication Professionals. Registered individuals unable to attend were subsequently emailed the survey.

Results: There were 63 respondents: 39.7% pharmaceutical companies, 25.4% medical communications agencies, and 9.5% publishers. A total of 80% of all respondents (96% of pharmaceutical respondents) reported that Good Publication Practice 2 (GPP2) was already or was being incorporated into their publications policy. There was no clear consensus on measuring publication planning effectiveness ($n=39$): 36% use acceptance rates, 28% use publication timelines, and 18% use publication numbers. In the future, 45.2% and 41.3% of respondents expect a decline in industry-sponsored supplements and reviews, respectively, with 16.1% and 11.1% suggesting these will become non-existent. Additionally, 41.3% expect independent statistical analysis to become standard for industry-sponsored publications.

Conclusions: This survey provides a snapshot of current publication practices and future expectations. While the sample is small and restricted to individuals at the forefront of publication ethics, the rapid uptake of GPP2 is reassuring. Overall, the sample predicts a decline in industry-sponsored reviews and supplements; this view is not echoed by the subset of publishers completing the survey, nor those to whom we have spoken separately. Ongoing discussion will be necessary to develop consensus on appropriate publication planning metrics.

Do medical journals have consistent authorship policies and procedures? A randomized survey

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Objective: Authorship in biomedical publications is universally signified by the byline. However, authorship policies and procedures vary significantly among journals, causing some confusion regarding what 'authorship' actually means. We sought to succinctly describe and compare authorship policies and procedures of biomedical journals.

Research design and methods: A total of 36 PubMed-indexed journals were selected randomly, and 15 were selected by identifying the three with the highest impact factors from five therapy areas. Journal websites were the data source. Authorship policy and procedures were ascertained, with a primary focus on criteria for authorship and details of author contributions. Our assessment comprised categorical (e.g., does the journal adhere to International Committee of Medical Journal Editors (ICMJE) authorship criteria?) and descriptive (e.g., how does the journal require authors to state their specific contributions?) data.

Results: Of 15 top-tier journals, 13 required that ICMJE authorship criteria be met (7 used a prepared form) compared with 19 of 36 randomly selected journals (8 had a prepared form). Only 5 of 15 top-tier journals and 10 of 36 randomly selected journals required any further information about author contributions. Moreover, of the 10 randomly selected journals that required detailed description of author contributions, 6 did not require attestation to ICMJE authorship criteria.

Conclusions: Neither top-tier nor randomly selected biomedical journals have consistent authorship policies. Greater uniformity in this area would enhance credibility and trust regarding authorship and provide a more transparent and fair basis for evaluating authors' work.

Evidence-based guidance for publication professionals on publication misconduct and plagiarism

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Objective: Previously, we showed that publications retracted for misconduct were significantly associated with first authors who were affiliated with lower-income countries. The primary objective of this follow-up study was to investigate whether the type of misconduct (plagiarism, data falsification/fabrication) differs between lower- and higher-income countries. Secondary objectives were to investigate other author/publication factors associated with plagiarism.

Research design and methods: We conducted a large, systematic, controlled, retrospective study of misconduct retractions from PubMed (limits: English, human, January 1966 to February 2008). An independent statistician reviewed the design and conducted all analyses (odds ratios [OR], 95% confidence intervals [CI], chi-square tests).

Results: Of the 213 publications retracted for misconduct, 42% (89/213) were retracted for plagiarism, 57% (121/213) for fabrication/falsification, and 1% (3/213) for unknown reasons. The odds of plagiarism (with fabrication/falsification as reference) were higher for first authors affiliated with lower-income countries (OR, 95% CI; 15.37, 4.47–52.86; $p < 0.0001$), for first authors affiliated with non-native English-speaking countries (3.20, 1.80–5.70; $p < 0.0001$), when publications were review articles or commentaries (8.35, 3.27–21.30; $p < 0.0001$), or when manuscripts were published in low-ranked journals (4.86, 2.40–9.85; $p < 0.0001$).

Conclusions: This is the first study to demonstrate that the type of publication misconduct differs between lower- and higher-income countries. Publication professionals should be aware of the author and publication factors significantly associated with misconduct involving plagiarism.

Expediting timelines of publication submission using a publications steering committee approach

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Objective: Implementation of the US Food and Drug Administration Amendments Act in September 2007 raised concerns regarding inability to submit a manuscript before posting of results to the registry, the date usually being the first anniversary of last patient last visit (LPLV). We piloted an approach to determine the feasibility of expediting submission timelines.

Research design and methods: Raw data were made available within 4–8 weeks of database lock and shared with authors (external and internal) at an off-site steering committee meeting. Statisticians, clinical trial coordinator, publication planner, and medical writer were additional attendees. The focus of this meeting included in-depth review and interpretation of the data, and discussion of the need for additional statistical analysis. Another component of this meeting was to discuss the contents of the primary manuscript, including the introduction and discussion sections, and journal selection. All authors contributed to this discussion.

Results: Differences of opinion among authors on interpretation of the data were resolved during the meeting. Based on the verbal discussion and subsequent agreement on the contents of the manuscript, the draft was developed within 2–3 months after the steering committee meeting. All authors reviewed, provided additional input, and approved the final version that was submitted. The overall time to complete a final draft for submission was within 6–7 months after LPLV.

Conclusions: Our case study indicated that manuscript submission can be completed at least 5 months before posting of results to the registry.

Familiarity of non-industry authors with good publication practice and clinical data reporting guidelines

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Objective: This study evaluated the familiarity of non-industry authors with guidelines for good publication practice and clinical data reporting.

Research design and methods: Non-industry authors for ≥ 1 publication in the last 2 years involving a single communications agency completed a nine-question online survey that evaluated experiences with professional medical writers and familiarity with guidelines (not, a little, somewhat, or very familiar).

Results: Of 287 authors contacted, 8% (23/287) responded to ≥ 1 question. Among respondents, 65% and 30% had received editorial assistance on ≤ 2 and 3–5 publications, respectively; 48% received significant or full-service (including outline, drafts, copy edit) assistance. More than 50% of respondents were somewhat or very familiar with guidelines of the International Committee of Medical Journal Editors and Good Publication Practice (GPP), while $>50\%$ of respondents were not or a little familiar with guidelines of GPP2, Consolidated Standards of Reporting Trials, European Medical Writers Association, and American Medical Writers Association. Many respondents (27–68%) were not familiar with ≥ 1 of the guidelines. Only 23% of respondents indicated that their institution has a specific policy regarding use of professional medical writers. A majority (77%) agreed that there is a role for professional medical writers in medical publications. High levels of satisfaction with professional medical writers were reported; 83% were very or extremely satisfied with overall writing quality and 96% were very or extremely satisfied with grammar and writing style.

Conclusions: A significant proportion of non-industry authors were not familiar with key guidelines governing good publication practice and clinical data reporting.

Impact of a structured training program on development of medical writers

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Objective: On-the-job (OTJ) training is essential for trainee medical writers (TMWs), but it is often difficult to identify appropriate development opportunities in a busy agency environment. Reasons include: availability of suitable projects, risk avoidance, increased turnaround time to allow for slower working, and time for feedback and monitoring. We introduced a 6-week structured training program to establish baseline skills in a risk-free environment that would prepare newly recruited TMWs for effective working on live accounts.

Research design and methods: We mind-mapped the key skills for professional medical writers and identified the baseline skill requirements. A bespoke training course, including tutorials and practical exercises, was designed and delivered. Exercises followed existing standard operating procedures and were subject to standard quality control and feedback mechanisms. The primary outcome measurement was client-chargeable time during the first 6 months of employment, compared with the previous intake of TMWs who had received mainly OTJ training.

Results: Interim analysis at 4 months of employment showed mean chargeable time for each successive month to be 3%, 37%, 72%, and 93% with structured training, and 51%, 71%, 55%, and 62% with OTJ training. The first 2 complete post-training months (3 and 4) after structured training averaged 83% chargeable time, compared with 58% for the OTJ trainees for the same period.

Conclusions: A structured training program appears to reduce the time taken for TMWs to achieve an acceptable level of chargeable time.

Incorporating 21st century technology to modernize scientific posters

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Objective: Scientific posters remain an essential tool to communicate cutting-edge clinical data to healthcare professionals. However, the overall look and feel of scientific posters has not evolved significantly from the purely textual medical posters that originated in the late 1800s. In an effort to improve and modernize the delivery of scientific information, we have employed the use of new smart technologies, such as Quick Reader (QR) codes. This study explored the incorporation of QR codes in scientific posters to increase visibility, accessibility, and usability of clinical data for healthcare professionals.

Research design and methods: We designed a pilot program to assess the intrinsic and potential value of using QR code technology in scientific posters. Six posters with QR codes were included in the pilot. Healthcare professionals scan the QR code to receive an electronic copy of the poster via smart phone technology. The number of downloads and interactions related to the technology were captured.

Results: Personal interactions at the poster sessions increased by 25%. Overall, 120 poster PDFs were downloaded. We reduced the number of printed handouts by 75%.

Conclusions: Our pilot has clearly demonstrated the value of incorporating QR code technology into scientific posters. QR codes provide a valuable function by facilitating the electronic sharing of information, reducing the total number of printed handouts, and setting a new standard. Healthcare professionals were intrigued by the new technology, increasing the level of interaction at the poster session.

Monitoring the external publications environment: one company's commitment to ensuring the highest standards in medical publications

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Objective: Industry-sponsored publications continue to be under increased scrutiny related to concerns over ghostwriting practices. This persistent trend has led medical journals to change their editorial policies in an effort to address these concerns.

Research design and methods: To facilitate adherence to the highest standards in publication development, we rolled out a company-wide standard operating procedure for publications and established the Monitoring the External Publications Environment (MEPE) task force. The MEPE task force was convened in January 2009 to collect information on journal publication policies with regard to industry-sponsored medical writing support. The task force is responsible for reviewing, summarizing, and communicating significant new developments in publication policies by medical journals, new guidelines from the International Committee of Medical Journal Editors, and changes in academic policies for authorship, as well as for monitoring important developments in the lay press. Timely communication is provided to senior leadership to inform them of such developments and trends, as this information may be relevant from a business and compliance perspective.

Results: This presentation will describe MEPE's significant accomplishments in the last 2 years and will highlight the importance of a firm commitment to monitoring and communicating new developments in the external publications landscape to key internal stakeholders.

Publication practices in medical technology and pharmaceutical companies

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Objective: This survey sought to understand publication planning and evidence publication in medical device, pharmaceutical, and biotechnology companies.

Research design and methods: A 15-question survey was sent to company representatives ($N=12,146$) using SurveyMonkey. Questions included: importance of publication planning and execution, publication policies, resources dedicated to publication activities, roles and responsibilities within the company related to publication planning and publishing, and familiarity with good publication practices. Initial email correspondence provided an active link to the survey, with a response requested within 4 weeks. A reminder email was sent 2 weeks following the initial request. Chi-square was used to test differences in responses by company type.

Results: A total of 92 responses were received: 28 pharmaceutical, 24 medical device, 14 biotechnology, and 26 other (primarily medical communication firms that were excluded from further analysis). A significantly lower proportion ($p<0.05$) of respondents from medical device companies indicated that publication planning and publishing were very important; a higher proportion indicated that levels of resources devoted to publication planning and publishing are less than appropriate. A significantly greater proportion of pharmaceutical and biotechnology companies indicated that publication management staff oversees publication activities and reported having a defined process in place for publication planning ($p<0.05$). Awareness of Good Publication Practice 2 guidelines was significantly higher ($p<0.05$) for pharmaceutical and biotechnology company representatives.

Conclusions: Despite the low response rate, information obtained from the survey indicates differences between medical device and pharmaceutical/biotechnology companies in the importance and resource allocation for publication activities.

Publications and regulation: are we strangling the science?

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Objective: This survey sought to determine if authors of scientific publications are familiar with guidelines of the International Committee of Medical Journal Editors (ICMJE), Pharmaceutical Research and Manufacturers of America (PhRMA), and Good Publication Practice (GPP).

Research design and methods: Authors ($n=95$) were surveyed via the SurveyMonkey website. The 17-question survey probed familiarity with publication guidelines, authors' willingness to collaborate with pharmaceutical companies/medical education companies, if barriers exist as a result of these guidelines, and timeliness and acceptance rate of publications.

Results: A majority of authors were familiar with ICMJE (88.9%), PhRMA (61.1%), and GPP (77.7%) guidelines. When asked if the guidelines have led to barriers in the publication of important data, 55.6% responded 'no'. Barriers were identified as suppressing the publication of negative results and requiring that clinical trials be registered. Authors (55.5%) indicated guidelines could affect publication timeliness, and about half felt financial support by pharmaceutical companies contributed to a higher manuscript rejection rate. Nevertheless, respondents were amenable to collaboration with pharmaceutical companies on primary (77.8%), but less likely on secondary/review (38.9%) articles. Respondents (77.2%) also were likely to collaborate with medical education companies. When asked if guidelines prompted them to submit to lower-tier journals, 62.5% responded 'no' for primary and 55.6% responded 'no' for secondary/review manuscripts.

Conclusions: Most authors were familiar with publication guidelines. Timeliness of publications, manuscript rejection rate, and pharmaceutical financial support may be impacted by publication guidelines. Nevertheless, authors continue to collaborate with pharmaceutical companies and their medical education companies.

Scientific platforms: building a scientific foundation for education

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Objective: This study sought to understand the pharmaceutical community's definition of a scientific platform and the current role of pharmaceutical professionals in its development.

Research design and methods: A web-based survey of 5000 subscribers to *PharmaVOICE* was conducted in December 2010.

Results: A total of 33 responses were obtained. The majority of the responders (67%) said scientific platforms are developed for >50% of approved compounds. Most (55%) selected the scientific platform as the first step in preparing an asset to achieve communication objectives; interestingly, 39% selected a commercial plan as the initial step. However, the timing of implementation varied (during phase I, 50%; phase III or post-launch, 39%). Core elements of a scientific platform deemed to have significant value included development of core communication concepts and scientific communication points. By contrast, landscape analyses, bibliography/reference binders, and lexicon development were considered necessary but of limited value. There was a general agreement that various team members should be involved in development of a scientific platform; publication specialists were 2 and 3 times less likely to be considered essential than commercial and clinical colleagues, respectively.

Conclusions: These data suggest there are opportunities to increase the understanding of the value and necessity of a scientific platform. An additional opportunity exists for publication professionals to be involved in the development of a platform by providing scientific and clinical input into addressing the unanswered scientific questions for the asset.

Solutions for challenges faced by professionals publishing clinical data – survey results

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Objective: Industry-sponsored clinical trial publications face continued allegations of ghostwriting and undue commercial influence. We sought to better understand challenges faced by medical publications professionals and to identify potential ethical, practical solutions for publishing clinical trial data.

Research design and methods: We surveyed members of the International Society for Medical Publication Professionals and the American Medical Writers Association to identify the type, severity, and frequency of the challenge and measure the level of support for potential solutions. In addition to fixed responses, open fields were available for comments.

Results: Of the 150 respondents, 49.7% had ≥ 10 years of experience, 40.1% worked in a medical communications agency, and 52.7% had a doctoral degree. Only three respondents indicated that they were unaware of current publications guidelines. Most respondents reported that challenges were only occasional. The majority (89.2%) faced challenges in publishing clinical data and most challenges were low in severity; the notable exception was moderate or high severity challenges faced with journal editors and the journal review process. Respondents strongly felt that the role of a professional medical writer was poorly understood (84.3%). There was strong support for journals to use a completely blinded process so that manuscript evaluation is solely on the merit of content and unbiased by reaction to sponsorship or involvement of medical publication professionals.

Conclusions: This is a first step to developing a best-practice model that can be applied fairly and uniformly and for improving the environment for publishing clinical data.

Survey of conflict of interest disclosure policies of Asian medical journals

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Objective: There has been a significant increase in biomedical research publication in Asian journals. To help readers identify potential bias in literature and promote consistency, the International Committee of Medical Journal Editors (ICMJE) recommends use of a uniform disclosure form. We evaluated the conflict of interest (COI) disclosure policies and extent of adoption of ICMJE recommendations in Asian medical journals.

Research design and methods: We surveyed COI disclosure policies of English-language Chinese (15), Japanese (15), and Indian (11) journals with top impact factors as well as Chinese-language core medical journals (15).

Results: Approximately 50% of English-language Asian medical journals require COI disclosure (Chinese, 53%; Japanese, 47%; Indian, 45%). While the Chinese-language journals did not have comprehensive COI policies, they did require funding sources disclosure. Only 4% of journals surveyed use a specific COI form, and 1 of 56 journals surveyed have adopted the ICMJE disclosure form. It is unclear from the websites of the Indian and Japanese journals whether COI information influences publication decisions. A total of 38% of English-language Chinese journals requiring disclosures state that COI information impacts acceptance.

Conclusions: COI disclosure policies are variable across Asian biomedical journals. The adoption of ICMJE standards is limited. More effort to promote standardization of COI disclosure in Asia may be warranted. Consistent with the trend of Chinese journals moving toward publication in English, English-language journals exhibit stricter COI policies than those published in Chinese.

The expanding use of health outcomes and economic evaluations in clinical publications: an example from cardiovascular disease literature

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Objective: Multiple forces drive the inclusion of health outcomes and economic evaluations (HOEE) in research to demonstrate the value of health technology. Research in chronic diseases, including cardiovascular disease (CVD), uses a host of HOEE terminologies. Significant healthcare resources are used in hypertension treatment and CVD risk factor prevention. The purpose of this research is to evaluate literature published from January 1, 1999 to December 31, 2009 that utilized HOEE terminology in clinical studies relating to hypertension treatment in CVD versus CVD risk factor prevention in adults, and identify the changing trends in the utilization of HOEE terminology in selected studies.

Research design and methods: The search strategy consisted of a PubMed database search, using search terms for hypertension treatment in CVD and primary prevention of CVD risk factors.

Results: There is an increasing trend in the utilization of health outcomes terminology in clinical publications: A total of 59% of articles that included *health outcomes* terminology relating to hypertension treatment in CVD were published in the last 5 years.

Conclusions: Use of health outcomes terminology in core clinical journals is rising; however, only 26% of the journal articles relating to hypertension treatment in CVD over a 10-year period included terminology relating to health outcomes, suggesting that many of the studies published in core clinical journals may have used inconsistent terminology to measure health outcomes and perform economic evaluations.

The role of the medical publication professional in achieving ethics standards in the publication of clinical trial results

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Objective: The study aims at defining the responsibilities of medical publication professionals for ensuring the ethical presentation of clinical trial results when they are made public. The focus is on the evolving role of the responsibilities of the medical writer, but this is put in relation to the responsibilities of editors, publishers, and clinical trial registry administrators.

Research design and methods: The study is based on a review of current standards for the ethics of publishing clinical trial results, including: (1) standards from international, regulatory, and professional organizations; (2) recent articles challenging the legitimacy of the publication professional; and (3) discussions within professional organizations in Europe, the US, and globally.

The Declaration of Helsinki provides a central reference for the controversies and the challenges in achieving the ethical responsibilities of the medical publication professional. The Code of Ethics of the International Society for Medical Publication Professionals is used to show how ethics can be incorporated into practice.

Results: The study brings out the ethical challenges facing the medical publication professional today: transparency, disclosure, scientific judgment, professional responsibility, and completeness. These results are explained in their practical consequences and applications.

Conclusions: The study demonstrates the increasing responsibility of the medical publication professional in ensuring the ethics of making public clinical trial results. It demonstrates that this is not a 'lone responsibility' but rather an 'interdependent responsibility' based on a heightened scientific and societal role in the research process.

The use of citation factors as a measure of publication planning success

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Objective: This study sought to measure the impact of a publication plan using citation factor analysis.

Research design and methods: Twelve published clinical studies (reference articles) supporting a branded-product label were analyzed with a citation database to create bibliographies of papers that cited the 12 reference articles. Each reference article's bibliography was separated into 'self-citations', in which the sponsoring pharmaceutical company cited their own reference article in subsequent papers, and third-party citations from publications that were independent of the pharmaceutical company's publication plan. For each of the 12 reference articles, the number of self-citations was divided by the number of years since publication to calculate internal citation factors (ICFs); corresponding calculations were performed for third-party citations to derive external citation factors (ECFs). The ICF, ECF, and host journal's impact factor were compared for each reference article.

Results: The ECFs were 8.5 and 13.0 for the two pivotal studies, and ranged from 4.8 to 11.75 for other randomized controlled trials ($n=4$), from 1.0 to 6.0 for open-label studies ($n=3$), and from 4.2 to 5.0 for pharmacokinetic studies ($n=3$). The ECF was greater than both the ICF and the impact factor of the host journal for 11 of the 12 reference articles.

Conclusions: The publication plan analyzed here appeared successful in achieving significant scientific/clinical impact; 11 of 12 publications demonstrated rates of third-party citations (ECFs) that exceeded the mean citation rates (impact factors) of the host journals. This approach can be broadened to compare competitor publication plans and establish benchmarks for success within a field.

Threaded publications – the future of scientific communication?

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Objective: Scientific communication can now claim to have taken a step forward in connectivity and transparency with the introduction of 'threaded publications'. This concept by providing a complete solution seeks to address the current problem of disconnected articles and sound research failing to be published.

Research design and methods: Altman and Chalmers presented a solution in their 1999 article in *The Lancet*: "Electronic publication of a protocol could be simply the first element in a sequence of 'threaded' electronic publications, which continues with reports of the resulting research... followed by deposition of the complete data set." Presently, researchers are required to register their trials in internationally recognized databases before publishing their research in their chosen journal, and, increasingly, their summary results in ClinicalTrials.gov. This often makes it hard to follow research from conception to publication. What has been needed is a publication platform to unify all the steps of the research and publication process, and incentives for authors to publish results regardless of the study outcome.

Results: We propose a solution in the form of 'threaded publications'. This allows seamless links between trial registration records, protocols, and results, with the aim of helping scientists, readers, and patients find more complete information about a treatment, and help reduce the potential for wasteful duplication of research efforts. As Professor Altman recently stated, the "initiative facilitates the publication of a series of linked publications from a single trial beginning with the study protocol and continuing with reports of the resulting research and deposition of the complete data set."

Conclusions: This presentation will seek to demonstrate how threaded publications can work in practice and will discuss the benefits such an initiative can bring to scientific communication.

Trends in medical writing acknowledgment in medical journals over the last decade

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Objective: Improper reporting of medical writing support in medical journals has garnered considerable negative press coverage and can potentially undermine confidence in the scientific publication development process. A report by Nastasee in 2010 identified a two-fold increase in the frequency of reporting medical writing acknowledgment in 2007 from 2002. We sought to evaluate this trend by extending the timeline in our analysis.

Research design and methods: MeSH terms for key therapeutic areas (from CenterWatch and Pharmaprojects) were used to identify 16 journals publishing peer-reviewed articles of randomized clinical trials (RCTs) in drug development during 2002 and 2009. Each article was reviewed for medical writing/editorial assistance acknowledgement and funding disclosures.

Results: The study comprised 1520 articles. Compared with 2002, fewer RCTs were identified in 2009 (788 versus 732 articles); however, the proportion of industry-funded RCTs published increased from 42% (95% confidence interval: 39–45%) to 49% (45–53%). Overall, the proportion of articles acknowledging medical writers increased from 11% (9–13%) to 18% (15–21%). This increase was only observed among articles with disclosed industry funding (2002: 17% [13–21%]; 2009: 29% [25–32%]) than without (2002: 6% [4–8%]; 2009: 6% [4–8%]).

Conclusions: In 2009, there was a greater than 1.5-fold increase in the frequency of acknowledged medical writing assistance in medical journals compared with 2002. Further analyses to include years 2001 and 2010 are ongoing and will be presented.

US medical school policies and perceptions regarding collaboration with industry on medical publications: follow-up to the 2009 survey

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Objective: Media attention continues to highlight concern for the manner in which industry and academia collaborate on medical/scientific publications. A 2009 survey of US medical schools revealed variability in institutional policies regarding faculty and industry collaborations on medical/scientific publications. To provide a longitudinal perspective and to investigate potential evolution in how industry and academia partner on publications, we repeated the 2009 survey.

Research design and methods: A total of 126 accredited US medical school deans were solicited to participate in an online survey during a 2-week period. Eight multiple-response items addressed the status, nature and scope of institutional policies, with two new items assessing professional medical writers/editors.

Results: Sixteen of 96 (17%) contacted deans responded (compared to 23% in 2009). While there were notable similarities with 2009, more institutions have developed or initiated policies, and these have become more consistent and prescriptive with greater clarity on definitions. Relationships with medical writers/editors were largely positive.

Conclusions: Medical schools continue to address the nature in which academia collaborates with industry, represented by clearer and more sophisticated policies. Professional medical writers are enjoying greater acceptance among academic researchers. While further analysis is needed, these preliminary results suggest improvements in industry-academia partnerships toward the publication of medical and scientific data.