GPP3 IN THE AP: WE CAN GET THERE FROM HERE!

Moderator: Rebecca A. LEW, ISMPP CMPP™

Interviewer: Professor Karen L. WOOLLEY, ISMPP CMPP™
THANK YOU TO ALL ATTENDEES… WHEREVER YOU MAY BE!

- Ni hao
- Chao
- Konnichi wa
- Kia ora
- Lei hou
- Selamat siang
- Selamat tengahari
- Annyeong haseyo
- Kumasta kayo
- Namaste
- Hello
- Sawatdee kah
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• ISMPP (not-for-profit)
  - > 1300 members
  - Write, plan, edit, publish, peer-review, research . . .

• Education
  - Webinars (Asia-Pacific, international)
  - Conferences (including in the AP region in 2015)

• International certification
  - Certified Medical Publication Professional (CMPP™)
    • Next application deadline = 1 February 2015
    • Testing centres = 62 in Asia-Pacific region!
    • Increasing CMPP™ professionals in Asia-Pacific region
• Join your colleagues – join ISMPP!

FIND OUT MORE…
www.ismpp.org
DISCLOSURES

• Financial
  - Employee of the Envision Pharma Group (we provide publication planning and medical writing services to for-profit and not-for-profit clients around the world)
  - Director, Sunshine Coast Hospital and Health Services Board (Government appointment; we employ 4,500 healthcare professionals)
  - Professor, University of Queensland, Australia
  - Professor, University of the Sunshine Coast, Australia

• Nonfinancial
  - ISMPP Trustee and Chair of ISMPP’s Asia-Pacific Advisory Committee
  - GPP3 Steering Committee Member; GPP2 Reviewer
 ABOUT THE TITLE... GPP3

Good Publication Practice 3
(aiming for publication in 2015; NOT finalized yet!!)

Vision

Good publication practice embraces all the procedures and practices that are necessary for planning, publishing and communicating research and scholarship supported by pharmaceutical, medical device and biotechnology companies within a framework of scientific integrity

Core Values

GPP3 will continue to focus on GPP (2003) and GPP2 (2009) core values
Integrity, Completeness, Transparency, Accountability, Responsibility
ABOUT THE TITLE… “HERE”

There

Here (wherever you may be)

Good Publication Practice 3 (aiming for publication in 2015)

GPP2 expert in AP (or elsewhere)

Familiar with GPP2

Not aware of GPP2
ABOUT THE FORMAT

1. Authorship
2. Disclosures
3. Professional medical writers
4. All clinical trial results

Interview
(slides as a resource for all, especially English-as-second language listeners)

Your questions
ABOUT OUR EXPERTS

Dr Anita JAIN  
BMJ India  
Editor perspective

Dr Takako KOJIMA  
Tokyo Medical University  
Academic perspective
DISCLOSURES

• Anita Jain
  • I am a full-time employee of The BMJ
  • With respect to this presentation, I have no other relevant competing interests

• Takako Kojima
  • I am a full-time teaching staff member at the Department of International Medical Communications, Tokyo Medical University
  • I am a paid consultant for Ronbun.jp, a website run by Taiho Pharmaceuticals Ltd., for materials on authorship and publication ethics
  • The opinions expressed in this presentation are the personal views of the speakers and do not represent the views of their employers or ISMPP
MORE EXPERTS
“GPP3 IN THE AP CHAMPIONS”

ISMPP Leadership Summit (Tokyo; August 25-26, 2014).

ISMPP Leadership Summit (Beijing; August 28-29, 2014)
*Front row (L-R):* LI Yang Li, Li Li, WU Kai-run, WEIGEL Al, SUN Ping SUN, CAMPBELL Nick, MIAO Charley. *Second row (L-R):* YANG Rui, HU Jason, SHAO Bruce, NEWMAN Julie, WANG Xiaoling, DONG Haijun (Lou), CHEN Huili, ZHANG Joanna, MAO Jingmei, KOJIMA Yuko.
1. AUTHORSHIP
AP AUTHORS COLLABORATING

Increasing International collaboration in prestigious journals

Nature Publishing Index 2013 Asia Pacific
1. AUTHORSHIP
GPP3 AND THE 4TH CRITERION

The ICMJE recommends that authorship be based on the following 4 criteria:

- Substantial contributions to the conception or design of the work; or the acquisition, analysis, or interpretation of data for the work; AND

- Drafting the work or revising it critically for important intellectual content; AND

- Final approval of the version to be published; AND

- Agreement to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

MUTUAL trust among all authors!

WHAT IMPACT DO YOU THINK THIS FOURTH CRITERION WILL HAVE ON INTERNATIONAL COLLABORATION WITH AUTHORS FROM THE AP REGION?

• Hard to determine if the fourth criterion will promote international collaboration or not

• A more definite definition of authorship is necessary

• Many Japanese and international researchers afraid to collaborate because of difficulty verifying authorship

• Need for increased education on authorship in Japan
WHAT DO YOU THINK AUTHORS AND COMPANY SPONSORS IN OUR REGION COULD DO TO HELP BUILD TRUST WITH INTERNATIONAL COLLABORATORS AND TO ENSURE THE FOURTH CRITERION CAN BE MET?

• International collaborations are essential
• Mutual benefits and mutual investment
• COMMUNICATE
• Clear framework for project roll-out, data sharing, and publications
• Open and democratic discussions about authorship at every stage
The ICMJE recommends that authorship be based on the following 4 criteria:

- **Substantial contributions** to the conception or design of the work; or the acquisition, analysis, or interpretation of data for the work; AND

- Drafting the work or revising it critically for important intellectual content; AND

- Final approval of the version to be published; AND

- Agreement to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

WHAT ADVICE DO YOU GIVE AUTHORS IN TERMS OF WHAT THEY NEED TO DO TO MAKE A “SUBSTANTIAL CONTRIBUTION”?

• The term ‘substantial’ is vague; should be given a certain definition to help authors

• ‘Substantial’ contribution = without that substantial contribution, the conclusion of the study would be different
WHAT ADVICE WOULD YOU GIVE ABOUT WARNING AUTHORS (ESP. IN VERY SENIOR POSITIONS) THAT PROVIDING FUNDING OR RECRUITING MANY PARTICIPANTS IS NOT ENOUGH TO MEET ALL FOUR AUTHORSHIP CRITERIA?

- Greatly affected by culture and environment, with possible negative consequences for authors
- Should encourage journals to proactively ask if last author or corresponding author meet authorship criteria
- If not, journals should have sanctions that are internationally agreed on
- Need to continue educating authors about authorship
  - Our experience at Japanese medical schools
1. AUTHORSHIP
GPP3 AND AVOIDING GHOSTS AND GUESTS

COMMENTARY

Time to Finger Point or Fix? An Invitation to Join Ongoing Efforts to Promote Ethical Authorship and Other Good Publication Practices

Karen L. Woolley, Art Gertel, Cindy W Hamilton, Adam Jacobs, Gene P Snyder. the Global Alliance of Publication Professionals

As leaders of the noncommercial Global Alliance of Publication Professionals (GAPP; www.gappgroup.org), we advocate for ethical publication practices, both in industry- and nonindustry-sponsored research. In particular, we support professional medical writing and condone ghostwriting, ghost authorship, and guest authorship. We welcome the opportunity to comment on Fishbeyn’s article, “Ghost- and Guest-Authored Pharmaceutical Industry-Sponsored Studies: Abuse of Academic Integrity, the Peer Review System, and Public Trust,” and we invite readers to join ongoing efforts to promote ethical publication practices.

An Important Topic...and a Different Perspective

Fishbeyn focuses on an important issue, but readers deserve the opportunity to evaluate this topic from different perspectives. Fishbeyn offers one, and GAPP offers another. Relevant to providing readers with direct insights into current industry publication practices, we work with academic authors and sponsors to ethically and efficiently prepare manuscripts for peer-reviewed journals. Unlike Fishbeyn, we abhor ghost and guest authorship. We are concerned, however, that Fishbeyn may not have direct and recent experience with publishing industry-sponsored research. We do. We recognize that no single article can address every issue and it is challenging to include all pertinent evidence. Nevertheless, Fishbeyn did not identify several current and influential guidelines affecting industry publication practices and did not cite recent evidence indicating where unethical practices may be most (or least) likely to occur. We trust that our commentary can complement, extend, and challenge the issues raised by Fishbeyn and, in so doing, provide readers with a more balanced overview of this topic.

Ultimately, patients, health care professionals, and payers need access to important and timely information generated by industry-sponsored research, but they must also be able to trust this information. Enhancing industry publication practices helps build this trust. As readers of The Annals would be aware and, as reinforced in a recent JAMA editorial, “Many of the great breakthroughs in medicine over the past 20 years are a result of the irreplaceable commitment to and investment in research by the pharmaceutical industry.”

Table 1. Unethical Authorship Practices

<table>
<thead>
<tr>
<th>Type of Contributor</th>
<th>Authorship Criteria Met</th>
<th>Identified in Manuscript</th>
<th>Definition</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ghost author</td>
<td>Yes</td>
<td>No</td>
<td>Contributor meets authorship criteria but is not listed as an author</td>
</tr>
<tr>
<td>Ghostwriter</td>
<td>No</td>
<td>No</td>
<td>Contributor does not meet authorship criteria but involvement is not disclosed (i.e., not listed in acknowledgments)</td>
</tr>
<tr>
<td>Guest author (or gift or honorary author)</td>
<td>No</td>
<td>Yes (as an author)</td>
<td>Person does not meet authorship criteria but is listed as an author; person may or may not have made a contribution to the manuscript; authorship is “given” rather than earned</td>
</tr>
</tbody>
</table>

*Ghostwriters are not the same as professional medical writers. Professional medical writers disclose their involvement and funding source (usually in the acknowledgement section) and adhere to ethical publication practices throughout the manuscript development process.*

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ISMPP GPP3 in the AP
WHAT IS YOUR VIEW ON THE INVOLVEMENT OF COMPANY EMPLOYEES IN PRESENTATIONS AND PUBLICATIONS? DO YOU THINK THERE SHOULD BE A LIMIT ON THE NUMBER OF AUTHORS, PARTICULARLY THOSE FROM THE COMPANY AND WHERE SHOULD THEY BE POSITIONED, IN YOUR VIEW, IN THE ORDER OF THE AUTHORS?

- Written publication agreements between company sponsors and investigators that conform to good publication practice
- ICMJE authorship criteria to be employed consistently for all contributors including investigators, sponsor employees, and individuals contracted by the sponsor
- Contributorship and acknowledgements to specify role of the sponsor

http://www.bmj.com/content/bmj/339/bmj.b4330.full.pdf
Management of severe sepsis in patients admitted to Asian intensive care units: prospective cohort study

Jason Phua, consultant¹, Younsuck Koh, professor², Bin Du, professor³, Yao-Qing Tang, professor⁴, Jigeeshu V Divatia, professor⁵, Cheng Cheng Tan, consultant⁶, Charles D Gomereall, professor⁷, Mohammad Omar Faruq, professor⁸, Babu Raja Shrestha, consultant⁹, Nguyen Gia Binh, consultant¹⁰, Yaseen M Arabi, associate professor¹¹, Nawal Salahuddin, associate professor¹², Bambang Wahyuprajitno, consultant¹³, Mei-Lien Tu, respiratory therapist¹⁴, Ahmad Yazid Haji Abd Wahab, consultant¹⁵, Akmal A Hameed, consultant¹⁶, Masaji Nishimura, professor¹⁷, Mark Procyzhyn, respiratory therapist¹⁸, Yiong Huak Chan, biostatistician¹⁹ for the MOSAICS Study Group

Footnotes

The MOSAICS Study Group


We thank all staff in the intensive care units and hospitals that participated in this study.

Contributors: JP and YK conceived the study. All authors participated in the design of the study. YK, BD, Y-QT, JVD, JP, CCT, CDG, MOF, BRS, GBN, YMA, NS, BW, M-LT, AYHAW, AAH, and MN coordinated patient enrolment and data collection for their respective countries. MP managed the data collection website. JP and YHC performed the statistical analyses. JP and CDG wrote the first draft of the report. All authors revised the text and approved the final version of the report. All authors had full access to all of the data (including statistical reports and tables) in the study and can take responsibility for the integrity for the data and the accuracy of the data analysis. YK is guarantor.
WHAT ARE SOME OF THE RISKS THAT COULD BE ASSOCIATED WITH A COMPANY GIVING MONEY TO AUTHORS WHO PREPARE A MANUSCRIPT ABOUT THAT COMPANY’S PRODUCT?

- Company reputation as “buying” positive views
- Positive aspects over-emphasized in a paper
- Authors would be afraid to be associated with that company
- Important for authors to disclose ALL interests for public trust
WHAT DO YOU THINK ABOUT PAYING AUTHORS TO PUBLISH COMPANY-SPONSORED RESEARCH AND WHAT WOULD YOU WANT TO SEE IN THE DISCLOSURES STATEMENT ABOUT SUCH PAYMENTS, IF THEY OCCURRED?

• ICMJE: Disclosure of Potential Conflicts of Interest

“report all sources of revenue relevant to the submitted work that accrued either directly to you or were paid to your institution on your behalf over the 36 months prior to submission of the work. This should include all monies from sources with relevance to the submitted work, not just monies from the entity that sponsored the research. Please note that your interactions with the work’s sponsor outside the submitted work should be listed here.”

http://www.icmje.org/conflicts-of-interest/
DISCLOSURE OF PAYMENTS

- Favour greater, rather than lesser, disclosure
- All articles submitted to journals
- Abstracts, posters, and oral presentations at conferences
2. DISCLOSURES
GPP3 AND COMPLETE TRANSPARENCY

• **Term = Disclosure**

• Rather than conflict of interest or competing interest
WHAT SHOULD OUR LISTENERS DO IF AN EDITOR WANTS TO REMOVE A DISCLOSURE STATEMENT OR APPEARS TO JUDGE A MANUSCRIPT BASED PRIMARILY ON DISCLOSURE OF COMPANY SUPPORT?

• Write to the journal editors

• Editors and peer reviewers also responsible for disclosure

• COPE (Committee On Publication Ethics): Journal editors are accountable for adhering to best practice standards and providing an unbiased review

WHAT SHOULD OUR LISTENERS DO IF THEY THINK THAT AN AUTHOR MAY HAVE OTHER RELATIONSHIPS THAT THEY HAVE NOT DISCLOSED?

• Problems with disclosure are common everywhere, not just Japan, and are greatly affected by culture and tradition

• Japanese journals are eager but inexperienced in handling disclosure problems. *(Do you make it obligatory for members of the editorial committee of your journal to make COI disclosures when they are appointed? ⇒ obligatory: 49.6%; not obligatory: 47.9%; NR: 2.5%)*¹

• Authors should contact the editor-in-chief (even anonymously) of suspicious cases, and other organizations that deal specifically with publication ethics

FROM YOUR INTERACTIONS WITH EDITORS, INTERNATIONALLY AND IN OUR REGION, WHAT IMPRESSION DO YOU THINK EDITORS HAVE WHEN AUTHORS DISCLOSE (APPROPRIATELY!) MEDICAL WRITING SUPPORT–IS IT SEEN AS A SIGN OF WEAKNESS?

• Need to foster understanding of the role of medical writers
• Greater emphasis on training medical writers in accepted standards of publishing
• If authors use writing support, they should disclose the writer’s name, affiliation, and funding source as per GPP2 (BMJ 2009)
IF DISCLOSURES ARE NOT DONE PROPERLY, WHAT DAMAGE COULD OCCUR TO COMPANY REPUTATIONS AND THE RELATIONSHIPS COMPANIES MIGHT HAVE WITH EDITORS AND AUTHORS?

• Will create concern and suspicion at all 3 levels:
  − Author
  − Editorial
  − General public/patients

• Reliability of future results in jeopardy
IF DISCLOSURES ARE NOT DONE PROPERLY, WHAT DAMAGE COULD OCCUR TO COMPANY REPUTATIONS AND THE RELATIONSHIPS COMPANIES MIGHT HAVE WITH EDITORS AND AUTHORS?

- Undermines public trust in medical research
- Perpetrates suspicion and confusion
3. PROFESSIONAL MEDICAL WRITERS
GPP3 – AUTHORS, SPONSORS, WRITERS
(NO GHOSTWRITERS!)

MAY have lower odds of retraction for misconduct

Publications retracted (1966-2008) N = 463; misconduct n= 213, 46%

3. PROFESSIONAL MEDICAL WRITERS
GPP3 – AUTHORS, SPONSORS, WRITERS
(NO GHOSTWRITERS!)

MAY have better adherence to reporting guidelines

Jacobs A. Adherence to the CONSORT guideline in papers written by professional medical writers. EMWA Journal The Write Stuff. 2010; 19(3):196-200
Faster by ≈ 50 days

Faster by ≈ 30 days

Declaration of Medical Writing Assistance in International, Peer-Reviewed Publications and Effect of Pharmaceutical Sponsorship
Karen Woolley,¹,² Julie Ely,² Mark Woolley,² Felicity Lynch,² Jane McDonald,¹ Leigh Findlay,² and Yoonah Choi²

http://www.ama-assn.org/public/peer/program.html (ProScribe Medical Communications); Australia and Japan
WHAT IF AN AUTHOR EXPECTS THE WRITER TO DRAFT A MANUSCRIPT WITHOUT SUBSTANTIAL INPUT FROM THE AUTHOR FROM THE START, FOR EXAMPLE, AT THE OUTLINE STAGE?

• Educate authors about the importance of maintaining the integrity of the ‘Golden Triad’ of authors, societies, and publishers

• Need for authors and medical writers to define the roles and responsibilities at the beginning of planning a research project

• Lack of in-house professional medical writers available at Japanese medical institutions

• Important to educate researchers on how to work ethically with professional medical writers; distinguish from medical editors
3. PROFESSIONAL MEDICAL WRITERS
KNOWLEDGE OF ETHICAL GUIDELINES

MAY have stronger knowledge than authors

Five-step authorship framework to improve transparency in disclosing contributors to industry-sponsored clinical trial publications

Marušić et al. BMC Medicine 2014, 12:197
http://www.biomedcentral.com/1741-7015/12/197

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HOW ELSE DO YOU THINK WE CAN HELP AUTHORS IN OUR REGION TO BECOME AWARE OF AND ADHERE TO ETHICAL GUIDELINES?

• International research collaborations have a role

• Foster initiatives to build research capacity

• Networks: Asia-Pacific Association of Medical Editors, AuthorAid

• The BMJ Research Methods & Reporting section
  http://www.bmj.com/research/research methods %26amp%3B reporting

• Individual responsibility
4. ALL CLINICAL TRIAL RESULTS
GPP3 AND RESULTS (POSITIVE OR NEGATIVE)

30. Authors, editors and publishers all have ethical obligations with regard to the
publication of the results of research. Authors have a duty to make publicly available
the results of their research on human subjects and are accountable for the completeness
and accuracy of their reports. They should adhere to accepted guidelines for ethical
reporting. Negative and inconclusive as well as positive results should be published or
otherwise made publicly available. Sources of funding, institutional affiliations and
conflicts of interest should be declared in the publication. Reports of research not in
accordance with the principles of this Declaration should not be accepted for
publication.

36. Researchers, authors, sponsors, editors and publishers all have
ethical obligations with regard to the publication and dissemi-
nation of the results of research. Researchers have a duty to make publicly available the results of their research on human subjects and are accountable for the completeness and accuracy of their reports. All parties should adhere to accepted guidelines for ethical reporting. Negative and inconclusive as well as positive results must be published or otherwise made publicly available. Sources of funding, institutional affiliations and conflicts of interest must be declared in the publication. Reports of research not in accordance with the principles of this Declaration should not be accepted for publication.
WHY DO YOU THINK IT IS SO CHALLENGING FOR RESEARCHERS TO PUBLISH ALL CLINICAL TRIAL RESULTS?

- Selective publication is a concern: Scientific community needs to address it cohesively
- All Trials Campaign
WHY DO YOU THINK IT IS SO CHALLENGING FOR RESEARCHERS TO PUBLISH ALL CLINICAL TRIAL RESULTS?

• Supply and demand
  • Positive results accepted more by journals
  • Authors cannot be blamed for wanting to focus on positive results

• Changes need to start with journals
  • Electronic databases to provide enough space for negative results
YOUR QUESTIONS?

1. Authorship
2. Disclosures
3. Professional medical writers
4. All clinical trial results

Interview
(slides as a resource for all, especially English-as-second language listeners)

Your questions
REMINDER...
HOW TO ASK A QUESTION

I can type my question here – only the moderator and speakers can see it.
Asia Pacific Educational Events in 2015

- Four more free webinars, starting in February
  - Topics for 2015 currently being decided – your input is welcome!

- A 1-day conference in Tokyo and a 1-day conference in Beijing, most likely in early September
  - Building on the success of the innovative Leadership Summits
  - Authors, editors, publishers, government, industry, publication professionals (reserve time and budget now!!)
  - Meet in person to discuss publication practices in the AP region
  - Sponsorship opportunities will be available

- More information on these events will be distributed soon
Asia Pacific Educational Task Force 2014

- Julie Newman (Chair)
- Tim Collinson
- Balaji Ganesan
- Rebecca Lew
- Bruce Shao
- Kanaka Sridharan
- Eric Yu

Looking for new members in the region for 2015
THANK YOU FOR ATTENDING!

• We hope you enjoyed today's presentation

• Please complete a 2-minute survey that ISMPP will load to your browser in just a moment (after the webinar has ended)

• Your feedback will help us develop future educational events for the Asia-Pacific region