BACK TO BASICS: UNDERSTANDING PUBLICATION ETHICS

**Moderator:** Rebecca A. Lew, PhD, ISMPP CMPP™

**Presenters:** Jake Burrell, PhD, ISMPP CMPP™
Bao-cheng Liu, PhD
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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 Asia-Pacific region

International certification
- Certified Medical Publication Professional (CMPP™)
  - Next application deadline = 1 August 2016
  - Testing centres = 62 in Asia-Pacific region!
  - Increasing CMPP™ professionals in Asia-Pacific region
• Join your colleagues – join ISMPP!
ISMPP ANNOUNCEMENTS

• Registration is open for ISMPP’s 12th Annual Meeting, April 11-13, 2016, Gaylord National Resort & Convention Center, National Harbor, MD; *early bird registration ends March 9!*

• If you’re interested in registering for a workshop at the Annual Meeting, sign up now—seating is limited, and popular offerings fill up fast.

• Follow ISMPP on [Twitter (@ISMPP)](https://twitter.com/ISMPP) and check out ISMPP’s [LinkedIn Group Page](https://www.linkedin.com/groups/15196036).

• Presentations from the 2016 European Meeting of ISMPP are now available in the Archives ([www.ismpp.org/annual-meeting-archive](http://www.ismpp.org/annual-meeting-archive)).

• Good luck to those taking the CMPP examination in March!
• The 2016 Asia-Pacific Educational Task Force webinars will go “Back to Basics”

• Four free webinars planned:
  1. Understanding Publication Ethics (today)
  2. Understanding Encores and Translations
  3. Understanding Authorship Requirements
  4. Understanding the Role of the Professional Medical Writer
QUESTIONS...

• Questions will be addressed at the end of the webinar.
• To ask a question, please type your query into the Q&A box
  • To ensure anonymity and that all panelists receive your question, please choose the drop down box option, *"Hosts, Presenters and Panelists."* Otherwise, all audience members will be able to see your submitted question
  • Because of the nature of this presentation, we may not be able to respond to all questions about research by faculty on whom we are reporting, but we will be happy to reach out to them later with your queries

NOTE: Make sure you send your question to “Host, Presenter and Panelists”
DISCLAIMER

- Information presented reflects the personal knowledge and opinion of the presenters and does not represent the position of their current or past employers or the position of ISMPP.
SPEAKER PROFILES

- **Jake Burrell**, PhD, ISMPP CMPP™, was awarded his PhD in oncology from the Institute of Cancer Research in London. He began his career in medical communications at MeditechMedia in London, where he worked with a range of top-20 Pharma companies across a range of therapy areas including oncology, virology and haematology. He speaks fluent Chinese and has worked in Shanghai for over 3 years, where he is currently the director of Adelphi Consultech. Jake is an ISMPP Certified Medical Publication Professional™ (CMPP) and is a newly joined member of ISMPP’s Asia-Pacific Education Taskforce.
SPEAKER PROFILES

• **Bao-cheng Liu**, PhD, holds a PhD in Neuropsychiatry and Human Genetics from Shanghai Jiaotong University. He was a Research Fellow at the University of Michigan and was selected as the 2012 travel award winner to the XII World Psychiatry Conference, sponsored by NIMH and Harvard University. Bao-cheng has worked in global health communications for 3 years and joined Bohui Medical Communications Shanghai as Account Director in September 2015, where he focuses on health care communication and professional medical education.
Protecting the truth: Why do we need guidelines for ethical publication practices?

Jake Burrell, PhD, ISMPP CMPP™
Adelphi
DISCLOSURES

• Financial
  - Employee of Adelphi (we provide publication planning and medical writing services to for-profit clients in China)

• Non-financial
  - ISMPP Asia-Pacific Education Task Force Member
Section 1

AN INTRODUCTION TO ETHICAL REPORTING OF SCIENTIFIC DATA
ETHICAL REPORTING OF SCIENTIFIC DATA IS A VITAL PART OF SCIENTIFIC DISCOVERY
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• “For a successful technology, reality must take precedence over public relations, for nature cannot be fooled.”

  Richard Feynman

  This principle is particularly important in the field of medical research
WHAT ARE BIOMEDICAL PUBLICATIONS USED FOR?

• Establishing and reporting facts about medical conditions and therapies/interventions
  – Sharing information with:
    • The global or local medical community
    • Trial participants
    • Patients
    • The general public
    • Taxpayers etc.
  – Adding to the body of knowledge about a therapy or disease
  – Informing HCP decision-making
  – Marketing and commercial activities
“MUCH OF THE SCIENTIFIC LITERATURE, PERHAPS HALF, MAY SIMPLY BE UNTRUE”

- Comment from a seminar on the reproducibility and reliability of biomedical research, held at the Wellcome Trust, London

- Several factors contribute to this situation
  - Pressure to publish in high impact factor journals
  - Bias towards publication of ‘positive’, ‘novel’ results (less motivation to publish negative or confirmatory results)
  - Statistical significance over scientific relevance
  - Poor methodology (small sample size, over-interpretation of exploratory analyses, etc.)
  - Flaws in the peer review process

ACADEMIC MISCONDUCT AND THE CONSEQUENCES

• Researchers publishing false data, or other misconduct
  – Haruko Obokata: the stimulus-triggered acquisition of pluripotency cell scandal, which led to a retraction from Nature
  – This caused a loss of face for the researchers, ended the career of Haruko Obokata, and led to the suicide of a senior team member

• Manipulation of peer review
  – http://blogs.biomedcentral.com/bmcblog/2015/03/26/manipulation-peer-review/

• Pharmaceutical companies have faced large fines for withholding or misreporting data

Nature. 2014 Jul 3;511(7507):112
THREE OVERARCHING PRINCIPLES FOR ETHICAL PUBLICATION OF MEDICAL DATA AND INFORMATION
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- Validity of data
- Transparency of reporting
- Ethical research

Ethical publication
THREE OVERARCHING PRINCIPLES FOR ETHICAL PUBLICATION OF MEDICAL DATA AND INFORMATION

Validity of data

Publishing the truth
- Publishing accurate, unadulterated, complete data
- Interpreting data properly and fairly

Transparency of reporting

Ethical publication

Ethical research
THREE OVERARCHING PRINCIPLES FOR ETHICAL PUBLICATION OF MEDICAL DATA AND INFORMATION

Validity of data
- Publishing accurate, unadulterated, complete data
- Interpreting data properly and fairly

Publishing the truth
- Validity of data
- Transparency of reporting
- Ethical research

Publishing enough information to allow a reader to independently determine validity
- Study methods
- Author contributions
- Acknowledgements
- Conflicts of interest
THREE OVERARCHING PRINCIPLES FOR ETHICAL PUBLICATION OF MEDICAL DATA AND INFORMATION

Confirming research was conducted ethically and legally
- Trial registration details
- Ethical approval of research
- Confirmation of Good Clinical Practice

Ethical publication

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- Validity of data

- Ethical publication

- Publishing the truth
  - Publishing accurate, unadulterated, complete data
  - Interpreting data properly and fairly

- Transparency of reporting

The following are likely to become required for publication alongside clinical trial reports by an increasing number of journals in the future
  - Study protocol
  - Patient level data
  - Full clinical study report
SO, WHY DO WE NEED GUIDELINES FOR ETHICAL PUBLICATIONS PRACTICES?

- To ensure that the three key principles of ethical publication are met as fully as possible
- To ensure the truth is published
- To protect the people who will use medical products
Section 2

REPORTING ETHICAL RESEARCH
There are two commonly cited documents, which form the basis of many regional clinical research regulations:

1. The Declaration of Helsinki
   - Not legally binding, but sets out moral and ethical principles for clinical research

2. Guideline for Good Clinical Practice of the International Council for Harmonization (ICH)
   - Sets out the Good Clinical Practice international quality standard, which is integrated into clinical research regulations in many countries
Most biomedical journals require certain statements to be made about the conduct of clinical trials being reported:

- Written informed consent was obtained
- Compliant with the principles of the Declaration of Helsinki and ICH-GCP
- Approved by ethical review boards/institutional review boards
- Trial registration information
Section 3

VALIDITY OF PUBLISHED RESEARCH
HOW CAN WE ENSURE THE VALIDITY OF PUBLISHED RESEARCH?

Trial conduct

Good trial design and conduct
HOW CAN WE ENSURE THE VALIDITY OF PUBLISHED RESEARCH?

- Good trial design and conduct
- Appropriate analysis and use of statistics
HOW CAN WE ENSURE THE VALIDITY OF PUBLISHED RESEARCH?

Good trial design and conduct

Appropriate analysis and use of statistics

Careful reporting of methods and balanced reporting of results, based on consideration of full study data
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Publication professionals can play a role throughout this process, especially if they are involved in a publication steering committee early in the process.
A p-value of <0.05 does not automatically mean a result is clinically meaningful
- P-values are over-used and over-interpreted
- There is a trend towards placing more importance on reporting of 95% confidence intervals

Statistically ‘negative’ results should also be published

Interesting article about interpreting statistical significance versus clinical meaning

*BMJ* 2014; 348: g2130
Section 4

TRANSPARENCY OF PUBLISHED RESEARCH
WHAT DOES TRANSPARENCY MEAN?

- Every aspect of published research should be traceable back to the person responsible for it.
- Any conflicts of interest (COI) should be reported.

Who conceived and designed the research?

Who analysed the data?

Who interpreted the data?

Did anyone other than the authors contribute intellectually?

Who conducted/organised the research?

Who wrote the manuscript?

Did anyone involved have conflicts of interest?

Who paid for the research?

Did anyone provide editorial support for the manuscript and who paid for it?
WHO IS RESPONSIBLE FOR A PUBLICATION?

- Once a clinical trial is completed, developing the publication often involves many stakeholders and collaborators:
  - Authors
  - Medical writers
  - Statisticians
  - Pharma industry staff
  - Peer reviewers
  - Journal editors
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- The named authors are responsible for the publication and all of the content.
  - But, everyone who is involved in the development of the manuscript should be accountable for their contributions.
AUTHORSHIP CRITERIA

Most Science Citation Index journals (but not all) use the four International Committee of Medical Journal Editors authorship criteria (available in multiple languages)

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

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

3. Final approval of the version to be published; AND

4. 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

http://www.icmje.org/recommendations
GETTING THE FULL STORY: DISCLOSURES AND COIS

- A reader should also know of external factors which may have influenced the publication
- Disclosures and COIs should not be seen as incriminating or accusatory but a state of affairs
EXAMPLE OF A COI

• **Funding:** The funder Delta Crystallon BV provided support in the form of salaries for authors [JMvN, MB, PJN, RV and EHGV] but did not have any additional role in the study design, data collection and analysis, decision to publish, or preparation of the manuscript. The specific roles of these authors are articulated in the ‘author contributions’ section. This commercial affiliation does not alter the authors' adherence to PLOS ONE policies on sharing data and materials.

• **Competing interests:** JMvN, MB, PJN and RV are paid employees of Delta Crystallon BV; EHGV is a paid consultant of Delta Crystallon BV. JMvN holds equity in Delta Crystallon BV. Intervention in multiple sclerosis with HspB5 is the subject of international patent application PCT/NL2014/050383.

KEY TAKEAWAYS

• Developing biomedical publications often involves many stakeholders

• There can be serious consequences for academic misconduct and misreporting of data; either intentional or accidental

• The readers of biomedical publications should be able to determine the following three things:
  − Validity of data
  − Ethical trial conduct
  − Transparency of reporting

• Ethical publication guidelines provide best practice for the publication development process
USEFUL RESOURCES

• Declaration of Helsinki
  - *JAMA.* 2013;310(20):2191-2194

• ICH-GCP

• Equator network (collection of reporting guidelines)
  - http://www.equator-network.org/

• GPP3 guidelines
  - http://www.ismpp.org/gpp3

• ICMJE recommendations
  - http://www.icmje.org/recommendations/

• SAMPL guidelines for reporting statistics in biomedical journals

• The COMPare project
  - http://compare-trials.org/
Thank you!
• Employee of Bohui Medicalconsult (provide medical writing services to for-profit clients in China)

• All contents are from personal observations/viewpoints and do not represent those of ISMPP
CHINA WILL BE THE WORLD'S LARGEST PRODUCER OF SCIENTIFIC RESEARCH BY 2020

- 2nd place after the US: Chinese researchers published 1.37 million SCI papers during the years 2004-2014 (update by Sep 2014)

- 2nd place five consecutive years: In the year 2013, there were 1.7 million SCI papers in total globally - China had 231,400 papers (13.5%)

2 A brief report on statistics and analysis of Chinese papers in 2013, 2015
The total Chinese citation number is 10.37 million, in 4th place after US, Germany and UK (or 9th according to Nature comment\(^1\)).

China ranks 100th for citation per paper globally\(^2\) (Citation number per paper is 7.57 in 2014, better than 6.92 in 2013, but lower than global average of 11.05).

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WHY CHINESE RESEARCHERS PUBLISH IN SCI JOURNALS SO PASSIONATELY

- Publish or perish- it works in China too
- Most funding measurements are based on your publication record
- More credit is given for Scientific Citation Index (SCI) journals than local journals
- Publication-oriented policy for promotion and graduation
- Money award for publishing a paper catalogued by SCI score
THE MEDICAL PUBLICATION SERVICE BUSINESS IS BOOMING

• Medical publication services in China are often equal to ghost writing (Note: this is only a personal observation)
• Searching for “publication” on Taobao shows 209,800 items, and the best-selling merchant has 122,971 monthly sales, and 95,356 comments from buyers (graduation theses repetition check service)
• Publication service sales volumes are increasing:
  - 2007: 180–540 million
  - 2009: 1 billion
  - 2011: (Equal to 27 million yuan)

http://news.xinhuanet.com/theory/2010-05/19/c_12117584.htm
https://detail.tmall.com/item.htm?spm=a230r.1.14.1.VHaPnl&id=45159737260&ns=1&abbucket=3
http://paper.dxy.cn/article/28491

For the college graduation thesis, there is a rule that the duplication rate has to be lower than certain rate (~15%). Therefore students (usually someone who has some ctrl C+V skills) will seek a duplication check software to check their thesis does not exceed the 15% rate
2015 CHINA MAINLAND PAPER RETRACTION SCANDAL

• “Fabricated” peer review resulting in numerous retractions:
  - In March 2015, BioMed Central (BMC) retracted 43 papers; 41 came from China, involving 38 3rd-level hospitals (the top hospitals in China) and medical universities
  - In August 2015, Springer retracted 64 papers, of which 61 came from China, involving 42 3rd-level hospitals
WHY WERE THESE PAPERS RETRACTED?

• BMC 41 retractions:
  - One is for the inappropriate use of patient photographs in a case report
  - 40 are for **fake peer review, possibly involving third-party companies selling peer review as a service**

• Springer retracted 61 Chinese papers for “**fabricated peer review reports**”

http://retractionwatch.com/2015/03/26/biomed-central-retracting-43-papers-for-fake-peer-review/
http://www.springer.com/gp/about-springer/media/statements/retraction-of-articles-from-springer-journals/735218
Retraction analysis of Chinese authors in biomedicine 2013

Retraction distribution by impact factor (IF):

- IF >10: 2.50%
- IF >5-10: 11.40%
- IF >3-5: 15.40%
- IF 0-3: 58.90%
- Not SCI: 11.80%
Retractions stratified by reason for retraction

- Plagiarism and multiple publication: 40%
- Unknown reason or not disclosed: 26%
- Scientific misconduct: 15%
- Authorship or copyright: 8%
- Fabricating data: 5%
- Editor or publishing misconduct: 3%
- Unmet journal criteria: 1%
- Funding issue: 1%
- Cheating others' results: 1%

Retraction analysis of Chinese authors in biomedicine 2013
WHAT IS THE PUNISHMENT FOR PRINCIPAL INVESTIGATORS AND PROFESSORS CAUGHT FOR ACADEMIC MISCONDUCT?

- Public or private
- Revocation of a doctoral/master degree (Peking U)
- China Medical U releases PI/Professors’ names publicly and dismisses their title (associate professor/associate director/student mentorship), and they can not apply for grants for 3 years
- Involved project funding will be recalled by National Natural Science Foundation of China (8 from BMC and 14 from Springer)
Search for “medical publication ethics” in CNKI/Wanfang; around 150 papers are found, excluding duplication print and medical ethics.

The following are two well-known statements:

2006: Joint Statement of Establishing Chinese Clinical Trial Registration and Publishing System 《创建中国临床试验注册和发表机制的联合宣言》 also known as Chengdu statement

2011: Joint Statement on Promoting Development of Publication Ethics among Medical Journals in China 《推动我国医学期刊发表伦理发展的联合声明》

Medical Journal Publication Ethics  www.mjpe.net  – (link does not work currently)
Establishment of academic credit files, increase in academic misconduct investigations and punishment of serious academic misconduct will be released to the public.

Educate and guide scientists to strengthen the integrity of self-discipline, adherence to academic ethics, strictly prohibit falsification of data and other academic fraud.

Restriction of any form of plagiarism or stealing other people's papers and research.

Prohibit the use of intermediaries or other third parties to write, or money transactions to domestic and foreign journals.

http://www.gov.cn/zhengce/content/2016-01/13/content_10591.htm
## Copyright Statement

### Confirmation of No Multiple Submissions

Before submitting your manuscript to the **Chinese Medical Journal**, please ensure the following:

- **Nagowong转让协议**: I agree to the **Nagowong转让协议**.
- **一稿多投**: I agree to the **一稿多投**.

Submit your manuscript using **IE8, 9, 10 browsers**.

If you have any questions or need assistance, please contact the editorial office at 010-65158789.
HOW DO CHINESE ACADEMICS VIEW MEDICAL PUBLICATION SERVICES?

Though there is not a concrete Chinese publication guideline right now, most Chinese scientific researchers are generally in compliance with the GPP2/3.

Some of my observations when we talk about the medical publication services to Chinese scientists:

Why they need agency help
• Language polishing/data analyzing/experiment design
• Saving time
• Qualification to build the trust
• Assuming agency have the journal GUANXI (relationship), which could guarantee their paper a fast track

Why they refuse to work with agency
• Don’t need to, think agency is no help
• Peer pressure: working with 3rd-party agency can be seen as not have the capability themself
• Unqualified medical capacity
• Losing control of the submission and publication
• Fee cost

http://annals.org/article.aspx?articleID=2424869
CASE SHARING: MEDICAL PUBLICATION SERVICE IN CHINA

Brief:

A global company will introduce their device to treat/relieve disease symptoms. They have performed their clinical trial with PIs from a 3rd-level hospital. The trial lasted around 1.5 years, primary rough data have been collected.

The client hopes to find a medical publication agency to help them to work with the PIs to analyze the data, draft the manuscript, provide journal suggestion and support the submission.
IDEAL MEDICAL PUBLICATION FLOWCHART VS. PRACTICAL

DRAFT

Discussion with authors’ team
First/revised draft produced by first medical writer

Reviewed by second medical writer
Reviewed by project manager

First writer inputs the changes

Reviewed by team leader/ authors’ team

First writer inputs changes

Quality control by ‘non-account’ reviewer and authors’ team
Submissions in-line with approved plans. Tracking, reporting
• Big opportunity for medical publication service agency as unmet need for publication from pharmaceutical/academic is huge

• Branding, expertise (specialty) and service quality are key criteria when pharmaceutical/academic choose an agency to work with

• Official government and academic association have policies regarding the medical publication agency, still need time to validate
THANKS

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QUESTIONS?
To ask a question, please type your query into the Q&A box.

To ensure anonymity, before sending please choose the drop-down box option, "Hosts, Presenters and Panelists." Otherwise, ALL audience members will be able to see your submitted question.
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UPCOMING ISMPP Us

• **March 2016**
  • **Date/Time:** TBA

• **May 2016**
  • **Date/Time:** Wednesday, May 25, 11:00AM-Noon
  • **Topic:** Transparency in clinical trial reporting
  • **Presenter:** Jennifer Miller, Assistant Professor at NYU
    President of Bioethics International, Creator of the Good Pharma Scorecard
THANK YOU FOR ATTENDING!

- We hope you enjoyed today's presentation. Please take a few moments to complete the survey that will appear on your screen immediately after the presentation. We depend on your valuable feedback and take it into account as we develop future educational offerings.