



## Preface

Dear Colleagues:

We are pleased to share with you our second collaborative journal effort to showcase the recent research conducted by members of the International Society for Medical Publication Professionals (ISMPP). This supplement includes 25 abstracts accepted for presentation at the 6th Annual Meeting, *Delivering Value and Driving Advocacy in Medical Publications*, April 19–21, 2010, Arlington, VA, USA. This original research demonstrates our organization's commitment to understanding the trends and issues, and translating this information to our members to drive and support best practices in publication planning and management.

We would like to thank our partners at CMRO for their continued support of ISMPP and, in particular, their outstanding partnership in publishing this supplement that highlights our members' research efforts. As ISMPP

continues to grow, we will look to build on these types of activities that support medical publication professionals through education and keep ISMPP at the forefront of information sharing and debate of medical publications issues.

Sincerely,

A handwritten signature in black ink that reads 'Julia Ralston'.

Julia Ralston  
President, ISMPP

A handwritten signature in black ink that reads 'Joanne Conaty'.

Joanne Conaty  
Abstract Committee Chair

## 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 The selection and peer review of abstracts was carried out by ISMPP; they have not been peer reviewed by CMRO.

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# Current Medical Research and Opinion

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# Editorial

## The International Society for Medical Publication Professionals

Kim Pepitone<sup>1</sup> and Al Weigel<sup>2</sup>

This journal supplement, which is based on the abstracts submitted to the 6th annual meeting of the International Society for Medical Publication Professionals (ISMPP), provides the ideal venue to check the pulse of this society, which was founded a mere five years ago based on a vision to be the recognized and respected authority for the pharmaceutical, biotechnology, and device industries' medical publication professional. Today, ISMPP membership comprises nearly 900 representatives from various walks of medical publications—from those responsible for the conduct of industry-funded clinical trials to those who publish the clinical trial results.

ISMPP was formed in March of 2005 in recognition of the need to develop a dedicated society to support medical publication professionals. ISMPP's initial leadership comprised a small group of experts who found themselves speaking publicly on topics that ranged from the nuts and bolts of how to publish clinical trial data to how to do so with integrity, and sought to turn their individual experiences into a broader, far-reaching educational platform. Other issues that helped to spur the formation of the society included the shift in the key stakeholders for medical publications within the sponsoring companies, the separation of publications from other medical communications initiatives, and the need to define the role of professional medical writers and differentiate them from 'ghostwriters'.

ISMPP's initial efforts remain a main goal of the organization: to support sound, ethical, transparent publishing practices, and increase the credibility and expertise of medical publication professionals through education. This goal is realized at all of ISMPP's annual meetings through hands-on workshops on a variety of topics and a plenary agenda that tackles the hard questions. Each year the annual meeting includes an 'editors panel', which provides a forum for medical publication professionals to hear directly from the editors of key juried journals. ISMPP also launched its monthly educational ISMPP U webinars in

2005, and they continue with upwards of 100 participants at each program.

Amongst ISMPP's newest initiatives is the Certified Medical Publication Professional (CMPP) credential, which is earned by passing a rigorously-designed 150-question computer-based examination that tests the knowledge and practice levels of eligible candidates. The need for the certification program became apparent as ISMPP's leadership sought to identify a systematic approach to the professional development of medical publication professionals in response to increasing scrutiny from a range of stakeholders with varying agendas, and realized that, in fact, one did not exist. The acceptance of the CMPP credential has surpassed all expectations, as evidenced by the fact that there are now more than 150 CMPPs within the medical publishing profession, and that number is expected to reach over 200 by the time of the 6th annual meeting.

Members of ISMPP's volunteer committees have also authored articles in peer-reviewed journals on the topics of authorship<sup>3</sup> and good publication practice<sup>4</sup>. Like ISMPP's other initiatives, these publications provide strong evidence of ISMPP's successful support of the medical publication professional, and its commitment to advance the medical publication profession through education and advocacy; drive integrity, excellence, and transparency in medical publications; and lead the establishment and adoption of medical publication standards and best practices.

<sup>1</sup>Director of Credentialing and Professional Development, ISMPP.

<sup>2</sup>Director Medical Publications, Boehringer-Ingelheim and President, ISMPP, 2009–2010.

<sup>3</sup>Norris R, Bowman A, Fagan J, *et al.* International Society for Medical Publication Professionals (ISMPP) position statement: the role of the professional medical writer. *Curr Med Res Opin* 2007;23(8):1837–1840.

<sup>4</sup>Graf C, Battisti W, Bridges D, *et al.* Good publication practice for communicating company sponsored medical research: the GPP2 guidelines. *BMJ* 2009; 339:b4330.

# Abstracts

## A novel 'strength-of-voice' metric to evaluate quality of publications

Mukund Nori, Joanna Bloom, Beth Young, Cara Coffey, Dan Donovan

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**Background:** Typically publications programs are evaluated by their share-of-voice compared with competing programs. However, this approach does not assess the publications' quality, as all types of publications, whether a case report or a landmark clinical trial, are weighted equally.

**Purpose and objective:** To develop a new metric, 'Strength-of-Voice Factor' (SVF)<sup>®</sup>, that measures the significance of individual publications and publications programs.

**Methods:** The components of SVF are: (A) impact factor of journal; (B) author strength-of-voice; (C) number of times article is cited; and (D) level of evidence of the article. Author strength-of-voice (B) = number of citations of the author during the period/number of articles author has published during the same period. For an article,  $SVF = A \times B \times C \times D/100$ ; for a publications program, SVF = average of SVFs for each article in the program.

**Results:** For proof of concept, we evaluated the first 3 'statin' articles published in 2006 for each of five categories for level of evidence identified in a PubMed search. SVFs generally support the ranking of primary articles > reviews > meta-analyses > case studies > letters, but can also distinguish strength within these categories. A more detailed evaluation will be presented.

**Conclusion:** Although further refinement is in progress, we believe we have a novel, unique metric to determine the SVF for a given publication and thereby better assess the quality of a publications program.

## A survey of adherence to the Consolidated Standards of Reporting Trials (CONSORT) guidelines for abstracts

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**Background:** In January 2008, the Consolidated Standards of Reporting Trials (CONSORT) group published a checklist of 17 essential criteria for inclusion in randomized controlled trial (RCT) abstracts<sup>1</sup>.

**Purpose and objective:** To evaluate compliance with that list, except 'author contact details', which are specific to conference abstracts.

**Methods:** We randomly selected five International Committee of Medical Journal Editors (ICMJE) member journals, five psychiatry journals listed as ICMJE compliant, and five psychiatry journals not listed on the ICMJE site. We searched PubMed for RCTs published in 2009 in these 15 journals. As the number of published studies was large ( $n = 444$ ), we further restricted the search period from October 1 – December 31, 2009 ( $n = 97$  in 14 journals).

**Results:** None of the 93 abstracts included all reported criteria from the checklist. There was variation in degree to which the criteria were reported between journals and within the same journal. 'Interventions' and 'conclusions' were described in all abstracts in all journals. Least adherence was observed for describing 'randomization', 'blinding', 'recruitment', and 'funding'.

**Conclusion:** Although two years have elapsed since the CONSORT guidelines for abstracts were published, our survey results suggest that adherence to these guidelines is not uniform. This observation is limited by the small sample size, and the uneven distribution of abstracts among the selected journals.

## Reference

- Hopewell S, Clarke M, Moher D et al. PLoS Med 2008; 5(1): e20. doi:10.1371/journal.pmed.0050020

## Acceptance rate analysis for Pfizer-supported manuscripts

LaVerne Mooney, Daireen Garcia, Lorna Fay

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**Background:** Delays in the publication of scientific data have the potential to impact treatment decisions and transparency. Two factors that influence delays are: rejections of manuscripts by peer-reviewed journals, and subsequent manuscript re-submissions.

**Purpose and objective:** (1) Determine the acceptance rate of Pfizer-supported manuscripts on first submission to a journal, and the cumulative acceptance rate upon subsequent re-submission(s). (2) To reduce the number of journal re-submissions and to accelerate the availability of Pfizer data to health care professionals and patients.

**Methods:** Pfizer-supported manuscripts ( $n = 171$ ) were analyzed, including data from seven drugs in three therapeutic areas. For each drug, every manuscript submitted for the first time between 1/1/08 and 6/30/09 was tracked, and acceptance rates were calculated. A subset ( $n = 55$ ) was analyzed for time from initial submission to publication and, if rejected, the reason for rejection. The acceptance rate is presented as a range when at least one manuscript is awaiting a journal decision. This analysis will track all manuscripts until each outcome is known.

**Results:** The acceptance rate for all first-time submissions was 56–61%; to date, the cumulative acceptance rate was 78–89%. Of those manuscripts rejected on first submission, 63–76% were accepted on second submission to a different journal. Each additional submission delays publication ~3 months. Of the manuscripts rejected, 30% were due to inappropriate journal selection for the manuscript.

**Conclusion:** Although some manuscripts may require more than one journal submission, most Pfizer-supported manuscripts are accepted and published in peer-reviewed journals.

## Acknowledgment of medical writers in medical journal articles: a comparison from the years 2000 and 2007

Susan A. Nastasee

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**Background:** Authorship and use of unacknowledged writers are important issues for journal editors, scientists, medical writers, and publication professionals.

**Purpose:** The purpose of this study was to determine whether the acknowledgment of medical writers' contributions to papers published in medical journals has increased over time.

**Methods:** Articles from nine medical journals published during the years 2000 and 2007 were reviewed to determine whether the contributions of a medical writer were acknowledged. Other information retrieved included whether the article delineated the specific contributions of the author(s) to the manuscript and the funding sources for the study.

**Results:** A total of 581 articles were reviewed. Of the 334 articles reviewed that were published in 2000, 17 (5.1%) included an acknowledgment of a medical writer. Of the 247 articles reviewed that were published in 2007, 28 (11.3%) included an acknowledgment of a medical writer. The authors' specific contributions to the manuscript were listed in 34.1% of the articles from the year 2000 and 59.1% of the articles from the year 2007. The frequency of acknowledgments of funding sources was similar for both years (62% and 61% for 2000 and 2007, respectively).

**Conclusion:** In the journals and timeframe studied, an overall two-fold increase in the frequency of acknowledgments of medical writers was observed. More comprehensive research is needed to confirm these findings and to discern the reasons for the observed increase.

## An assessment of author disclosure requirements by medical congresses

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**Background:** Author disclosure requirements for manuscript publication have become widely known due to increased scrutiny resulting from concerns about author conflicts of interest and charges of 'ghost writing'. Little attention has been paid to the disclosure requirements of organizations that host medical congresses.

**Purpose and objective:** To assess the level of author disclosure required by medical congresses for abstract submissions and presentations compared to medical journals.

**Methods:** The author disclosure requirements from a random sample of medical congresses were examined. The categories of author disclosure were taken from those required for manuscript submission to *JAMA*. These include: author contribution, author financial interest, study funding support, writing assistance, and the name of the writer and/or agency providing writing assistance.

**Results:** In general, medical congresses do not require the level of author disclosure that is found in medical journals such as *JAMA*. The most frequent disclosure requirement was author financial interest, followed by funding support for the study. Disclosure of author contribution, support for writing assistance, and name of the writer/agency providing writing assistance were rarely required.

**Conclusion:** Currently, author disclosure requirements for medical congress abstracts and presentations do not reach the level of those for medical journals such as *JAMA*. The reduced level of author disclosure required by congresses may be due to the fact that the public has relatively little exposure to medical congresses. Whether this continues in the future remains to be seen.

## An ICMJE journal survey: what is the extent of the trend toward rejecting industry-sponsored publications?

Victoria Blasberg, Julie Collins, Monica Gunther, Debra Wolinsky

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**Background:** Several journals have instituted policies discriminating against manuscripts with fully disclosed involvement of pharmaceutical or medical education companies. These policies present substantial obstacles for actively practicing physicians to publish valuable data in quality journals.

**Purpose and objective:** This survey was developed to ascertain the extent of this trend toward journals rejecting manuscripts from pharmaceutical and medical education companies.

**Methods:** Six hundred journals that follow the uniform requirements of the International Committee of Medical Journal Editors (ICMJE) were sent a three-question survey to determine their position on pharmaceutical and medical education company submissions. The journals were also queried as to when they would be implementing the ICMJE Uniform Disclosure Form for Potential Conflicts of Interest.

**Results:** Data collection is in progress. Results of this survey will be presented at the 2010 Annual Meeting of the International Society for Medical Publication Professionals. Results will include the total number of responding journals as well as the tally of respondents who do and do not accept submissions from pharmaceutical and medical education companies. Data will be broken out by therapeutic areas, tiers, and global versus U.S. journals. The number of respondents who will be implementing the ICMJE disclosure form will also be reported.

**Conclusion:** This information will provide an indication of the extent of this trend and will be a valuable asset for authors in determining target journals, as well as for pharmaceutical and medical education companies to better manage publication planning.

## Authorship above reproach: Amgen's continuing commitment to maintain the integrity of scientific publications

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**Background and purpose:** Ethical authorship is a persistent issue of scrutiny in the landscape of industry-sponsored medical publications. Allegations of 'ghostwriting' and 'guest authorship' abound and call into question the integrity of the scientific information presented. To allay such concerns and refocus attention on the merits of scientific research, pharmaceutical companies should evaluate their publication practices to ensure alignment with current industry guidelines and best practices.

**Methods:** Amgen has elevated its existing publication policy to a company-wide standard operating procedure (SOP). Amgen's publications SOP ensures that author involvement in publications is transparent and continuous. Authors are engaged at the earliest stages of publication development and must provide substantial intellectual contributions throughout the process via kickoff meetings and critical review and editing of drafts. All authors must approve final versions and attest that they meet the authorship guidelines of the International Committee of Medical Journal Editors (ICMJE). The SOP was created by representatives from Amgen's legal, compliance, publication-planning, and medical-writing functions. Individuals at Amgen involved in any aspect of publication development are trained via interactive electronic modules and live, team-specific trainings. A variety of tools were developed to assist in Amgen's execution of the SOP.

**Results:** We will describe the development and execution of the SOP, present the tools that support it, and discuss a plan for monitoring adherence.

## Authorship, acknowledgement, serology and statistics: a study of vaccine literature in the 1980s, 1990s, and 2000s

Lisa DeTora

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**Background:** In publications describing pharmaceutical products both in medical journal articles and the public media, issues of disclosure, especially of financial and writing support, have been prominent. In recent publications about 'ghost authors', statisticians were identified as a key group of contributors to scientific studies who are frequently omitted from author lists or acknowledgements in industry-sponsored studies. In vaccine research, support from both statistical and serology experts is common. Little information is available about vaccine studies in the context of disclosure of writing and tactical support.

**Purpose and objective:** To identify the response of authors and sponsors of vaccine trials to guidelines about authorship and disclosure via examination of author bylines and acknowledgements in peer-reviewed publications.

**Methods:** Data will be obtained from publications describing the primary results of clinical trials of various widely used vaccines. Papers will be identified by MEDLINE<sup>®</sup> searching by decade (1980–1989, 1990–1999, 2000–2009) in core clinical journals (as defined by MEDLINE<sup>®</sup>). Control papers written by academic groups will be selected for comparison. Citations of contributions or authorship by serologists, statisticians, clinical research associates, and professional writers will be identified and tabulated by vaccine and decade and also by relationship to key clinical research or publication guideline updates (Declaration of Helsinki, International Committee of Medical Journal Editors, Consolidated Standards of Reporting Trials).

**Results:** Acknowledgements of statisticians, clinical research associates, serologists, and writers will increase over time. A peak in the increase of acknowledgements is anticipated shortly after the release of new guidance documents.

## Awareness and attitudes for guidelines and policies on authorship of clinical publications

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**Background:** Guidelines regarding the conduct and ethical communication of clinical trials were issued by organizations, including the International Committee of Medical Journal Editors, Association of American Medical Colleges, Pharmaceutical Research and Manufacturers of America, American Medical Writers Association, and the International Society for Medical Publication Professionals. Despite these guidelines, considerable confusion exists regarding authorship, transparency, and the role of technical writers and editors from medical education groups in developing peer-reviewed publications.

**Purpose and objective:** To assess the awareness and attitudes about authorship guidelines and policies to implement them.

**Methods:** Three questionnaires specific to academic medical centers, clinical practitioners, and pharmaceutical sponsors were developed. Questionnaire topics included authorship guidelines, 'ghost writing', compensation, and the effect of guidelines on institutional resources. The responses were gathered by telephone or via the Internet.

**Results:** In the first wave of the study, 25 clinical practitioners from each of the following specialties were surveyed: cardiology, dermatology, neurology, oncology, pediatrics, primary care, and psychiatry. Findings for clinical practitioners will be compared with those from physicians in academic medical centers and pharmaceutical sponsors.

**Conclusion:** To date, this is the first study to characterize the level of awareness, attitudes, and policies regarding use of authorship guidelines among key stakeholders of clinical study publications. These data are expected to provide insights further enhancing the processes to ensure transparency and opportunities to improve public perceptions of industry-sponsored publications.

## Best practices for development of non-primary data publications: a needs-based approach

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**Background:** Compliant publication planning begins during strategic development of the plan and often includes non-primary data projects such as review manuscripts, secondary analyses, and case studies. Peer-reviewed, scientific communications must address valid, unmet educational needs of healthcare professionals.

**Purpose:** To ensure that scientific communications address legitimate, unmet educational needs, a best-practice process is essential.

**Methods:** As a best practice, the following five-step process for publication plans that include review manuscripts, secondary analyses, and case studies is recommended. (1) Conduct a literature search using terms defined by indication, clinical behavior, disease state, emerging therapies, and patient-access issues. (2) Perform a gap analysis based on literature search results to identify areas of unmet educational need. (3) Validate those needs through feedback from independent clinical experts. (4) Develop a publication plan based on results of the gap analysis and feedback from clinical experts. (5) Initiate the plan by identifying authors who want to satisfy unmet need.

**Results:** Use of this five-step best practice ensures that non-primary data publications are valid, needs-based scientific communications.

**Conclusion:** Best practices that result in more robust and clinically meaningful publications enable publication planners to achieve educational objectives and provide healthcare professionals with information that may improve patient outcomes.

## Clinical trial identifiers in publications and accessibility of clinical trial data

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**Background:** The guidelines set forth by Good Publication Practice, the International Committee of Medical Journal Editors, and the Food and Drug Administration Amendments Act (FDAAA) mandate increased transparency of clinical trial results from pharmaceutical company-sponsored studies.

**Objective:** This study will evaluate compliance with these guidelines as well as accessibility of trial results and publications.

**Methods:** Peer-reviewed publications reporting clinical trial results for three chronic obstructive pulmonary disease drugs from different companies (published 2004–2009;  $n=98$ ) were examined for inclusion of trial identifiers (National Clinical Trial [NCT] number or company trial number/name). Accessibility of trial results and publications from ClinicalTrials.gov listings was also investigated.

**Results:** The number of pharmaceutical company-sponsored publications containing any trial identifier in the PubMed abstract rose from 4/12 (33%) to 13/22 (59%) over the last four years. No publications reported the NCT number in the abstract/text in 2004–2005, but all 2009 publications did. Using NCT numbers as a search term on PubMed retrieved only 23 out of the 62 corresponding publications, and these 23 publications were accessible through links from ClinicalTrials.gov listings. Few trials (6%) directly posted results on ClinicalTrials.gov, but most trial results (90%) were available on company websites, although not identified by NCT number. Of the six trials required to post results based on FDAAA regulations, five did so on ClinicalTrials.gov and/or company websites.

**Conclusions:** Although it can be difficult to match clinical trial numbers to older publications, cross-referencing and accessibility appear to be improving, possibly because of increased compliance and new regulations.

## Comparison of journal guidelines within and across therapeutic areas and healthcare audiences

Danita Sutton, Jason McDonough, Staci Deaton, Bob Margerum, Ashley O'Dunne, Bo Choi

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**Background:** The clear, accurate, and transparent reporting of biomedical research by authors is important, particularly in the current evolving environment of medical publishing. Yet journal guidelines can vary greatly in type of direction given to authors submitting papers.

**Purpose and objective:** To determine whether differences exist in the type of information provided to authors in published journal guidelines within and across therapeutic areas and healthcare audiences.

**Methods:** Published journal guidelines (i.e., author instructions) will be analyzed for differences within and across specific therapeutic areas and by healthcare audience type. Analysis will focus on use of the uniform requirements of the International Committee of Medical Journal Editors (ICMJE), disclosure/acknowledgments, authorship criteria, and mention of medical writers. Published journal guidelines for five therapeutic areas will be assessed: oncology, dermatology, infectious disease, endocrinology/metabolism, and cardiology/vascular disease. Within each area, a cross section of journals will be evaluated such that comparison can be made based on audience type (e.g., specialist, nurse, pharmacist), journal stature (e.g., society journal), impact factor, and geographical region of the publisher.

**Results/conclusion:** Preliminary results in oncology demonstrated that the *Journal of Clinical Oncology* uses ICMJE criteria for authorship. The two oncology nursing journals (*Oncology Nursing Forum*, *Cancer Nursing*) do not mention ICMJE uniform requirements. Full results and conclusions will be available at the 2010 Annual Meeting of the International Society for Medical Publication Professionals.



## Compliance in scientific publications: pharma's response to GPP2

Craig Ornstein, Ira Mills, Michael J. Stevinson, Sheri Cappucci

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**Background:** There is an increased focus on the need to maintain compliance in scientific publications that disseminate pharmaceutical company-sponsored medical research. Regulatory guidelines have been established to ensure full disclosure for authorship and in acknowledging the degree of contributions from pharmaceutical company personnel, professional medical writers, and editors.

**Methods:** To identify the degree of pharmaceutical company response to the recent scientific publication guideline changes, a survey will be distributed to the members of the International Society for Medical Publication Professionals (ISMPP). This survey is designed as a 'post-hoc' assessment of the recently published, updated ISMPP GPP2 guidelines (Graf C, Battisti WP, Bridges D, *et al.* Good publication practice for communicating company sponsored medical research: the GPP2 guidelines. *BMJ* 2009;339:b4330). The survey will contain five questions regarding authorship, five questions regarding contributorship, and 10 questions regarding the use of professional medical writers and editors.

**Results:** Data will be collected using the SurveyMonkey™ tool (<http://www.surveymonkey.com/>), and results will be available for presentation at the 2010 Annual Meeting of the International Society for Medical Publication Professionals.

**Conclusion:** Results of this survey are expected to underscore the need to maximize transparency in the development of scientific abstracts, posters, and manuscripts disseminating pharmaceutical company-sponsored medical research.

## Getting ready for GPP2: the Caudex Medical experience

Tina Kohnstam, Liz Bullock

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**Background:** Caudex Medical, a full-service medical communications agency with a strong heritage in publication planning, responded to the earlier version of Good Publication Practice (GPP) by developing a written acknowledgments policy<sup>1</sup>. Development of the updated GPP2 meant that an overhaul of processes, including the acknowledgments policy, would be required.

**Purpose and objective:** To ensure that the processes necessary to implement GPP2 were in place.

**Methods:** A working group, including representatives from medical writing, editing, and account management, was convened to discuss the implications of draft GPP2 provisions presented in 2009<sup>2</sup>. The draft guidance was discussed on a topic-by-topic basis and responses agreed. As soon as possible after publication of GPP2, a final meeting was held to review and amend the initial responses against published guidance.

**Results:** Detailed advice, including draft documentation and process instructions, was devised to cover publication responsibilities, disclosures, acknowledgments, and review papers. New working practices were set up for freelance writers and editors, and rigorous standards introduced for documentation. It became apparent that there was a need for training on GPP2 within our own organization and for our clients. The working group responded with a series of internal briefings and by acting as internal 'GPP2 champions'; a training workshop and a consultancy service were made available for our clients.

**Conclusion:** Through a systematic approach, we achieved our objective of being ready to implement GPP2. The level of training required was higher than anticipated.

## References

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- Graf C. Good publication practice for communicating research sponsored by pharmaceutical, medical device and biotechnology companies (GPP2). International Society for Medical Publication Professionals Annual Meeting, April 20–22 2009, Philadelphia, PA, USA

## Improving staff assessment and understanding of compliance guidelines

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**Background:** Regulatory authorities, the pharmaceutical industry, and professional societies continue to refine guidelines for interactions between the pharmaceutical industry and healthcare professionals, including activities relating to scientific publications and promotional medical communications. Employees of pharmaceutical companies and medical communications agencies must understand and consistently comply with these laws, regulations, and guidelines. Research indicates that on average, employees operate with only a 55% level of competence; 15% of the information employees act on is wrong, while they are confident that they are right.

**Methods:** Based on employee feedback, we revised our annual internal compliance testing to improve the process and to integrate an additional learning opportunity by using a confidence-based learning (CBL) methodology. As an online learning process, CBL quantifies both the learner's knowledge and their confidence in that knowledge. A built-in self-learning mechanism reinforces their understanding in areas of uncertainty. The program was designed to test the individual until they achieve validated mastery of the information.

**Results:** Data from our compliance test using CBL (currently ongoing) will be evaluated and compared with these reference values.

**Conclusion:** Medical communication agencies must ensure a high level of compliance with laws, regulations, and industry guidelines by all relevant employees. Measuring both knowledge and confidence has been shown to be an enhanced method of assessment and training, and is expected to reduce liability and risk associated with employee error.

## Information derived from the ClinicalTrials.gov database: analyses and applications to strategic publication planning

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**Background:** Information contained in the ClinicalTrials.gov database includes compound/drug, indication(s), phase/status of trials, number of subjects enrolled in clinical trials, start/end dates for trials, clinical investigators, investigational sites, and the ClinicalTrials.gov identifier number for the trial. Analyses, including graphical displays of aggregate data from this database, can allow for strategic insights to be derived that are of value to strategic publication planning and competitive intelligence initiatives.

**Purpose and objective:** Clinical trial-related information was analyzed for 15 compounds listed within the ClinicalTrials.gov database and classified as belonging to the vascular endothelial growth factor receptor inhibitor (VEGFi) drug class. Specific applications to strategic publication planning and competitive intelligence initiatives were considered.

**Methods:** XML downloads of data from ClinicalTrials.gov were obtained, analyzed, and evaluated through the use of a clinical trial database analysis tool.

**Results:** Graphical displays and analyses of data were produced for 15 VEGFi compounds for the following data categories: phase/status of trials, number of subjects enrolled, start/end dates for trials, clinical investigators, and investigational sites.

**Conclusion:** Graphical display and analyses of data obtained from the ClinicalTrials.gov database allowed for strategic insights to be defined for key compounds belonging to the VEGFi drug class. A probable set of communication plans for study data deriving from VEGFi clinical development programs was defined. This information has strategic value for publication planning and competitive intelligence initiatives.

**Interactive poster sessions: a case study**Rachel Jones<sup>a</sup>, Donna Casparro<sup>b</sup>, Jim Owers<sup>c</sup><sup>a</sup>AstraZeneca, Macclesfield, UK<sup>b</sup>PAREXEL, Hackensack, NJ, USA<sup>c</sup>PAREXEL, Worthing, UK

**Background:** The aim of any poster presentation is the effective communication of scientific data. The majority of posters presented at medical congresses are currently produced in two dimensions. Many posters do not convey data in a way that stimulates reader interest and discussion.

**Purpose and objective:** To explore novel ways of developing interesting and stimulating poster sessions utilizing existing rich media assets such as animation and video interviews.

**Methods:** With help from PAREXEL, AstraZeneca and the study investigators explored the possibility of presenting data electronically at a major congress.

**Results:** The interactive poster will be piloted at the 2010 International Society for Bipolar Disorders Congress. The poster will report findings of a major international survey of 643 healthcare professionals and 2688 patients with bipolar disorder, their carers, and patient advocacy groups. The 'virtual' poster will be presented electronically via a touch-screen plasma display. As well as reporting major outcomes from the survey, the poster will also include audio interviews with the study investigators, patient/physician sound bytes, and an interactive section in which the participant will be invited to respond to survey questions. Electronic links to reference materials further broaden the utility of the poster.

**Conclusion:** Interactive presentations may represent a valid alternative to conventional printed posters. This technology may ultimately change the way in which poster sessions are convened, promoting the on-line dissemination of data.

**Medical information access preferences: results of a survey of physician assistants and nurse practitioners**Frank J. Rodino<sup>a</sup>, James F. Cawley<sup>b</sup><sup>a</sup>Churchill Communications, LLC, Maplewood, NJ, USA<sup>b</sup>The George Washington University, Washington, DC, USA

**Background:** The influence of physician assistants (PAs) and nurse practitioners (NPs) in the delivery of healthcare has grown over the past 40 years. There are few data available that describe how PAs and NPs access the latest medical information.

**Purpose and objective:** It may be hypothesized that PAs and NPs obtain medical information from sources similar to those of physicians. To examine this issue, the authors conducted a study of PAs and NPs to explore their perceptions of how their medical information access preferences compare with those of the physicians and patients they regularly encounter.

**Methods:** The authors surveyed more than 500 PAs and NPs from varied clinical specialties and practice settings. Professional and demographic information, specific topics of interest, most frequently accessed journals and websites, and frequency and amount of time spent accessing medical information were queried to learn respondents' medical information access preferences. Electronic survey vehicles were utilized. Addresses were obtained from a medical mailing house, and from websites frequented by PAs and NPs.

**Results:** At the time of this abstract submission, data were being collected, tabulated, and analyzed.

**Conclusion:** Final results will be presented at the 2010 Annual Meeting of the International Society for Medical Publication Professionals.

**Optimizing online medical information**Amy Walencik<sup>a</sup>, Jeff Pfister<sup>a</sup>, Amy Van Note<sup>b</sup>, Steven Tiger<sup>b</sup>, Kyle Nahrebne<sup>a</sup><sup>a</sup>Merck, Kenilworth, NJ, USA<sup>b</sup>Complete Healthcare Communications, Inc., Chadds Ford, PA, USA

**Background:** Historically, medical information was available almost exclusively to clinicians. Now patients and the general public have access to the same information via the Internet through PubMed and medical websites that routinely pull information from peer-reviewed publications. By producing high-quality publications, pharmaceutical researchers can help indirectly to provide the public with accurate, timely medical data.

**Purpose and objective:** To assess the use and impact of public access of online medical information, and the quality of information available at medical information websites.

**Methods:** Searches were conducted to assess public utilization of online medical information and its impact on clinician-patient interactions.

**Results:** Estimates of use of medical information websites vary (16%–64% in the U.S.; 49% in Paris, France). Use by patients seeking information about specific disorders or general symptoms is estimated at 57%–70% in the U.S., 27%–74% in the European Union. In the U.S., ≥20% of patients report that they discuss information obtained online with their physicians. Most patients trust online information, but professional evaluations of online information in the U.S. and European Union give quality ratings averaging only 58%–59% of optimal scores.

**Conclusion:** Online medical information has significant limitations. By optimizing the quality of peer-reviewed publications, pharmaceutical researchers, working with scientific leaders, can have an indirect, positive influence on the quality of information reaching the general public.

**Publication of the results of Chinese trials after registration in ClinicalTrials.gov versus ChiCTR**Liu Xuemei<sup>a</sup>, Li Youping<sup>a</sup>, Song Shangqi<sup>b</sup>, Yun Senlin<sup>b</sup><sup>a</sup>West China Hospital of Sichuan University, Chengdu, China<sup>b</sup>West China School of Medicine Sichuan University, Chengdu, China

**Background:** Publication of full study results is one of the main ways to improve trial transparency.

**Purpose and objective:** To investigate the publication status of Chinese trials registered in ClinicalTrials.gov and the Chinese Clinical Trial Register (ChiCTR).

**Methods:** We searched ClinicalTrials.gov and ChiCTR to identify the registration records of Chinese trials. A systematic search was conducted in PubMed, Embase<sup>®</sup> and three main Chinese databases to attempt to obtain the resulting publication. We called the authors of completed trials to ask for the publication details when publication results were unavailable through the systematic search. The search was updated on July 14, 2008.

**Results:** A total of 1171 registration records of Chinese trials (428 in ChiCTR and 743 in ClinicalTrials.gov) were identified. The resulting publication rates of Chinese trials in ClinicalTrials.gov and ChiCTR were 36.6% (53/145) and 36.3% (89/245) respectively. The publication rate of the results of trials sponsored by industry was lower than that of trials sponsored by non-industry (24.1% vs. 42.1%). The publication rate of non-randomized trials was higher than that of randomized trials (23.7% vs. 19.6%). The publication rate of interventional studies was higher than that of observational studies (38.5% vs. 32.1%).

**Conclusion:** The publication rate of the results of registered Chinese trials is low with no significant difference between ChiCTR and ClinicalTrials.gov. An effective mechanism is needed in China to promote the publication of results for studies registered in the trial registration system.

## Round up the usual suspects? Involvement of medical writers and the pharmaceutical industry in retracted publications

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**Background:** Claims have been made that medical writers and the pharmaceutical industry are highly likely to have been involved in publications retracted for misconduct. Advocates of medical writers and the pharmaceutical industry have had limited evidence to counter such claims.

**Purpose and objective:** We conducted the largest study to date on misconduct retractions to quantify, for the first time, how involved declared medical writers and the pharmaceutical industry have been in publications retracted for misconduct.

**Methods:** We used PubMed (limits: English, human, 1966–2008) to identify publications retracted for misconduct or mistake. Standardized definitions and data collection tools were used (inter-rater reliability = 100%). Mistake retractions served as the control group. An independent academic statistician analyzed the data.

**Results:** Of the 463 retractions retrieved, 213 (46%) were misconduct retractions. Of the misconduct retractions, three (1.41%) involved declared writers, eight (3.76%) involved declared pharmaceutical sponsorship, and none (0.00%) involved both declared writers and pharmaceutical sponsorship. The odds ratio (95% confidence interval) of a misconduct versus mistake retraction was 0.16 (0.05–0.57) for publications with declared writers and 0.25 (0.11–0.58) for papers with declared pharmaceutical sponsorship.

**Conclusion:** The involvement of declared medical writers or the pharmaceutical industry in misconduct retractions is very low. Our results can help writers and sponsors counter claims about unethical publication practices and can reinforce the value of appropriate disclosure.

## Speaking of value: the need for common terminology for communicating health economic information

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**Background:** As the demands of the current regulatory climate call for greater outcomes-based evidence in healthcare, the scientific literature is increasingly incorporating health economic data into peer-reviewed publications in order to demonstrate value. Commonly used terms such as evidence-based medicine, cost effectiveness, comparative effectiveness, and, in particular, value proposition, continue to find their way into clinical papers and review articles.

**Purpose and objective:** It has been observed that numerous inconsistencies and considerable variations currently exist in how health outcomes data are described. The purpose of this presentation will be to demonstrate how clearer and more consistent terminology can be integrated into payer-focused publications and other vehicles in order to more effectively communicate critical economic and clinical information.

**Methodology:** Using specific examples from payer-focused publication and communications plans, the presentation will:

- Identify and analyze common terms used for communicating clinical and economic information to determine
  - if they have multiple and/or unclear meanings
  - how they are being used to convey information
- Define the specific meaning of these terms using language that is understandable to all stakeholder audiences
- Provide examples/case studies demonstrating how more uniform and consistent definitions can be integrated into payer-focused publications.

**Results/conclusion:** An overview of the findings regarding how to address specific areas of inconsistency and potential confusion will be provided, reiterating the need for clearer and more consistent terminology.

## Sponsored reviews and supplements: current approaches and future trends

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**Background:** Industry-sponsored reviews and supplements have recently come under increased scrutiny. Such publications can be perceived as potentially biased/promotional with limited educational use to physicians. Concerns over the quality of pay-to-publish supplements, potential lack of indexing, and compliance issues surrounding distribution have also contributed to questions surrounding their value. In response to the potential drawbacks surrounding such publications, a number of pharmaceutical companies and journal editors are beginning to issue recommendations and guidelines on best practice, although, as yet, no definitive policies have been published.

**Methods:** In order to investigate the current and future role of such publications, we developed a survey aimed at publication specialists responsible for global publication plans and editors at major publication houses. Questions included: type of reviews (systematic vs. narrative, solicited vs. unsolicited); scope of review (disease state vs. product vs. product class); internal development processes (assessing need, level and disclosure of internal review) and journal requirements and policies (level of journal engagement, use of needs assessments, open access).

**Results and conclusion:** Findings from the survey together with consensus statements on current practice will be presented. In addition, we will discuss how sponsorship and journal requirements may evolve to ensure such publications meet the needs of healthcare professionals.

## Survey of conflict of interest disclosure policies of medical journals

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**Background:** Most biomedical journals require authors to disclose conflicts of interest (COI) to the reader but policies and procedures vary significantly. Because uniform policies may facilitate compliance with disclosure requirements and enhance readers' ability to utilize disclosure statements to identify potential bias in the literature, the International Committee of Medical Journal Editors (ICMJE) developed (October 2009) a template for uniform disclosure of COI. Approximately 850 journals have requested inclusion in the listed journals participating in ICMJE uniform requirements for manuscripts submitted to biomedical journals. However, journals are not required to adhere to all ICMJE recommendations.

**Purpose and objective:** To evaluate medical journals' COI disclosure policies and procedures for consistency, comprehensiveness, and ease of presentation.

**Methods:** We surveyed at random 100 medical journals from the full list of PubMed indexed journals. COI disclosure policies were then evaluated (what is disclosed and when during the submission process). We also evaluated the top three journals (by impact factor) in cardiology, diabetes, oncology, and psychiatry therapy areas.

**Results/conclusion:** COI disclosure policies and procedures remain highly variable across biomedical journals as well as the timing of when this information is collected (30% at submission/70% at acceptance). Some journals publish disclosures, including the magnitude of financial relationships (*Journal of Clinical Oncology*) while ICMJE journals do not. ICMJE will launch an updated disclosure form in April 2010 that may gain increased support. Full survey results will be presented.

## Variation in developing scientific posters: one medical communications agency's perspective

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**Background:** Universal standards for developing scientific posters do not exist.

**Purpose and objective:** To determine variations in scientific poster development within one medical communications agency working in multiple therapeutic areas with several pharmaceutical/biotechnology companies.

**Methods:** A 40-item survey was developed to collect information on scientific poster development, including format/layout, authorship/review, length, and acknowledgments. Medical directors completed separate surveys for each brand they supported.

**Results:** All brands ( $n = 13$ , representing six different companies) developed a standard poster format and bulleted style; most ( $n = 10$ ) included brand colors without logo. Abstract inclusion varied (4 'always', 4 'when requested by congress specifications', 3 'sometimes', 1 'rarely', 1 'never'). Responses regarding modification of the accepted abstract (9/12 'rarely' or 'never') or title (13 'rarely' or 'never') were fairly consistent across brands. The seven brands reporting that the methods section length they used was 'just right' indicated that, on average, methods represented 20% ( $n = 6$ ) or 10% ( $n = 1$ ) of total poster text. Most ( $n = 9$ ) agreed that including 4–6 figures/tables was ideal. First draft development by non-industry/external authors occurred 'never' ( $n = 5$ ), 'rarely' ( $n = 3$ ), or 'sometimes' ( $n = 5$ ). Inclusion of the ClinicalTrials.gov identifier varied (7 'yes', 3 'no', 3 'sometimes'). Most ( $n = 10$ ) included an acknowledgment section on all posters; nine acknowledged writing support.

**Conclusion:** While some scientific poster practices varied, all brands developed a standard poster format; most agreed on ideal figure/table numbers and acknowledged writing support. A universally agreed upon standard could enhance uniform reporting of information.