



Preface

Dear Colleagues,

The 8th Annual Meeting of the International Society for Medical Publication Professionals, (ISMPP), 'Practical Solutions for a Complex Medical Publications World', provides a forum for attendees to hear about real-life practical issues, and learn about potential solutions to help us address the challenges we face in our everyday professional lives. The lessons presented during the meeting continue to build on things that we have learned in the past, while addressing the key challenges we face today and need to prepare for in the future.

The abstracts that were accepted for oral and poster presentation at the April 2012 meeting represent yet another quantum leap in the quality of the research that ISMPP members are conducting to add to our collective body of knowledge regarding best practices in the field of medical publications. Further, they support the general theme of the meeting, providing in many cases solutions to an array of the day-to-day challenges we face.

This edition of CMRO marks our 4th collaborative journal publication effort, showcasing the research conducted over this past year by members of ISMPP. In addition, this issue includes the abstracts that were accepted for poster presentation at the 2011 European Meeting of ISMPP, November 15–16, 2011, Alderley Park, Cheshire, UK.

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,

Russell Traynor, MSc
ISMPP Certified Medical
Publication Professional™
President
ISMPP (2012–2013)

Faith DiBiasi, MBA
ISMPP Certified Medical
Publication Professional™
2012 Abstract
Committee Chair

Transparency

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 The selection and peer review of abstracts was carried out by ISMPP; they have not been peer reviewed by CMRO. CMRO has received remuneration from ISMPP for reprints of the supplement, but has received no funding or support from ISMPP for its development and production. ISMPP declares no funding support for the development and production of this supplement.

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Editorial

Will the ghosts haunt us forever? Rebuilding trust and credibility in medical publishing

Robert J. Matheis*
Kim Pepitone†

Address for correspondence:

Kim Pepitone
International Society for Medical Publication
Professionals (ISMPP)
PO Box 2523
Briarcliff Manor, NY 10510, USA
kpepitone@ismpp.org

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Once upon a time, medical publications served an almost singular purpose: to support healthcare decision making by informing healthcare practitioners (HCPs) about new information on disease states and their treatments. In today's world – where information moves at lightening speed across the Internet – medical publications serve to provide a full range of stakeholders, including the public, with up-to-date information on medical technology and practices.

With our expanded stakeholder base, however, comes increased scrutiny over publication practices, further reinforcing the need to ensure that medical publication professionals contribute to credible published literature to guide the appropriate use of health technologies. So how do we manage our critics?

In general, our current approach to responding to our critics is more reactive than proactive, and often takes a defensive posture. As such, we spend much of our time trying to convince our critics, paper by paper, that they misunderstand our intentions and have misrepresented our practice. Although it is imperative that our voice is heard, this is most likely not the most effective approach to enact change. Why? Defense as a singular strategy will not work; it is both inefficient and nearly impossible to manage from a volume perspective. Even more problematic, *only* defending ourselves is largely ineffective given that defense engenders defense and does not promote true, meaningful changes in attitude and perception; defense alone will not generate credibility or create trust.

In order for there to be a true change in public perception, medical publication professionals need to engage in a comprehensive strategy to transform attitudes. Thus, we propose a four-pronged, integrated approach that addresses the problem of credibility from multiple angles: (1) reactive education (defense), (2) proactive education, (3) unity among parallel partners, and (4) alignment among non-parallel forces. At its heart, this approach focuses on education and relationship building, which, when combined, provides a powerful opportunity for changing public perception.

Proactive and reactive education provides a mechanism for correcting misinformation and presenting positive, proactive evidence about medical publishing. Uniting with parallel partners will bring together the numerous stakeholders in medical publishing, which, by taking advantage of 'power in numbers,' is bound to be more effective than working in isolation. Of greatest impact, however, will be nurturing relationships among critics of medical publication professionals to truly create understanding and awareness, generate strength from points of common interest and agreement, and potentially build new, positive relationships.

The International Society for Medical Publication Professionals (ISMPP) is the premier not-for-profit organization that has education, advocacy, and the

*Senior Director, Medical Communications, Evidence Based Medicine, Sanofi, US; President ISMPP (2011-2012); ISMPP Certified Medical Publication Professional™

†Senior Director, Knowledge Management, ISMPP; ISMPP Certified Medical Publication Professional™

generation of best practices as its core mission. ISMPP recognizes the need for generating trust and credibility and has positioned itself to employ components of the four-pronged model described.

- **Reactive education (defense).** ISMPP employs a social-media approach to respond to our critics and supporters alike through LinkedIn, Twitter, and appropriate blogs. We will continue these activities as we build on the other three prongs.
 - **Proactive education.** ISMPP's educational platform includes our well-known activities such as the Annual Meeting, the now annual European Meeting, and our monthly ISMPP U webinars. We are also working on a chapter-by-chapter release of our Standards Handbook, and have recently created a new committee called Research, Grants, and Publications. As well, through the activities of our Issues & Actions (I&A) Committee, we are addressing the literature with responses designed to not only defend, but also to educate.
 - **Unity.** ISMPP has established a forum for uniting parallel forces, including leadership from AMWA, EMWA, COPE, and DIA. Through this, we will share information and forge solidarity, with the expected end result a true demonstration of the whole being greater than the sum of the parts.
- **Alignment.** In this last, yet critical, component of the model, ISMPP will invite our most vocal critics to speak with us around issues related to medical publishing. Indeed, both publication professionals and our critics share the common interest of ensuring that peer-reviewed medical literature is accurate and reliable, and remains the most credible source for medical information and scientific exchange. With this as our common goal, we will work together on initiatives that seek to resolve differences and ensure scientific integrity.

What can you do as medical publication professionals?

Individually, medical publication professionals can generate and disseminate positive literature and media on medical publishing. We can conduct research, publish, blog, and discuss with colleagues the benefits that our profession brings to the practice of medicine. Collectively, as members of ISMPP, we can work together to address criticism through education and partnership, and transform the public perception of our profession to one of high regard and value in the communication of medical information.

Abstracts

A survey of global publication practices for authors of commercially-sponsored original research and review articles

Bryce McMurray^a, Iain Spray^c, Diana Faulds^b and Neil Lamont^a

^ainScience Communications, Chester, UK

^bAdis, Auckland, New Zealand

^cWolters Kluwer, Chester, UK

Objective: The purpose of this study is to assess the author publication practices around the world when engaged in the development of original research and review articles sponsored by pharmaceutical and medical device companies.

Research design and methods: The research is being conducted as an online survey consisting of 20 questions relating to topics such as assistance from professional writers, prevalence of steering committees, use of a publication agreement, choice of journal, etc. Invitations to participate were sourced from investigator contacts from major clinical trial registries, and authors who have worked with the authors of this paper and their organization. Responders were offered a personal journal subscription (nominal value US\$99) in return for participation, or had the option to remain completely anonymous.

Results: During the first 4 weeks of data collection, 37 complete responses were collected. Initial data show that while more than 80% of respondents participated in five or more studies during the last 10 years, 42% indicated that they had not been an author of a paper reporting a study. Other responses show 25% of authors working with a professional medical writer, and with wide variations in the knowledge of publication agreement and involvement in journal selection.

Conclusions: The initial results indicate that historical rates of clinical trial publication (phase II, III, IV studies) are patchy, and that authorship practices vary considerably over regions. The survey will continue through Q1 2012.

A survey of medical publication professionals on the role of copy editors

Russell A. Gazzara, Susan Collins and Christina Rogers

ReSearch Pharmaceutical Services, Inc., Fort Washington, PA, USA

Objective: The objective of this survey was to determine the opinion of medical publication professionals on the importance of utilizing and acknowledging copy editors in developing publications.

Research design and methods: A total of 505 medical publication professionals were invited to take the survey. The survey consisted of 10 questions, including questions on the role of the respondent in publications, the utilization of copy editors, the role of the copy editor, and whether copy editors should be acknowledged in publications. Responses were collected, analyzed, and graphed.

Results: Responses were obtained from 95 participants, for a response rate of 18.8%. Most of the respondents were publication managers (48.4%), followed by publication writers (12.6%). A majority of the respondents utilize copy editors (77.9%), and believe that copy editors serve a necessary function (83.2%). A majority of the respondents believe that writers should not perform the copy editing of a publication (68.4%), and think that copy editors should limit their involvement to editorial accuracy (54.7%). Finally, a minority of the respondents believe that copy editors should be acknowledged in the publication (33.7%). Additional results will be presented at the meeting.

Conclusions: It is clear from the results of this survey that medical publication professionals utilize copy editors, that copy editors provide an essential service, and that writers should not perform this function. However, it is the majority view that copy editors should not be acknowledged in publications.

Acceptance and utilization of digital congress poster presentations: a survey of medical publication professionals

Melissa S. McGrath^a and Richard J. Fisher^b

^aMedical Affairs, Department of Cardiovascular + Metabolic Medicine, Boehringer Ingelheim, Ridgefield, CT, USA

^bScientific Affairs, Global Clinical Development + Medical Affairs, Boehringer Ingelheim, Ingelheim am Rhein, Germany

Objective: The purpose of this study was to gain insight into the overall impact, acceptance, and utilization of interactive digital poster presentations in medical/scientific congresses, and to educate members of the International Society for Medical Publication Professionals (ISMPP) on perceived advantages and disadvantages of this form of data communication.

Research design and methods: A 10-question survey questionnaire was designed and circulated via e-mail to ISMPP members, with responses invited between December 20, 2011 and January 9, 2012.

Results: Of 111 respondents who completed the survey (48.6% pharmaceutical company, 40.5% medical communications company, 3.6% publisher, and 7.2% other), 28.8% work with interactive posters, 50% utilize quick response codes, and 43.2% have viewed interactive posters in a congress setting. Responses suggest the greatest potential advantages of interactive posters include: increased audience engagement (56.9%), wider data dissemination (47.1%), enhanced poster metric tracking (49%), and increased capacity for audio/visual presentation (67.6%). An increased need for an overall technology management resource was cited as the greatest disadvantage (80%). Other obstacles included cost (33.6%) and current congress regulations (27.1%). The majority of respondents agree/strongly agree that this format allows for better communication of data versus traditional printed posters, and that congresses will slowly adopt this technology (56.9% and 63.9%, respectively).

Conclusions: The majority of respondents believe interactive digital posters enhance communication and dissemination of data and offer a dynamic forum for presenters to increase audience engagement. As congresses adopt these technologies, it will be important to monitor whether differences among guidelines emerge, as well as any potential compliance issues.

Accesses versus citations: why you need to measure both to assess publication impact

Tom Rees, Katherine Ayling-Rouse and Sheelah Smith

PAREXEL International, Worthing, UK

Objective: Article accesses and citations provide two metrics to assess article impact. However, the relationship between the two is not constant or well understood. We investigated the relationship between article accesses and citations in three general medicine journals with different journal rankings.

Research design and methods: We collected the numbers of article accesses and citations from a representative selection of original research articles published in 2009 and 2010 in three peer-reviewed, international, online-only, open-access journals: *PLoS Medicine*, *BMC Medicine*, and the *International Journal of General Medicine* (IJGM) (SCImago journal ranking: 1.04, 0.49, and 0.06, respectively).

Results: The sample included 104 articles (two outliers were excluded).

Table: Mean (SD) accesses, citations, and rank correlation coefficients.

Journal	Accesses	Citations	Citations/1000 accesses	<i>r</i>
<i>PLoS Medicine</i>	5605 (590)	31.4 (4.8)	5.2 (0.4)*	0.82
<i>BMC Medicine</i>	5245 (454)	12.6 (1.6)	2.4 (0.2)†	0.48
<i>IJGM</i>	1923 (87)	1.6 (0.3)	0.8 (0.1)	0.44

* $p < 0.001$ vs. *BMC Medicine* and *IJGM*; † $p < 0.001$ vs. *PLoS Medicine* and *BMC Medicine*.

Conclusions: The relationship between article accesses and citations varies, with the highest ratio of citations : access for journals with the highest journal ranking. For open-access journals with a low impact factor, overall article reach may be higher than expected on the basis of citations.

An analysis of industry-funded studies published in the *New England Journal of Medicine*

Sarah Feeny^a, Ray Magee^a, Stephanie Tortell^a, Elaine Wilson^b and Alice Choi^b

^aComplete Medical Communications Ltd, Macclesfield, UK

^bComplete Medical Group Worldwide Ltd, Macclesfield, UK

Objective: Wager *et al.*, (PLoS ONE 2010;5(10):e13591) showed the *New England Journal of Medicine* (*NEJM*) published more randomized controlled trials (RCTs) solely funded by industry than *JAMA* (approximately 30 vs. 15 manuscripts/year [2002–2008], respectively). We often encounter authors and/or sponsors interested in publishing in high-tier medical journals and wished to profile industry-funded RCTs recently published in the *NEJM*.

Research design and methods: Articles from all issues of the *NEJM* published in print between January 1, 2011 and December 31, 2011 were extracted. RCTs were identified based on study methodology and classified as: industry-funded (IF); joint industry/non-commercial funding (J); industry-supported (IS) (when manufacturers provided materials or funding only); non-commercial (N); or no funding/funding not stated (NS).

Results: The *NEJM* published 121 manuscripts reporting RCTs in 2011; approximately one-third of RCTs were classified as IF and approximately one-third as N. The numbers of patients enrolled in IF RCTs varied significantly. Studies in cardiovascular disease, oncology, and viral disease accounted for approximately 70% of IF RCTs. It was not uncommon to find more than one IF RCT in a particular therapy area published in the same journal issue. A time-analysis correlating date of RCT publication and date of Food and Drug Administration approval has been conducted.

Conclusions: The *NEJM* published more IF RCTs in 2011 than previously. Understanding the profile of previously published articles will help stakeholders assess whether *NEJM* is an appropriate target journal.

Authorship criteria in medical journals: a review of guidance

Jackie Marchington, Ally Bexfield and Catherine Kidd

Caudex Medical, Oxford, UK

Objective: Professional medical writers do not qualify as authors under current guidelines issued by the International Committee of Medical Journal Editors (ICMJE) Uniform Requirements for Manuscripts Submitted to Biomedical Journals. We conducted a survey of instructions for authors (IAs) to determine how widely ICMJE criteria were cited and what guidance was offered in the absence of ICMJE criteria, among journals with high and low impact factors and in a range of therapeutic areas.

Research design and methods: We selected the top (T) and bottom (B) five journals as ranked by impact factor from the PubsHub Journals and Congresses database, in six different journal categories. If a journal appeared in more than one category, the lower ranked appearance was discarded and replaced with the next highest or lowest ranked journal in the category. Journal selection criteria were acceptance of unsolicited original research articles and availability of IAs online and in English.

Results: IAs from 60 journals were reviewed for authorship criteria. In all, 28 journals declared they followed ICMJE guidelines for manuscript preparation (19/30 T and 9/30 B). Of the remaining 32 journals, 20 gave no guidance for authorship criteria in their IAs (5 T and 15 B). Only 12 IAs (11 T and 1 B) provided guidance on disclosing the role of medical writers.

Conclusions: Clarity of authorship criteria has been the subject of recent debate. This survey reveals a lack of consideration of authorship guidelines in IAs among journals in different categories.

Benchmarking Twitter hashtag usage at medical conferences

Ginny Boland, Todd Parker, Steven Palmisano, Paula Farmer and Angie Miller

MedThink SciCom, Raleigh, NC, USA

Objective: The microblogging service Twitter uses a hashtag to mark keywords or topics in a tweet. Hashtags traditionally are utilized at medical conferences to allow Twitter users to follow conference news and commentary. No benchmarks, standards, or 'amplification factor' exist for the use of hashtags at medical conferences. This analysis intends to benchmark the use of Twitter hashtags at medical conferences to facilitate future comparisons.

Research design and methods: Conference Authority was used to identify the top medical conferences by attendance in 2011 for four major therapeutic categories (general medicine, oncology, gastroenterology, and cardiology). Twitter activity for the duration of each conference was assessed using Radian6; tweet/retweet volume and total reach were recorded.

Results: Hashtags were utilized at 90% of the medical conferences. For the top five conferences with hashtags, hashtag usage was highest for oncology (mean, 3279 vs. 758 for cardiology, 331 for gastroenterology, and 329 for general medicine). Retweets accounted for approximately 30% of hashtag volume, extending the reach of the initial communication. Conferences in the United States had greater hashtag volume (mean, 1457) than non-US conferences (mean, 515). In oncology, a linear relationship between hashtag volume and conference attendance was observed ($R^2 = 0.86$).

Conclusions: Of the four therapeutic categories analyzed, oncology conferences had the greatest total hashtag volume, potentially increasing audience reach and providing valuable information for publications professionals. Future analyses will assess changes in Twitter usage and examine practical applications for publications professionals.

Benchmarking Twitter usage among scientific journals*

Todd Parker, Ginny Boland, Steven Palmisano and Angie Miller

MedThink SciCom, Raleigh, NC, USA

Objective: Social media, while new to the medical publication field, is revolutionizing the pace and reach of news (consumer and medical), and may have important implications for publication professionals. Anecdotal evidence suggests social media is beginning to be deployed by journals, but no benchmarks, standards, or 'amplification factor' for social media exist. This analysis intends to benchmark the use of one social media property, Twitter, by higher-tier journals to facilitate future comparisons.

Research design and methods: Journal Selector was used to identify the top 20 journals by impact factor for four major therapeutic categories: general medicine, oncology, gastroenterology, and cardiology. In addition to circulation, journal-specific Twitter handles were identified when available, and Twitter followers and tweet volume were recorded.

Results: Journal-specific Twitter handles were much more common among general medicine journals (70%) than among specialized audience journals (22%). There was also a greater number of Twitter followers for general medicine journals (mean, 10,768 vs. 844 for specialized audience journals). Average tweet volume was 37 tweets/month. No correlations were observed between Twitter followers and impact factor or circulation (all journals, $R^2 < 0.2$). However, there appeared to be some correlation between Twitter followers and impact factor of general medicine journals ($R^2 = 0.75$).

Conclusions: General medicine journals were much more likely to have a social media presence with significant Twitter followerships, potentially increasing audience reach. Future analyses will assess changes in social media usage and examine practical applications for publications professionals in gauging audience reach.

*Oral presentation.

Can free online tools help publication professionals identify therapeutic area experts and target journals?

Karen L. Woolley^{a,b,c}, Narelle J. Bramich^d, Julie A. Monk^d, Luke C. Carey^d and Cassandra D. Haley^e

^aProScribe Medical Communications, Noosaville, QLD, Australia

^bUniversity of Queensland, St Lucia, QLD, Australia

^cUniversity of the Sunshine Coast, Sippy Downs, QLD, Australia

^dProScribe Medical Communications, Melbourne, VIC, Australia

^eProScribe Medical Communications, Wollongong, NSW, Australia

Objective: Commercial software can help publication professionals identify therapeutic area experts and target journals. Budgetary restrictions, however, particularly in developing regions, may limit software access. We compared the functionality and output of six free online tools that could potentially be used to identify experts and journals.

Research design and methods: We conducted a prospective, systematic analysis of 64 features for each tool (Anne O'Tate, eTBLAST, GoPubMed, Jane, PubFocus, PubReMiner). Using a standardized search topic (Velcade OR bortezomib AND 'multiple myeloma'), we compared the extent of agreement among the tools for identifying the top ten experts and top ten journals publishing on that topic. An independent academic statistician conducted all analyses (Kendall's coefficient of concordance; Friedman's chi-square test).

Results: The tools differed in terms of basic features (e.g., updates, user-friendliness), search refinement (e.g., by country, year, article type), and output (e.g., text, graphics). GoPubMed had the highest functionality. No tool provided useful journal metrics. The search output from five tools (PubFocus froze repeatedly) showed strong evidence of concordance for identifying the top ten authors (0.64; $p < 0.0001$), but weak evidence for identifying the top ten journals (0.28; $p < 0.0947$); concordance increased when comparing three tools with similar ranking systems (authors = 0.81; $p < 0.0028$; journals = 0.90; $p < 0.0026$).

Conclusions: Free online tools can help identify experts and target journals. Significant concordance was evident, but each tool had limitations. Among these free tools, GoPubMed offers publication professionals the highest functionality.

Case reports: expanding clinical knowledge

John Fallows, Sara Eve and Iain Hrynaszkiewicz

BioMed Central, London, UK

Objective: Case reports often remain unpublished as journal editors face increasing page constraints in printed publications, or due to their perceived negative effect on impact factor. In addition, these viewpoints may be intensified by the value that one, albeit important, case report can offer on its own. However, once aggregated with related cases, case reports become increasingly valuable for informing clinical practice.

Research design and methods: Other 'supportive' content, such as negative results, also suffers from lower publishing representation. Publication of this type of data helps to complete the scientific record by increasing transparency and reducing publication bias, with the aim of enhancing scientific knowledge leading to advancement in clinical practice. As Professor Michael Kidd, President Elect of the World Organization of Family Doctors, has said: 'In the era of evidence-based practice, we need practice-based evidence.'

Results: It is a challenge to reach the ideal of a complete scientific record. However, in order for best practice to be achieved, there is the need for an accessible, practical solution to address the view that case reports and other 'supportive' content are less valuable. The collation of case reports in a single, online location would add value to the data by allowing comparison of similar cases, facilitating emergence and early identification of trends, and ultimately benefiting human health.

Conclusions: To achieve best practice, publishers and publication planners need to work together to increase transparency of clinical data. A practical solution to this is a freely accessible cases database in which a variety of publishers collate the data from all relevant journals, thereby ensuring that the value of each case report is maximized.

Corporate integrity agreements 2007–2011*

Thomas Babcock^a, Jamie Kendall^b and Christopher Rains^c

^aGlobal Publications Group, Shire Specialty Pharma, Wayne, PA, USA

^bCompliance Implementation Services (CIS), Media, PA, USA

^cGlobal Publications Group, Shire Specialty Pharma, Eysins, Switzerland

Objective: US Department of Health & Human Services, Office of the Inspector General (OIG) settles complaints alleging Medicare and Medicaid service provider misconduct by imposing fines and issuing Corporate Integrity Agreements (CIAs) with pharmaceutical companies. We identify patterns or trends in the scope and extent of publication-specific provisions within those CIAs.

Research design and methods: Public records of the OIG were searched and pharmaceutical company CIAs with publication-specific provisions were reviewed.

Results: Ten CIAs had provisions specific to publications. One 2007 CIA required disclosure of funding/sponsorship for manuscript authors. Six 2009 and 2010 CIAs imply publications activities are promotional. Authors must meet strict authorship criteria, have written authorship agreements, and disclose funding/sponsorship. Some CIAs require detailed needs assessment for publications and a monitoring program. By 2011, publication-related provisions were drafted with more specificity. One included a 'Publications Protocol Transparency Initiative' requiring submission of study protocols and statistical analysis plans to medical journals, with key sections publicly accessible. Another had provisions similar to those issued in 2009–2010, and a third focused on medical affairs activities and responses to off-label inquiries.

Conclusions: The progression of the language used in CIAs issued between 2007 and 2011 suggests the OIG developed a deeper understanding of pharmaceutical industry's publications processes. CIAs include publication-related provisions requiring, for example, the (1) justification for the type and quantity of publications; (2) approval from legal and compliance functions for publication plans; and (3) publication plan deviations.

Corporate integrity agreements: what they say about publications, publication planning, transparency, and ICMJE

Frank J. Rodino

Churchill Communications, Maplewood, NJ, USA

Objective: Corporate Integrity Agreements (CIAs) have become a significant means of compliance enforcement for the Office of the Inspector General (OIG) of the US Department of Health & Human Services. The objective of this review is to present in a factual manner common clauses from recent CIAs that affect publications, publication planning, and transparency.

Research design and methods: Ten CIAs issued to biopharmaceutical companies from January 1, 2009 through December 31, 2011 were reviewed. All documents were publicly accessible on OIG's website, <http://oig.hhs.gov/compliance/corporate-integrity-agreements/index.asp>.

Results: Five CIAs – those negotiated with Allergan, Astra-Zeneca, Forest Labs, Pfizer, and Novartis – included virtually identical verbiage relating to industry-sponsored publication activities and transparency. Each included specific recommendations for author agreements, publication plans, needs assessments, publication monitoring, posting of study results, and disclosure of relationships with authors.

Conclusions: The publishing behaviors OIG seeks to affect are consistent with currently accepted publishing guidelines described in the International Committee of Medical Journal Editors (ICMJE) Uniform Requirements, and Good Publication Practice 2. By making clear the importance of publication planning, needs assessments, adherence to ICMJE, and reporting of physician payments, CIAs provide the industry with clear guidance for responsible behavior when it comes to sponsored medical publications.

*Oral presentation.

Development and implications of a redacted clinical trial protocol for posting online with the published manuscript*

Namit Ghildyal^a, Yvette Ng^b, Craig Tendler^{a,b},
Chris H. Takimoto^a and Susan Glasser^a

^aJanssen Research & Development, LLC, Raritan, NJ, USA

^bJanssen Global Services, Raritan LLC, Raritan, NJ, USA

Objective: To ensure transparency and accurate reporting of study results, several medical journals, including the *New England Journal of Medicine*, *The Lancet*, and *Journal of Clinical Oncology* (JCO), now require submission of redacted clinical protocols as part of the submission and review process for manuscripts reporting on the results of phase II and phase III clinical trials, to be posted online along with the associated manuscript if accepted for publication. This report provides suggestions for addressing these journal requests with adequate detail and in a consistent format.

Research design and methods: The instructions for authors and requirements for submitting redacted clinical protocols from JCO (<http://jco.ascopubs.org/site/ifc/protocol.xhtml>) were reviewed and these requirements were compared with a subset of other medical journals. The objective was to develop processes and procedures to meet the requirements for submitting redacted protocols to medical journals with sufficient detail and consistent format.

Results: Using the guidelines provided by JCO, a redacted clinical protocol template was developed. Standard boilerplate language and other proprietary information, including names, addresses, and telephone numbers were redacted. Also redacted were exploratory studies considered not relevant to the original protocol design. However, all essential information on clinical trial details, including patient selection, treatment plan, measurement of treatment effect, and the entire statistical methods sections (including end points) were retained.

Conclusions: The instructions provided here have been used to successfully develop redacted protocols for submission to medical journals.

Evaluating factors influencing timelines for publication submission after implementation of GPP2 guidelines—raising the bar to shorten timelines*

Kanaka Sridharan^a, Mike McNamara^b, Laura Hendrickson^b
and Erin Huffman^a

^aNovartis Pharmaceuticals Corporation, East Hanover, NJ, USA

^bOxford PharmaGenesis Inc., Newtown, PA, USA

Objective: The Good Publication Practice 2 (GPP2) guidelines, released in 2009, recommend collaboration between authors and professional medical writers during preparation of an outline, the earliest stage of manuscript development. In 2010, we piloted a best-practice model wherein the author–medical writer collaboration was initiated immediately after study completion and database lock (before availability of the clinical study report). We report the influence of this early collaboration on timelines for manuscript submission.

Research design and methods: For all the data-driven manuscripts initiated during the years 2009 through 2011 where our publication team was involved, we analyzed timelines from start of the project until submission. A total of 22 data-driven manuscripts were completed during this time frame.

Results: In 2009, after implementation of GPP2 with the author–medical writer collaboration initiated at outline stage, the mean time-to-submission was 56.8 weeks (table). This reduced to 43.6 weeks in 2010, and 21.5 weeks in 2011 after initiation of our new pilot approach of engaging the medical writer immediately after database lock. In 2009, for approximately 90% of the manuscripts (10/11), the average time-to-submission was 31 weeks or more. In contrast, in 2011, 75% (3/4) were submitted with a mean time-to-submission of 30 weeks or less.

Conclusions: Our pilot model shows that publication submission timelines for data-driven manuscripts can be shortened with an approach of initiating collaboration of

authors and medical writers at a stage as early as database lock and availability of finalized data tables.

	2009	2010	2011
<i>N</i>	11	7	4
Mean, weeks	56.8	43.6	21.5
Median, weeks	54.0	46.0	18.5
Range, weeks	30–100	13–77	8–41

Industry-sponsored clinical trials: time to publication

Marla Mathias, K. Elizabeth LaFlamme and Tracy H. Johnson

Complete Healthcare Communications, Inc., Chadds Ford, PA, USA

Objective: The Food and Drug Administration Amendments Act stipulates that clinical trial results be reported within 1 year of completion. This study assessed the percentage of industry-sponsored clinical trials that are published within 1 year of the primary completion date and the average time from primary study completion to journal publication.

Research design and methods: Industry-sponsored, interventional, phase II–IV randomized controlled trials registered on ClinicalTrials.gov, with a 'last updated' date of January 1, 2007 to December 31, 2011, were included. Corresponding primary publications for each trial were identified from the registration entry; records not containing a primary publication were excluded. Co-primary endpoints were time from primary completion date to journal publication, and percentage of studies published within 1 year. Therapeutic area and publishing journal were also recorded.

Results: Of 359 clinical trials meeting the inclusion criteria, 96 (27%) records included a citation for the primary publication. Few studies (17/96 [18%]) were published within 1 year of the primary completion date; mean time from primary completion to journal publication was 1.65 years. Therapeutic areas with ≥ 10 publications included: cardiovascular disease ($n=13$), diabetes ($n=13$), cancer ($n=11$), and mental health ($n=11$); furthermore, the majority of studies were published in high-tier general medicine or specialty journals, suggesting that authors and journals place a higher priority on data that may impact treatment decisions in disease states with significant unmet medical needs.

Conclusions: These preliminary data may help guide the development of appropriate timelines for primary study publications.

Innovative, evidence-based, practical primer tools for publication professionals working with authors in the Asia-Pacific region

Rebecca A. Lew^a, Julie A. Ely^b, Jason Khoh^b and
Karen L. Woolley^{c,d,e}

^aProScribe Medical Communications, Melbourne, VIC, Australia

^bProScribe Medical Communications, Sydney, NSW, Australia

^cProScribe Medical Communications, Noosaville, QLD, Australia

^dUniversity of Queensland, St Lucia, QLD, Australia

^eUniversity of the Sunshine Coast, Sippy Downs, QLD, Australia

Objective: Increasing clinical research activity in the Asia-Pacific region will require more US-based publication professionals to know how to work ethically and successfully with authors in this region. The objective of our study was to prepare the first evidence-based, practical primer tools for Asia-Pacific countries, designed specifically for publication professionals.

Research design and methods: Quantitative and qualitative data were obtained from multiple sources, including: MEDLINE, via the Thomson Reuters Web of Knowledge (US co-authorship rates; 'control' countries included England, India), or PubMed (publication trends, misconduct rates); and in-depth interviews, using a standardized questionnaire, with publication professionals in each country (publication practices).

Results: We developed a user-friendly, two-page primer template populated with country-specific information, including general information, commonly used phrases, business etiquette (clothing, seating, cards), relevant associations,

*Oral presentation.

registration and disclosure policies (International Federation of Pharmaceutical Manufacturers & Associations statements recognized), publication statistics (output, retractions, US co-authorship), publication planning and delivery issues (main challenges), and authorship agreement clauses to reduce misconduct risk (based on evidence of main type of misconduct). The primers highlight important publication trends, e.g., the number of US co-authored publications increased exponentially for China (2002 = 1198; 2011 = 12,834), but not Japan (2002 = 7131; 2011 = 7554); plagiarism accounts for more misconduct (number of misconduct retractions per 10,000 publications) in China (1.443), than Japan (0.104). The primers reassure managers that staff are accessing critical information efficiently (multi-sourced information collated concisely; available online) and effectively (country-specific information is current and relevant).

Conclusions: We developed innovative, evidence-based primer tools to help publication professionals prepare to work ethically and successfully with authors in the Asia-Pacific region.

Journal impact factors benefit from the content of pharma-affiliated authors

Leighton Chipperfield, Matthew Richardson and Andrew Plume
Elsevier Ltd, Oxford, Oxfordshire, UK

Objective: We examine the citation impact of papers where one or more authors are affiliated with a pharmaceutical company, relative to the rest of the journal in which they were published. We also investigate the relationship between corporate research and development (R&D) investment and publication output.

Research design and methods: The top 15 pharmaceutical companies by 2010 R&D spend¹ were identified, and authors listing any of these as their affiliation in journal publications were deemed pharma-affiliated authors. Scopus was used to collect article and citation data for journals using the 2010 impact factor (IF) window.

Results: A total of 2570 journals indexed by Scopus published at least one paper involving a pharma-affiliated author in the 2010 IF window. Papers involving a pharma-affiliated author were cited 75% more often than other papers.

Amongst a selection of high-impact general medicine journals, the 2010 IF for these journals would have been 1.6–13.8% lower without papers from pharma-affiliated authors, the latter being *New England Journal of Medicine*. In a selected specialty – oncology – the 2010 IF would have been 1.0–8.1% lower without such papers.

R&D spend per pharma company correlates with journal article output by affiliated authors.

Conclusions: Papers with at least one pharma-affiliated author tend to be of higher citation impact than other articles in the same journals, and, therefore, contribute positively to the IF. A significant correlation exists between a pharmaceutical company's R&D investment and publications output.

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Making the grade: analysis of performance on the ISMPP CMPP examination

Robert J. Matheis^a and Kim Pepitone^b

^aSanofi, Bridgewater, NJ, USA

^bInternational Society for Medical Publication Professionals, Briarcliff Manor, NY, USA

Objective: The International Society for Medical Publication Professionals (ISMPP) developed a program to certify professionals with ≥ 2 years' experience and demonstration of professional knowledge and ethics in medical publishing. To date, examinee demographic and descriptive characteristics and factors related to examination performance are not well-understood. This analysis was undertaken to provide insights into Certified Medical Publication Professionals' (CMPP) characteristics.

Research design and methods: De-identified data across the first five testing sessions of the examination were pooled for analysis. To explore predictors of exam performance, a least squares multiple regression analysis was employed, with test

score entered as the criterion and experience (years), gender, position, and education entered as predictors.

Results: Significantly more examinees were female ($n = 291$) than male ($n = 137$), $\chi^2(427) = 55.4$, $p < 0.001$. A total of 56.5% of examinees had achieved post-baccalaureate, advanced education. Agency-based account service/business professionals and scientific personnel comprised 72.2% of examinees. Publication experience ranged from 2 to 35 years, $M = 7.71$, $SD = 4.53$. Results showed a significant model, $F(5, 395) = 5.83$, $p < 0.001$, accounting for 6.9% of the variance in test performance, $R = 0.26$. Greater education, $t = 4.4$, $p < 0.001$, and more years' experience, $t = 2.0$, $p = 0.04$, were associated with higher exam scores.

Conclusions: Results provide preliminary support that the current pool of CMPPs is well educated and well tenured, and these characteristics are significantly related with a strong performance on examination.

Monitoring the external publications environment: identifying and communicating significant developments to key stakeholders in a corporate setting

Geoff Smith^a, Jon Nilsen^a, Shawn Lee^a, Mee Rhan Kim^a,
Dikran Toroser^a, Erica Rockabrand^a, Lucy Hyatt^b,
Larry Kovalick^a and Juli Clark^a

^aAmgen Inc., Thousand Oaks, CA, USA

^bAmgen (Europe) GmbH, Zug, Switzerland

Objective: Knowledge of medical publication policies, issues, and trends is critical for pharmaceutical executives and research and development personnel in the drug and device industries who provide input on industry-sponsored publications. A poster presentation at the 2011 Annual Meeting of the International Society for Medical Publication Professionals outlined our company's efforts to provide such updates to internal stakeholders by means of a dedicated task force. Our task force is now entering its third year of service.

Research design and methods: The Monitoring the External Publications Environment (MEPE) task force was commissioned by our Scientific Affairs Medical Writing department to identify, summarize, and communicate significant policy changes, issues, and trends related to publications and authorship in the scientific/medical literature. It also monitors important publication-related developments in the lay press as an indicator of public opinion.

Results: The MEPE task force initiated processes to identify publication-related developments with potential business impact. We have robust assessment and review procedures that allow us to triage, assess, summarize, and report this information to senior internal leadership within 1 week via periodic-focused email updates. In the past year, we have provided four updates, which were evaluated as 'very' or 'moderately' useful by 96% of recipients.

Conclusions: The MEPE task force has provided value to key stakeholders by identifying, summarizing, and communicating publication-related external events, trends, and issues with potential business impact.

Novel approaches to conveying scientific communication outputs

Sheryl Selvey, Samantha Llanos, Erin Harvey and Lisa Underhill
Genzyme, a Sanofi Company, Cambridge, MA, USA

Objective: Attaining the support of internal company stakeholders helps a scientific communications team deliver timely, high quality publications to the medical community. We cannot (and should not) measure investment in publications by financial return, but other simple metrics and visuals can help to gauge overall productivity and success of the team.

Research design and methods: After consulting colleagues and reviewing the literature, we found little information on this topic, leading us to brainstorm ideas. We devised potential graphic presentations for metrics (such as percentage of publications submitted on schedule, proportion of abstracts accepted as oral presentations versus posters, and proportion of manuscripts accepted to the first target journal). We also established 'key performance indicators,' or KPIs, to help gauge the ability of the team to deliver on high-priority initiatives. One such KPI that we have found useful is to compare the actual quarterly submissions of key abstracts and manuscripts against the forecasted submission dates.

Results: We found that a 'dashboard' format effectively highlighted quantitative and qualitative outputs of the scientific communications team and that publication KPIs helped our teams to separate 'need to have' from 'nice to have' publication initiatives. KPIs should, however, be chosen carefully and projected timelines should be conservative.

Conclusions: Showcasing publication outcomes in an easily digestible dashboard format and using KPIs helped our teams (including management and non-medical colleagues) to understand the scope and impact of our work, and helped us prioritize our publication efforts.

Perceived challenges to open peer review and opportunities for education

Kristen Clark, Lisa Tamayne and Carol Berry

Quintiles Medical Communications, Parsippany, NJ, USA

Objective: Anonymous peer review, the trademark of most scientific journals, has been criticized for its lack of accountability/transparency. Open peer review, defined as a transparent process whereby the identities of those reviewing scientific publications are disclosed to authors, has only been adopted by a small number of journals/publishers. We examined receptiveness to an open peer review process.

Research design and methods: A nine-question, multiple-choice survey was emailed via QuestionPro to editors/publishers in the health sciences field; 56% (5/9) responded.

Results: No respondents employed an open peer review process; only one journal stated that the topic was currently under discussion. The remaining respondents who indicated no plans for an open peer review process cited as reasons: belief that the review quality would be negatively affected, increased difficulty in recruiting new reviewers, and disagreement with open peer review. When asked about their awareness of scientific research surrounding open peer review, 40% (2/5) indicated no awareness, 60% (3/5) indicated some awareness, and none indicated a high level of awareness. Interest in a forum where the risks/benefits of open peer review could be discussed was favored by 80% (4/5) of respondents. Participants rank-ordered five perceived challenges of open peer review. Belief that review quality would be negatively affected (80% [4/5]), and perceived difficulties in recruiting new peer reviewers were ranked as the top challenges to implementing open peer review (60% [3/5]).

Conclusions: While the survey size limits the ability to generalize, data indicate an opportunity for further education, discussion, and research in this area.

Plagiarism in medical publications: practical solutions for maintaining integrity in the industry

Doug Taylor, Cindy Busch, Gina Mushrock and Philip Sjostedt

The Medicine Group, New Hope, PA, USA

Objective: This study aims to create a standardized procedure to identify and combat plagiarism based on the existing practices of high-impact medical and scientific journals, professional publication societies, and established periodicals.

Research design and methods: A comprehensive analysis of plagiarism policies, protocols, and identification methods used by the organizations listed below reveals the best practices of each. This analysis includes the definitions of plagiarism as defined by target publications, measures taken to identify and prevent the practice, and responses to suspected impropriety. Organizations searched include: International Society for Medical Publication Professionals, American Medical Writers Association, European Medical Writers Association, American Medical Association, scientific journal publishers, various universities, News Corporation, and the New York Times Company.

Results: The search reveals significant variability in anti-plagiarism policies in the medical publication industry. Professional organizations, journals, trade publications, and media companies employ individual guidelines to thwart plagiarism. Journals requiring certification from anti-plagiarism software illustrate a shift in the medical publication industry. Similarly, associations representing publication professionals explicitly define plagiarism and their methods to stem the practice.

Conclusions: While plagiarism remains a threat to scientific credibility and a serious challenge for medical publications, this examination of industry practices reveals a framework of policies and preventative procedures to check for the theft of original thought. The best practices employed by the organizations analyzed in the present study inform the adherence policies of medical publication firms. In light of these findings, companies should develop a process to ensure the integrity of publications.

Positive and negative trial data: are there publication differences?

John Besemer^a, Ray Ashton^b, Tom Rees^b, John Kincaid^a and Sheelah Smith^b

^aPAREXEL International, Hackensack, NJ, USA

^bPAREXEL International, Worthing, UK

Objective: Previous studies indicate that positive trials are more likely to be published in a timely manner. We sought to investigate whether this trend is ongoing and to evaluate other variables in the publication of positive and negative clinical trials.

Research design and methods: A list of phase III pharma-sponsored trials with ≥ 500 patients in the cardiovascular therapy area, completed between July 2008 and June 2009, was obtained from www.ClinicalTrials.gov. PubMed and Google Scholar were used to determine if results were published. Abstracts and Trialrove were interrogated to determine if primary endpoints were met.

Results: A total of 44 clinical trials were evaluated. The primary endpoint was met in 65.9% (29/44), and 72.4% (21/29) were published. In all, 53.3% (8/15) of trials that did not meet their primary endpoint were published. No significant association between publication status and positive/negative results was found (Fisher's exact test, $p = 0.32$). While 6/8 published negative trials appeared in journals with an impact factor (IF) greater than the mean (12.4), there was no significant association between trial results and appearance in a high IF journal ($p = 0.49$). Only 18.2% (8/44) of trials (five positive, three negative) were published within 1 year of completion. All had enrollment greater than the median (1049 patients).

Conclusions: No significant difference in publication rate for positive and negative studies was observed, though publication within 1 year for both could be improved. These findings suggest that other factors, including broad clinical applicability, drive the timely publication of clinical data.

Publication planning at one pharmaceutical company: a guidance document creation to ensure compliance with industry best practices and laws

Gina D'Angelo^a, Slavka Baronikova^b and Brian Scheckner^a

^aGlobal Publications Group, Shire Specialty Pharma, Wayne, PA, USA

^bGlobal Publications Group, Shire Specialty Pharma, Turnhout, Belgium

Objective: This report provides practical guidance for the development process of a publication plan at Shire.

Research design and methods: The approach to publication planning and development can vary widely among publication professionals within the pharmaceutical industry. In early 2011, the publications group at Shire completed the development of a best practices guidance document to align the publication development process. A supplemental guidance document on the publication planning process was developed more recently to specifically address the development and updating of publication plans at Shire. The Shire Best Practices Publication Guidance Document, Shire policies and standard operating procedures on publication development, a review of various pharmaceutical company corporate integrity agreements that addressed publication-related activities, and feedback from Shire publication leads were used in the development of this current guidance document.

Results: The publication planning guidance document presents an overview of the publication planning process, including the initiation of a publication plan and publication tactics for different publications types. Additional sections included in this guidance document are: publication planning tools, gap analyses, needs assessments, and the role and responsibilities of publication service providers in the development of a publication plan. More detailed information on each of these areas will be outlined.

Conclusions: The Shire publication planning guidance document provides a practical, yet specific framework for how a publication professional at Shire should approach the development of, and update process for, a publication plan.

Publication steering committee development at a pharmaceutical company: experience 1-year post-departmental guidance document development

Brian Scheckner^a, Gina D'Angelo^a, Amina Elsner^b, Jürgen Wiehn^b and Fran Young^a

^aGlobal Publications Group, Shire Specialty Pharma, Wayne, PA, USA

^bGlobal Publications Group, Shire Specialty Pharma, Eysins, Switzerland

Objective: This report provides practical guidance for development of publications steering committees based on experience from one pharmaceutical company.

Research design and methods: In February 2011, the publications group at Shire introduced a publications best practice guidance document that included the creation of steering committees. Shire publication leads were surveyed in January 2012 in order to assess their experience with steering committee creation over the past year.

Results: Eight steering committees were convened in 2011 relating to eight clinical studies and one market research survey. Seven were developed with the single goal of supporting publication development specific to the study that the steering committee members were participating in, while one utilized an older model of including publications as part of an agenda of an overall clinical trial steering committee meeting. Overall, 79 Shire and external steering committee members were engaged through this process over the last year, and ideas were generated for 75 publications through the steering committee process. Practical matters regarding the steering committee process at Shire will be described, along with feedback from internal and external steering committee members.

Conclusions: The steering committee model was successfully implemented at Shire and was consistent with Shire and Good Publication Practice 2 guidelines. Full participation in the publication planning process by external advisors has become the standard for studies with steering committees. The guidelines may prove useful for other publication planners.

'Ripe' for change: introducing a new index of publication efficiency

Stephen W. Gutkin and Sara B. Glickstein Bar Zeev

Rete Biomedical Communications Corp., Wyckoff, NJ, USA

Objective: The purpose of this research was to develop an index of 'publication efficiency' of biomedical journals.

Research design and methods: Using data available from www.pubshub.com and other resources, we determined the Rete Index of Publication Efficiency (RIPE) as:

$$RIPE = \frac{\iota(\text{Influence}) \times \rho(\text{Reach})}{T_{\text{sub} \rightarrow \text{pub}}}$$

Where ι (*iota*, Influence) is computed as the sum of ascending rank orders (higher values = higher ranks) within specialty of Eigenfactor, impact factor (IF), and affiliation score (number of sponsoring/affiliated professional societies); ρ (*rho*, Reach), as the ascending rank order of the number of readers (print or electronic circulation, whichever is higher); and $T_{\text{sub} \rightarrow \text{pub}}$ as the average time from manuscript submission to print publication (days), assuming 28 days to incorporate peer review and review page proofs. The method assigns measures of journal quality ('influence' and 'reach') to the numerator, and a measure of production time to the denominator, to help address the question: 'Where will papers reach the most and highest-quality readers in the shortest period?'

Results:

Leading internal medicine journals	RIPE	IF
JAMA	132.61	30.01
BMJ	113.90	13.66
Ann Intern Med	103.48	16.73
Mayo Clin Proc	68.23	5.71
Lancet	63.13	33.63

Conclusions: Certain journals with lower IF values exhibit higher publication efficiencies because of greater influence or reach, or lower production time.

Further research is warranted to determine correlations between the RIPE and other key indices (e.g., IF), and whether a higher sum of RIPE values across a publication plan is associated with other key metrics (e.g., return on investment).

Social media usage by medical journals: implications for publication planning

Ira Mills^a, Kate Gardner^b, Mark English^b, Nathaniel Hoover^a, Sheelah Smith^b and Ken Youngren^a

^aPAREXEL International, Hackensack, NJ, USA

^bPAREXEL International, Worthing, UK

Objective: Recent data suggest the magnitude of social media usage (SMU) surrounding publication of a medical journal (MJ) article may provide a useful predictive tool in determining scientific impact¹. The objective of this study was to determine the extent of adoption of SMU by MJs that may have implications for publication planning, examining oncology as a representative therapeutic area.

Research design and methods: Oncology MJs were selected (impact factor [IF] >5) for assessment of SMU by Twitter/Facebook/Google+/LinkedIn/YouTube blogs, dichotomized by region (US/UK), versus general medicine leading MJs (LMJs) (IF >5). Oncology MJ SMU was further studied by characterizing Twitter MJ followers and activity.

Results: In all, 11 oncology MJs (US 8, UK 3) of 24 (46%) have adopted SMU by establishing a Twitter account or by allowing readers to tweet articles, versus 72% of LMJs ($n=18$). Of a sample of two US/two UK oncology MJs, MJ followers ($n=100/\text{MJ}$) were identified as individuals/unknown users (50%), healthcare professionals (12%), patients/survivors (5%), advocates (5%), research scientists (5%), commercial groups (4%), students (4%), and other (15%). Tweets from these MJs ($n=100/\text{MJ}$) comprised content alerts (54%), oncology-related retweets (31%), announcements (9%), and meeting information (6%).

Conclusions: Although SMU has been adopted by some oncology MJs, it remains underutilized compared with LMJs. Consideration of SMU by MJs may play a role in future publication planning, as the ability to highlight MJ content via SMU, and thereby increase impact, may play a greater role in author decisions regarding journal choice.

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Streamlining and improving the global publication development process to align with best publication practices

Susan Nastasee, Carolyn Carroll, Jamie Zhang, Thomas Malieckal, Ananya Bhattacharya and Samantha Gothelf
Bristol-Myers Squibb, Princeton, NJ, USA

Objective: Process improvements were initiated to effectively reduce the amount of time required to publish primary data and develop high-quality and timely medical publications.

Research design and methods: A critical analysis by an internal task force identified multiple opportunities for streamlining the publication development process, including decreasing the number of reviewers, the number of reviews by each individual, and increasing rigor around timelines. Key changes and new processes were implemented to reduce publication development times, improve publication planning globally, and align with best publication practices.

Results: A global simplification effort to improve publication development resulted in a 40% reduction of manuscript development time. Key early strategic planning steps were identified with established timelines for execution. Significant process changes included reducing the number of reviews and non-author reviews, with one reviewer accountable per functional area. Core steps for primary manuscript development were aligned and executed in parallel with the development of the clinical study report, thereby increasing efficiency. Relevant functional areas received training, and awareness was increased through development of

departmental posters and brochures. Implementation of a publication tracking tool enabled development of publications consistent with best practices and metrics generation.

Conclusions: Streamlining publication development processes reduced the amount of time required to publish primary data from clinical trials, with simplification of the review process and increased awareness of publication best practices.

Structuring publication teams to meet global needs – where are we now?

Diane Moniz Reed^a and Cherie Whitmore^b

^aBristol-Myers Squibb, Princeton, NJ, USA

^bKnowledgepoint360 Group, Lyndhurst, NJ, USA

Objective: We sought to understand the structure, operations, geographic representation, and publication strategy development process of publications teams.

Research design and methods: We conducted an online mini-benchmark with medical publication professionals to assess global, regional, local, and emerging markets publication team structure, strategies, and processes. A total of 34 invitations were sent.

Results: In all, 19 responses were received. All have a global-headquarters (global-HQ) publication team, and 63% also have local publication teams. Only 38% have regional teams. The US and European geographies were most often represented on global-HQ publication teams (89% and 72%, respectively), with Japan/Asia/Pacific represented on 39% of teams. Emerging markets of China (17%), South America (17%), and India (6%) were represented less often. Over half of local and regional publication teams included the local/regional medical director, global medical affairs, the local publication director, health outcomes, and clinical research. No formal process is in place to ensure the publication strategy developed by the global-HQ team is relevant for local and regional markets for 35%. However, local, regional, and emerging markets teams do develop publication strategies specific for their needs, either through adaptation of global strategy (65%), or independent development (24%). Local publication plans require approval by a global-HQ team (82%) and local market medical leadership (71%).

Conclusions: Global-HQ publications teams accommodate a range of geographies, although emerging markets are not strongly represented. Local publication teams have some autonomy in goal setting, structure, and process, with the global-HQ teams providing direction and assuring alignment.

Systematic review on the prevalence of ghostwriting: misleading, misguided, and mistaken 'evidence'

Serina Stretton^a and Sericka McGee^b

^aProScribe Medical Communications, Noosaville, QLD Australia

^bHamilton House, Virginia Beach, VA, USA

Objective: As ghostwriting is unethical, the perception that '50 to 100%' of industry articles are ghostwritten is alarming. This perception, however, undermines advocacy efforts highlighting ethical publication practices. Challenging this perception requires a clear understanding of the underlying evidence. Our primary objective was to conduct the first systematic review on the prevalence of ghostwriting.

Research design and methods: We searched electronic databases (e.g., MEDLINE, EMBASE, Cochrane Library) in March 2011. Search terms included variations on ghostwriting and ghostauthorship. We included primary and secondary publications in English reporting a numerical estimate of the prevalence of ghostwriting. Two independent reviewers screened all publications; discrepancies were resolved by consensus.

Results: We retrieved 137 publications and excluded 112. There were 25 eligible publications (9 original research, 16 reviews/commentaries). Estimates on the prevalence of ghostwriting varied markedly. Estimates were influenced by whether: (1) a definition for ghostwriting was provided; (2) conservative definitions were used; (3) errors were made in re-reporting data. Recent estimates from original research using conservative definitions indicated that the prevalence of ghostwriting is low (0.2–4.3%) and is decreasing.

Conclusions: The evidence that ghostwriting is pervasive is often misleading, misguided, and mistaken. Ghostwriting is unethical, but sensationalizing its prevalence won't reduce it. Our review highlights the importance of standardizing

the definition of ghostwriting and reporting results accurately. The most robust evidence indicates that ghostwriting is low and decreasing; this evidence should be leveraged in future advocacy efforts.

Use of stakeholder survey feedback for improvement of the publication review and approval process

Jean Barilla and Barbara Rowe

MedImmune, Gaithersburg, MD, USA

Objective: This study sought to develop a method to assess stakeholder feedback and improve the publication review process.

Design and methods: Survey Monkey was used to administer three sequential surveys. Recipients included reviewers and approvers of company publications for publication release and authors submitting publications to the process. Demographics included all company sites (US and ex-US), and all publication reviewers and authors that utilized the system in the last year. Survey 1, 'Reviewer Feedback' ($n=150$), was sent to approvers and reviewers of the publication release process to determine their feedback on the publication system. Survey 2, 'The Publication Review Process' was a survey of company authors ($n=544$). Survey 3, 'Response to Process Guidelines Checklist' evaluated feedback on a checklist developed on the basis of feedback from surveys 1 and 2, and was sent to authors ($n=544$).

Results: Stakeholder response rates were good; surveys 1, 2 and 3 were 28%, 39.7%, and 16.7%, respectively (10–15% average response rate to surveys). Feedback was divided into five areas: pre-submission to process, the process, training-related, software-related, and general comments. Responses were analyzed and common themes were observed. Comments on the review/approval process (46%) and steps prior to submission (30%) elicited the most responses.

Conclusions: Based on the results, stakeholders were engaged and contributed information that will enhance the process. Feedback will be incorporated into stakeholder training and will drive process improvements and system enhancements.

Utilization and attitudes on technological advances in medical publications*

Carol Hudson^a, Elizabeth Cecere^a, Ramana Yalamanchili^a, Mary Anderson^a, Michael Pucci^a, Deana Aloia^a and Brian Scheckner^b

^aSCI Scientific Communications & Information, Inc, Parsippany, NJ, USA

^bGlobal Publications Group, Shire Specialty Pharma, Wayne, PA, USA

Objective: Advances in communication technologies offer novel means of acquiring scientific information from published sources, such as online journals, podcasts, and mobile applications/quick response codes. Little is known about utilization and impact of these modalities on readers, authors, pharmaceutical sponsors, and medical communications partners. This survey assessed utilization of and attitudes on novel communications advancements in peer-reviewed scientific/medical journal publications.

Research design and methods: Questionnaires for clinicians, authors of scientific publications, and pharmaceutical sponsors/medical communications partners addressed topics, such as acceptance and utilization of publication modalities and consideration of the impact of new modalities. Responses were gathered via the Internet, with a \$65 honoraria for clinicians and authors.

Results: Data from 50 internal medicine and primary care practitioners showed 86% accessed peer-reviewed literature with novel modalities ≥ 1 time per week, and from 2010 to 2011, the overall proportion of information accessed with these modalities increased from 52.2% to 64.6%; mobile tablets showed the highest percentage increases. Preliminary results from 15 authors of ≥ 4 articles over the previous 3 years demonstrated that from 2010 to 2011, the proportion they submitted to print-only journals decreased from 25% to 15.3%. Impact of all modalities was rated moderately to highly favorable by authors.

Conclusions: Early findings suggest novel communications modalities are utilized by a growing proportion of readership and authors. Full analysis of these data is expected to provide insights to enhance understanding of the impact of new modalities on readers, authors, sponsors, and partners for the dissemination of peer-reviewed scientific information.

*Oral presentation.

The following abstracts were accepted for poster presentation at the 2011 European Meeting of ISMPP; 'Trends, Transparency, and Trust: From Insights to Actions'; November 15–16, 2011; Alderley Park, Cheshire, UK

A benchmark of publication planning compliance among pharmaceutical companies

Greg Thompson^a, Angela Cairns^b and Jim Mercante^c

^aKnowledgePoint360 Group, Secaucus, NJ, USA

^bMacclesfield, Cheshire, UK

^cTGaS Advisors, East Norriton, PA, USA

Objective: We sought to understand differences in how pharmaceutical companies are managing publication compliance.

Research design and methods: We conducted a mini-benchmark of publication planning professionals to assess the policies used to manage adherence related to scientific publication compliance guidelines. We invited 106 publication planning professionals to participate, and received 23 responses representing 20 pharmaceutical companies. The benchmark was web-enabled using QuestionPro technology.

Results: For 61%, responsibility for updating and maintenance of internal publication policies and procedures falls either to the Publications, Medical Affairs, or Medical Strategy department. A total of 35% responded that the publications planning team is responsible for self-monitoring of compliance, and 26% have no formal monitoring or auditing system in place to assess adherence to publications policies. A total of 52% reported not testing their employees' knowledge of compliance guidelines, though 58% of those reported they are considering testing. A total of 91% reported that they have a publications-related document retention policy; 48% of those are directed by corporate compliance and 52% directed by publication-specific guidelines. We also evaluated the role of marketing and medical science liaisons in the publication process, utilization of publication steering committees, and challenging aspects of publication practice.

Conclusions: The evolving focus on scientific publications sponsored by pharmaceutical companies has led to increased attention to internal compliance programs. This benchmark provides a current snapshot of how different companies manage publication compliance. However, the pace of change and the areas of focus vary among organizations.

Authorship: beyond the ICMJE criteria

Laurence Rouxhet, Isabelle Camby, Christine Vanderlinden and Tatjana Poplazarova

Global Clinical Research and Vaccine Development, Scientific and Public Disclosure Department, GlaxoSmithKline Biologicals, Wavre, Belgium

Objective: The International Committee of Medical Journal Editors (ICMJE) criteria for authorship are widely used. Few guidances tackle early involvement of all potential authors. We developed an authorship questionnaire (AQ) for early identification of potential authors based on their level of contribution to a study (1st ICMJE criteria), and evaluation of their interest in authoring, taking public responsibility, and critically reviewing and approving the final version (2nd & 3rd ICMJE criteria).

Research design and methods: The AQ is sent to all investigators and sponsor employees involved in the study at the end of the active phase, before study results are available. Completed AQs are collected before publication start. AQ completion is a requirement for authorship eligibility.

Results: Collected AQs help to clarify contributorship at each study step, to understand areas of expertise, and to gauge interest for involvement in publications. Although AQ feedback is helpful to establish contributorship at the publication start (1st ICMJE criteria), final authorship can only be confirmed at the end of publication development (2nd & 3rd ICMJE criteria). Order of the authors is determined through agreement by all authors.

Conclusions: The AQ is an effective tool for applying ICMJE criteria by defining appropriate authorship/contributorship and acknowledgements early in the publication process. This tool is especially helpful for multi-center/multi-country studies and allows transparency and fairness, with the same eligibility criteria

applying to all authors. It also helps establish final authorship and order of authors according to contribution.

Evolution of the 'strength-of-voice factor': updated bibliometric to evaluate publication quality

Beth Sesler, Joanna Bloom, Cara Coffey and Mukund Nori

UBC-Envision Group, Southport, CT, USA

Objective: The purpose of this study was to revise and further evaluate the 'Strength-of-Voice Factor' (SVF) bibliometric (presented at the 2010 Annual Meeting of the International Society for Medical Publication Professionals) measuring the significance of individual publications and publications programs.

Research design and methods: The revised SVF has four components: (A) journal impact (SCImago Journal Rank); (B) revised author score (number of author citations during the period/number of articles author published during the same period); (C) number of article citations; and (D) article level of evidence (based on Oxford Centre for Evidence-Based Medicine Levels of Evidence Table). For an article, $SVF = A \times B \times C \times D/100$; for a publications program (or other body of literature), mean and median SVF for the program are assessed. We examined 1-year SVF for the publications program of a drug approved for several indications, examining the launch year and 2 subsequent years (2007 and 2008).

Results: SVF scores varied within and across indications. Components B and C most frequently contributed to an SVF = 0/'low impact' article; there were fewer SVF = 0 articles in the launch year than in post-launch years. Publications plan mean and median SVF were generally greatest in launch years, and this industry-sponsored publications program produced higher mean and median SVF than non-sponsored publications from the same year.

Conclusions: SVF is an objective bibliometric determining the strength of an individual article or a body of literature (e.g., industry-sponsored publications plan, an academician's publications, or a journal's issues or supplements).

Health economics and outcomes research in journals with a high impact factor

Lucy Hyatt^a, Sarah Petrig^a and Elena Rossi^{a,b}

^aAmgen (Europe) GmbH, Zug, Switzerland

^bSDA BOCCONI, Milan, Italy

Objective: Health economics and outcomes research (HEOR) is increasingly important for gaining and maintaining access to treatments. We assessed whether HEOR studies are published in the high-tier journals distributed most widely to clinicians.

Research design and methods: A PubMed search was used to assess the total number of articles published in each clinical journal with a high impact factor (IF) (>10) ($n = 24$) between August 2008 and July 2011. A keyword search yielded the number of HEOR papers, which was used to calculate the percentage of HEOR papers (%HEOR) published per journal in the same period.

Results: The 24 journals covered general or specialist medicine, and had a total circulation of 1,031,412. The %HEOR published per journal between 2008 and 2011 ranged from 0.19% (*American Journal of Human Genetics*) to 17.67% (*BMJ*) (mean, 7.20%). Of six journals in the %HEOR upper quartile, five were in general medicine, including *Archives of Internal Medicine* and *Annals of Internal Medicine*. The %HEOR published between 2008 and 2011 in the journal with the highest IF, the *New England Journal of Medicine*, was 4.24%. There was no pattern of increase in %HEOR between 2008/9 and 2010/11. There was no relationship between %HEOR and either IF or journal base country.

Conclusions: HEOR papers comprise a low proportion of articles published in journals with IF > 10. Despite the increasing importance of HEOR for access, no pattern of increase in %HEOR publications was evident in high IF clinical journals from 2008 to 2011.

Industry authorship and transparency in Pfizer-sponsored manuscripts

LaVerne A. Mooney, Lorna Fay and Angela Sykes

Publication Management Team, Pfizer Medical, New York, NY, USA

Objective: Concern regarding transparency in authorship of industry-sponsored medical publications is often discussed in the scientific literature and press. The International Committee of Medical Journal Editors (ICMJE) guidelines are endorsed by many journals and companies as the backbone of authorship criteria. Little data are available to evaluate whether company medical researchers are included as authors. The objective of this study was to determine what percentage of published manuscripts, sponsored by a specific company, had ≥ 1 company author.

Research design and methods: Company-sponsored publications that were published or accepted (and not yet published) in 2009 were identified in DataVision. Company authors, journal impact factor (IF), and type of manuscript were recorded. Medians and ranges were calculated.

Results: Of 393 sponsored manuscripts published or accepted in 2009, 80% included ≥ 1 company author. A total of 17% of the publications were review articles. The percentage of review articles with ≥ 1 company author was lower (45%) than observed for all manuscripts (80%). For reviews, median IF was 2.15 (range 0–7.22) compared with 3.01 (range 0–52.59) for all articles. For reviews, the IFs were similar for manuscripts with or without company authors (2.01 vs. 2.20).

Conclusions: The presence of company authors on over 80% of company-sponsored scientific manuscripts published in peer-reviewed journals suggests that when company employees meet authorship guidelines, they are appropriately named as authors. This systematic study of the prevalence of company authors on industry-sponsored publications is a step towards improving transparency in the peer-reviewed literature.

Local publication management

Ralf Winnen and Christine Rech

Information & Publication Management, Medical Department, Bayer Healthcare Germany, Leverkusen, Germany

Objective: Publication management is about supporting a company to develop high quality scientific publications in an accurate, objective, and timely fashion, and in accordance with current relevant internal and external standards regarding, e.g., content, documentation, authorship, and transparency. Publication strategies and plans are generally made on a global level, focusing on top-ranked international congresses and journals. Country-based publications are often left to diverse functions in the local departments, which can lead to unclear responsibilities as well as inefficient publication management and outcome.

Research design and methods: We established a local publication management in the medical department of Bayer Healthcare Pharmaceuticals Germany that oversees and handles all scientific publications for all pharmaceutical products. It was empowered to lead all publication strategy/plan meetings, organize the internal publication reviews, track and analyze publications via a database, and care for compliance to internal publication standard operating procedures and Good Publication Practice in a constant dialogue with external and internal publication stakeholders.

Results: Overall, our local publication management is a success story. Looking at one central parameter, the total number of publications, our medical department oversaw 68 publications in the year before publication management was established, compared to 362 in 2010. Examples of last year's scientific publications include abstracts, slide presentations, posters (77%), and papers, short communications, and reviews (21%). Publication sources were, e.g., (domestic) clinical, health economics and outcomes research, or non-interventional studies.

Conclusions: We believe that publication management at Bayer Healthcare Pharmaceuticals Germany could be a blueprint for other local publication management teams.

Peer review: what is the need for change?

Jackie van Bueren^a, Farah Dunlop^b, Sally Tranter^a and Susan Scott^b

^aCommunion, Oxford, UK

^bIpsen Biopharm Ltd, Slough, UK

Objective: The most common processes for peer review of scientific publications are single- and double-blinded review, where authors or both reviewers and authors are blinded, respectively. Other systems are available, such as open peer review, where reviewers' names are made public, and post-publication peer review. The purpose of this survey was to collect opinions regarding the current peer-review systems and assess whether there is a need to change the process.

Research design and methods: A pharmaceutical company and a medical communications agency collaborated to design and write the survey. To receive a wide representation of thoughts and beliefs, different populations were targeted, including medical communications professionals, pharmaceutical company publication professionals, a range of publishers, journal editors, authors, and peer reviewers from various therapeutic areas. The survey consisted of 26 key questions, plus additional comments on the definition of peer review and the need for change.

Results: A total of 194 respondents started and 119 completed the survey. Almost 50% of respondents thought changes to the peer-review system were needed. All respondents considered peer reviewers should disclose conflicts of interest, and 92% stated that peer reviewers must acknowledge a team member who has assisted in the review.

Conclusions: The key drivers for peer review were the need for scientific credibility and quality of publications. The survey highlighted the desire for a clear and transparent peer-review process to ensure that these requirements are met.

Publication of past and future clinical trial data: perspectives and opinions from a survey of 607 medical publication professionals**

Ryan Woodrow^a, Adam Jacobs^b, Peter Llewellyn^c, Jay Magrann^d and Nigel Eastmond^e

^aWoodrow Medical Communications Ltd, Bollington, UK

^bDianthus Medical Ltd, London, UK

^cNetworkPharma Ltd, Oxford, UK

^dInforma Healthcare Communications, New York, NY, USA

^eEastmond Mediacomm Ltd, Whaley Bridge, UK

Objective: This survey canvassed medical publication professionals on (a) how much pharmaceutical data should be made public, (b) where these data should be published, and (c) the limitations of publishing negative data.

Research design and methods: A survey was conducted between August 2 and 21, 2011. Members of the International Society for Medical Publication Professionals (ISMPP), the American Medical Writers Association, the NetworkPharma community, and other relevant groups were invited to participate. Respondents were excluded if they answered 'no' to the question: 'Have you ever been involved with the publication of medical research in any capacity?'

Results: Of the 739 responders, 679 were eligible; 607 completed the survey and were included in the analysis. Amongst completers, 50% were European, 36% were ISMPP members, and 85% had received healthcare compliance training, mostly in the past year (62%). Approximately one-third of completers were aware of unpublished negative data from a clinical trial in the past 3 years. The main reasons for non-publication over any time included compound discontinuation (40%), journal rejection (36%), poor trial design (31%), and damage to the product profile (27%). Forty-five percent suggested that pharmaceutical companies should be obliged to publish trial data for a compound prior to phase II, with most (73%) responding that ClinicalTrials.gov, EudraCT, or a similar website would be acceptable. Only 20% indicated that raw data should be made public. The main cited barrier to publishing all data, including raw, was fear of misinterpretation (49%).

Conclusions: Even recent negative trial data remains unpublished. Reasons, barriers and suggested solutions will be discussed.

**Poster winner, Best Original Research, 2011 European Meeting of ISMPP.

Use of smart technology to reduce the environmental impact of poster presentations

Paul Farrow^a, Fran Young^b and Christopher Rains^b

^aOxford PharmaGenesis Ltd, Tubney, Oxfordshire, UK

^bShire Pharmaceuticals, Wayne, PA, USA

Objective: Use of quick response (QR) codes is increasingly common in the consumer world. When scanned using a smartphone or other mobile device, these icons direct the user to web-based content. We aimed to use QR technology as an alternative to printed handouts in order to reduce the environmental impact of poster presentations, while maintaining exposure.

Research design and methods: A simple cross-platform interface was developed to enable a wide variety of mobile devices to access an electronic-poster (e-poster) delivery system; from here, PDF files of posters could be downloaded or emailed to a delegate's account. Printed display posters incorporated QR codes; web addresses were also provided to allow access from personal computers.

Results: Including launch at the 2011 US Annual Meeting of the International Society for Medical Publication Professionals, the e-poster system has now hosted 26 posters presented at nine international congresses. During the initial 3-month pilot, 210 unique users visited the system. Over two-thirds of visits were made using mobile devices; of these, 65% were from the iPhone and 27% were from Blackberry phones. Posters were downloaded or emailed a total of 507 times; so far it is estimated that this has reduced the carbon footprint associated with printing and shipping of handouts by up to 161 kilograms of carbon dioxide.

Conclusions: Usage statistics suggest there is an appetite for e-posters; increasing use of mobile devices and the promise of lower international roaming data charges should increase appeal further.

