

ISMPP update

Highlights from the 6th Annual Meeting of ISMPP, Arlington, VA, USA, April 2010



Welcome to the Caudex ISMPP highlights

For their sixth annual meeting, the International Society for Medical Publication Professionals (ISMPP) moved to a new venue in Arlington, VA, USA, and on to a new theme, *Delivering Value and Driving Advocacy in Medical Publications*. As at previous meetings, the programme included a mix of the educational and the controversial, with

leaders from the industry generating debate and provoking discussion.

Once again, Caudex Medical planned to be active participants, with attendance by staff from our UK and US offices, an exhibition booth, and – for the first time – a poster presentation. Only a few days before the meeting was due to start, a volcano erupted in Iceland and the cloud of ash it produced led

to flights from Europe being cancelled. Our UK team were among the 70 or so delegates unable to get to the meeting, but the New York office flew the flag for Caudex, helped by Phil Loder from Oxford, who extended an unrelated US trip while he waited for the dust to settle.

Poster reprints are available from our Oxford and New York offices. See the back page for contact details.

Inside:

Delivering value in healthcare

Transparency: shamed into it?

Getting ready for GPP2

Advocacy and the ISMPP plan

Reaching non-physicians

Open-access publishing

Speaking out for ethics

Retracted publications

CMPP and Caudex

Journals and the pharmaceutical industry

ISMPP update

Delivering value in healthcare – the role of publications

Both patient-centred outcomes and innovative approaches to reform are key factors in making effective changes to the healthcare system in the USA, and medical publishing professionals have a key role to play in making these things happen. These were the main messages delivered by Dr Mark McClellan in his keynote address.

Among his other roles, Dr McClellan is the director of the Engelberg Center for Health Care Reform, which aims to provide practical solutions to achieve high-quality, innovative, affordable healthcare in the USA. He is also a former administrator of the US Centers for Medicare and Medicaid Services, and a former commissioner of the US Food and Drug Administration. Bringing this experience to bear, Dr McClellan briefly reviewed President Barack Obama's recent healthcare reform bill, and emphasized that fresh thinking and approaches would be key factors in achieving effective reform. "Expanding insurance coverage and squeezing prices won't do it," he said, continuing to explain that healthcare policy reform has to be linked with reform in real healthcare.

Healthcare policy reform has to be linked with reform in real healthcare

There needs to be better support for healthcare professionals when they take steps to improve quality of care, recommended Dr McClellan, stressing that healthcare reforms over recent years have focused on saving Medicare money, while healthcare professionals have been unsupported. He suggested that, with a greater focus on patient outcomes, payments would be based on the effectiveness of care.

There needs to be better support for healthcare professionals when they take steps to improve quality of care

Drawing his arguments together to focus on medical publications, Dr McClellan concluded that biomedical publishing plays a vital role in contributing evidence to the ongoing

debate around delivering value in healthcare. In his view, it will be essential to publish studies addressing practical questions relevant to healthcare, such as assessment of new payment systems and comparative effectiveness of alternative medical practices, treatments and policies. Dr McClellan believes there will continue to be a core role for medical publications in helping doctors to understand how they can treat their patients better.

Biomedical publishing plays a vital role in contributing evidence to the ongoing debate around delivering value in healthcare

ISMPP update

Shamed into transparency: is it the right way?

Promoting transparency must translate into promoting meaningful disclosure, stated David Verbraska as he opened his keynote presentation on the second day of the conference. Meaningful disclosure is an ethical obligation; there are evolving expectations of transparency in the pharmaceutical industry, he continued, and we need to be proactive, not shamed or legislated.

Meaningful disclosure is an ethical obligation

Mr Verbraska is Vice President of Worldwide Regulatory Policy and Intelligence at Pfizer Inc., and he emphasized that while the industry has made a start, there is still more to do. He went

on to comment that an understanding of the different audiences for whom medical communications are targeted, from patients and physicians, through to researchers, journal editors and industry competitors, is fundamental to meaningful disclosure; that the information should be in a format that is comprehensive, accessible and audience-specific. He highlighted the example of a follow-up communication to participants in a clinical trial in which the results of the trial were explained in lay language.

Information should be in a format that is comprehensive, accessible and audience-specific

Getting ready for GPP2 – Caudex responds to the challenge

In 2007, the Caudex Medical acknowledgements policy was presented at ISMPP and attracted wide interest. When plans to update the provisions for Good Publication Practice (GPP) were announced, we wanted to be sure that we remained at the forefront of ethical practice in publication planning.

Draft provisions for GPP2 were presented at ISMPP in April 2009. While waiting for the final guidance to be published, we made sure that we would be ready to implement GPP2 from the start. Our actions, including a full revision of our standard operating procedures, preparation of draft documentation, and staff training and mentoring, were detailed in a poster presented on Monday, 19 April 2010. To help our clients adapt their working practices for GPP2, we also created a training workshop for publication departments.

Mr Verbraska also represents Pfizer Inc. at IFPMA (at an international level) and at PhRMA (in the USA), and he presented an overview of the new IFPMA clinical trial portal. The portal brings together clinical trial information from around the world in an accessible and understandable format. He explained that GlaxoSmithKline and Lilly had led the way about 6 years ago in developing company clinical trial registries, but the IFPMA portal is a significant step forward because, at present, clinical trial data are scattered among a number of international, national and regional portals across the globe.

Looking to the future, Mr Verbraska forecast the necessity for more transparency – if not delivered proactively, then driven by legislative initiatives in development. However, a question from the audience remained unanswered as to the balance between transparency and revealing intellectual property.

The goal of transparency

To provide meaningful information and insight that enables patients to have informed conversations with their physicians about healthcare treatment options

ISMPP update

Stepping up to advocacy – the ISMPP plan

Advocacy is the pursuit of influencing outcomes, began the 'Advocacy Guru', Stephanie Vance, drawing on her experience of advocacy activities around the US Congress. She went on to explain that advocacy is distinct from education, in that the individual is generally asking for something rather than just passing on information, and as with building any relationship, it is best to start with a small 'ask'. She stated that assessing the relevance of requests to the individual(s) you are aiming to influence or asking to help you is important, as well as building trust, and also noted that persistence and effective follow-up are essential to successful advocacy.

Focusing on ISMPP, Ms Vance explained that advocacy is what the organization needs to concentrate on in order to move forward on issues. She continued, "It's great for ISMPP to get together to discuss the issues facing the industry, but advocacy will be key to making changes happen. As individuals, ISMPP members have the power to make a difference and speak out for this industry."

As individuals, ISMPP members have the power to make a difference and speak out for this industry

We want to build a long-term plan for ISMPP, explained Julia Ralston, the new ISMPP President, and this will include an advocacy plan. ISMPP represents all the stakeholders across the medical publication process, she continued and, while ISMPP has been establishing itself over the past 5–6 years, the focus has been on education rather than advocacy. She went on to say, "As advocacy has always been part of the ISMPP mission, we now want to plan and execute an advocacy plan in support of the membership and the profession in general. Support materials on core topics are planned for members, and a range of tactics is being assessed for the ISMPP organization to use for their advocacy communications."

Advocacy has always been part of the ISMPP mission

Ms Ralston concluded by highlighting that in the recent ISMPP membership survey, 80 out of 101 respondents had said that they were willing to act as advocates; a significant and encouraging show of support. She hoped that as delegates returned from the conference,

they would have the confidence to begin advocating for their profession, and spreading the word to colleagues.

Key reasons for ISMPP advocacy

- To establish a leadership position for the profession in public
- To correct perceptions surrounding the role of publication professionals, particularly in recent press
- To communicate that we act appropriately and are compliant with professional standards, thereby playing a significant role in ensuring the integrity of medical literature
- To tie our advocacy efforts to the education efforts aimed at raising standards in our profession
- Because we are caring, proud professionals

ISMPP update

Publications for non-physician healthcare providers

As medical care service needs continue to grow, physicians increasingly rely on their non-physician colleagues (nurse practitioners [NPs], pharmacists and physician's assistants [PAs]). Streamlined publications that specifically address their educational needs have, therefore, become increasingly required. Effective publications targeting the non-physician provider were discussed, in turn, by David Mays (Pharmacist), James Crawley (PA) and Frances Rankin (NP).

Pharmacists may consider their role as one of education, and are often the primary point of contact for patients. Publications discussing shared experiences that compare new therapeutic options with landmark therapies, and manuscripts challenging industry articles regarding a particular product, are valued. Pharmacists tend to be particularly concerned with disclosures and industry sponsorships, with a view to avoiding bias of opinion where possible. Interpretive pieces, critiques, best practices, consensus panel articles and experiences working in collaborative practices are particularly valued by pharmacists.

The role of PAs spans all practice settings and specialties; in particular, orthopaedics, cardiothoracic surgery and emergency medicine. PAs have a dual identity; not only are they healthcare providers, but they also share aspects of their training and practice with physicians. In addition to PA-specific journals, they often read the same journals as their physician colleagues and employers. Information regarding original clinical research is gathered from traditional medical journals, and PA-specific journals provide valuable clinical review articles and case studies.

Nurse practitioners are embedded in the patient setting in which they diagnose, manage, treat and look for improved patient outcomes. Two-thirds of NPs are in the primary care setting. NPs can prescribe medicines and, in rural settings, are sometimes the only providers a patient will see. Publications are, therefore, vital for the NP in disseminating information about guidelines, current practice, strategies, clinical trial results and pharmaceutical treatments. NPs have a particular interest in policy implication, cost effectiveness, patient teaching and adherence. Both NP-specific journals and general medical journals are valuable sources of information for research studies, case studies and practice-focused literature reviews.

Open-access publishing: new developments driving value

As Deborah Kahn was among those stuck in Europe because of the volcanic ash, Natasha Bailey was kind enough to give her presentation on her behalf, which focused on recent trends in open-access publications and the value open access can add to clinical publications. From 2005 onwards, submissions to open-access journals, available via Hindawi, BioMed Central and the Public Library of Science, have rapidly increased. Online open-access publications allow virtually unlimited supplementary files, easy linking to data repositories, and information on trial registration and protocol. To medical publication planners, online open access allows greater visibility for clinical research in a new venue, with faster and wider dissemination of the clinical data important for patients and physicians, and the potential for increased transparency – ultimately maximizing the impact and pace of research and sharing of research results.

ISMPP update

Publications soapbox: speaking out for ethics

Professor Karen Woolley and Dr Donald Samulack donned town crier and hunchback outfits, respectively, to facilitate the inventive ‘Soapbox’ and ‘Blackbox’ session, a new format for the ISMPP conference. The soapbox component provided an outlet for speakers who are especially passionate about hot topics affecting the profession, whereas the Blackbox part allowed past presidents of the American Medical Writers Association (AMWA) and ISMPP to highlight the great ideas coming from these organizations on similar topics. PowerPoint® slides were banned, 5 minutes was the time limit, so it was stand up, speak up and sit down!

Dr Kirby Lee, from the University of California at San Francisco, took to the soapbox to highlight the practice of selective reporting – ‘cherry picking’ results so that there is a discrepancy between the information published and the original protocol. Dr Lee emphasized that selection had also been seen in articles from academia, and both governmental and non-governmental organizations.

Journal editors were the target as Dr Larry Hirsch (Becton Dickinson Medical) stepped forward; specifically those with bias against the pharmaceutical industry. Journal editors have

a lot of power, he explained, and they should do their job in a neutral and objective manner. ‘Conflict of interest’ information has morphed from a factual state of affairs to ‘guilty until proven innocent’. ‘Competing interests’ or ‘multiple interests’ might be better terminology.

Journal editors ... should do their job in a neutral and objective manner

ISMPP does not support selective reporting, began ISMPP’s Gene Snyder, and he also agreed that journal editors should be neutral and objective in fulfilling their roles. He then highlighted the key initiatives that ISMPP has taken in this area, such as the Code of Ethics, GPP2, and the Medical Publishing Insights and Practices project, developing a bridge between journal editors and the pharmaceutical industry. Concluding, Mr Snyder emphasized that ensuring the integrity of the medical literature must be everybody’s ultimate goal.

Last to take the stage was Cindy Hamilton from AMWA, who described the development of their organization’s code of ethics, originally written in

1973. The ethics module is a compulsory component of all AMWA certificates, and members must read the code each year before signing their membership renewal.

Key questions from the speakers at the end of their talks

Dr Lee: *Does your organization have a formal policy that requires consistency in reporting the primary and secondary outcomes listed in the clinical trial protocol with those in the manuscripts?*

Mr Snyder: *Based on what you have heard, do you have what you need to advocate, within your organization or with your stakeholders, and ensure sound and ethical publication practices?*

Ms Hamilton: *Does your organization routinely evaluate personnel to ensure they are aware of, and adhere to, current ethical publication practices?*

ISMPP update

The involvement of medical writers and the pharmaceutical industry in retracted publications: round up the usual suspects?

“Round up the usual suspects,” says Captain Renault to his subordinates near the end of the classic film, *Casablanca*. By saying this he diverts attention from Humphrey Bogart’s character, who has just shot the ‘bad guy’. The ‘usual suspects’ are, of course, already known to be felons, and sometimes medical publications professionals feel that precisely that judgement has already been made about them. For example, “It is now fairly well known that pharmaceutical companies launder their promotional efforts through medical communications companies that ghost write articles and then pay ‘Key opinion leaders’... to affix their signatures to the fraudulent articles...” (McHenry L. *Ethical Issues in BioMedicine* 2008; 6:146–56).

In order to determine the validity of this statement for the first time, Professor Woolley and ProScribe Medical Communications investigated the proportion of retracted publications, particularly those retracted for misconduct, which involved medical writers or pharmaceutical industry sponsorship.

In the analysis of retracted publications spanning 1966–2008 (in English), it was found that 92% of all retractions (n=463) and 96% of retractions

for misconduct (n=213) were from non-pharmaceutical sources. Publications involving pharmaceutical companies or medical writers were responsible for only 8% and 5% of all retractions, and only 4% and 1% of retractions owing to misconduct, respectively. When medical writers and pharmaceutical companies partner for manuscript development, less than 1% of all retractions, and no retractions owing to misconduct, were found. As the odds of retraction for misconduct are 6.23-fold and 3.74-fold higher when a medical writer or

industry sponsorship, respectively, are not involved, it is reasonable to ask why industry is considered guilty until proven innocent.

Manuscripts developed by collaboration between medical writers and pharmaceutical companies accounted for less than 1% of retracted manuscripts

CMPP success for Caudex

We are delighted to announce the success of all Caudex Medical staff members who sat the Certified Medical Publications Professional (CMPP) exam in March 2010:

- Carol Cooper
- Polly Field
- David Gibson
- Catherine Kidd
- Jackie Marchington
- Nikki West

The CMPP credential was introduced by ISMPP in 2009 to establish professional standards and promote adherence to Best Practice in publication planning.

In line with our commitment to the highest standards in publication planning, Caudex Medical continues to support CMPP and looks forward to announcing more successful candidates in the future.

ISMPP update

Journals and the pharmaceutical industry

In the increasingly regulated environment, a full understanding of the roles of the pharmaceutical industry and medical publication professionals is essential to bridge the gap that exists between industry and medical journals. Drs Rita Redberg and Jeffrey Susman, editors of the *Archives of Internal Medicine* and *The Journal of Family Practice*, respectively, discussed their perspectives of the good, the bad and the ugly in industry and peer-reviewed journals.

The pharmaceutical industry provides high-quality clinical research and information in publications aimed at medical professionals and patients. Medical journals and journal editors aspire to changing practices and improving patient health. Journal editors are primarily concerned with ensuring objectivity and scientific accuracy. Any conclusions that appear insufficiently supported by the data presented may suggest a bias in data interpretation.

The key role for medical publication professionals is to get research studies published and widely accessible to the public. Medical writers bring valuable writing skills that can help to bridge the gap between industry and journals, but an accurate portrayal of the data is essential, alongside full disclosure statements and a clear indication of the author- and contributor-specific roles in the development of the manuscript, drafting of the initial article, data interpretation and analyses.

Caudex Medical: leaders in good publication practice

The Caudex team who participated in the ISMPP meeting in Arlington, VA, were Dana Fox, Bindhu Gopalan, Phil Loder and Janet Shaw. If you have feedback or questions, or would like to discuss how we could assist you with your communication, publication planning and medical writing needs, please feel free to get in touch with your regular Caudex contact, or Phil Loder in the UK (philip.loder@caudex.com) and James Karcher in the USA (james.karcher@caudex.com). For more details of our other areas of expertise, such as key expert engagement and international meetings management, please see our website at www.caudex.com.

This publication was produced by Caudex Medical – please feel free to forward it to your colleagues for their information. The opinions expressed are not necessarily those of ISMPP or the presenters.

© 2010 Caudex Medical Ltd and Caudex Medical Inc.

WESTWAY HOUSE • ELMS PARADE • BOTLEY • OXFORD • OX2 9JW • UK
TEL: +44 (0) 1865 254300

111 EIGHTH AVENUE • SUITE 723A • NEW YORK • NY 10011 • USA
TEL: +1 212 462 7820