THANK YOU FOR JOINING ISMPP U TODAY!

The program will begin promptly at 11:00 am EDT

January 28, 2015

ISMPP WOULD LIKE TO THANK. . .

. . . the following Corporate Platinum Sponsors for their ongoing support of the society

ISMPP ANNOUNCEMENTS

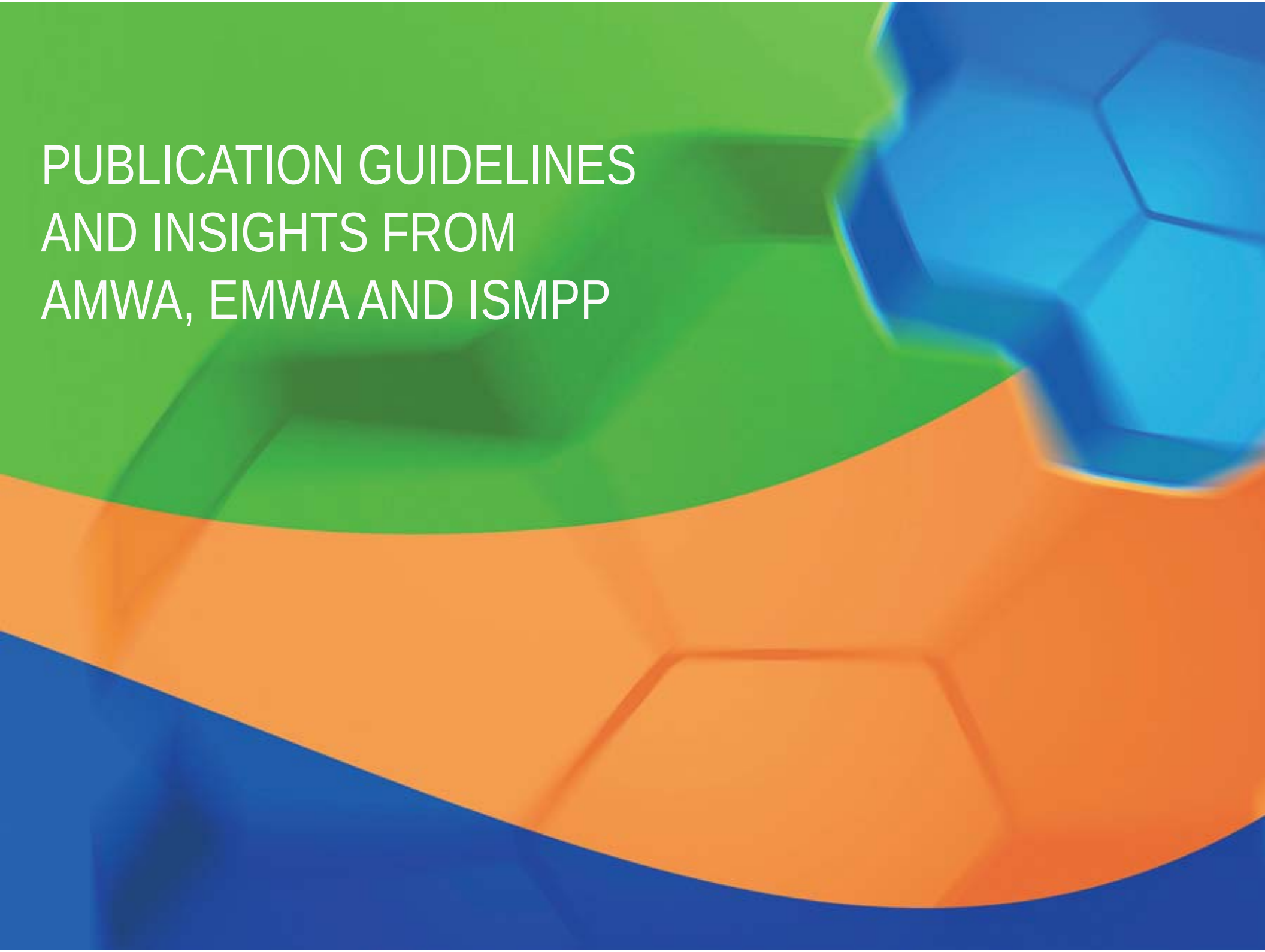
- Registration is now open for the 11th Annual Meeting of ISMPP, April 27-29th, see www.ismpp.org
- Interested in taking the March CMPP exam? Don't miss the February 1st deadline.
- Did you know your company can sponsor an ISMPP U webinar? If you're interested or would like more information, contact ismpp@ismpp.org.
- Get social! Follow us on Twitter (@ISMPP) or join the conversation at ISMPP's LinkedIn group page.

FOR THE BEST LISTENING EXPERIENCE . . .

To optimize your ISMPP U webinar experience today, please:

- Turn up the volume of your computer speakers
- Use the fastest internet connection available to you
- Use a hardwire connection if available
- If you experience audio problems, please consider switching to a different browser (eg, Chrome vs Internet Explorer)

PUBLICATION GUIDELINES AND INSIGHTS FROM AMWA, EMWA AND ISMPP



INTRODUCTIONS

- **Moderator:** Michael Platt is President of MedVal Scientific Information Services, LLC, the current Vice-chair of the CMPP Board, and a member of the ISMPP U Committee, and a prior member of the ISMPP Resource Development Committee. He has over 19 years of industry experience and a broad knowledge of the pharmaceutical, biotechnological, and healthcare fields, with focused experience in biologics, oncology, rare diseases, cardiology, allergy and asthma, infectious disease, gastroenterology, urology, and rheumatology. His background includes pre-launch, launch, and post-launch activities, including publication planning, advisory boards, sales training, e-digital and other web-based initiatives, and prior to 2003, live and enduring continuing education programs. He came to MedVal from Fission Communications, a New York-based medical education and communications company he founded in 2001. He began his career in the research sector of the pharmaceutical industry as a project technician at OSI Pharmaceuticals, a drug discovery company based in New York.

TODAY'S OBJECTIVES

- At the conclusion of this educational session, attendees should be able to:
  - Be knowledgeable about resources containing detailed information on applicable guidelines
  - Understand which guidelines are industry best practices and which guidelines provide direction in specialized areas or disciplines relevant to medical publications
  - Be knowledgeable about different sites, resources, and professional organizations that provide medical publication guideline information
  - Understand the current educational initiatives AMWA, EMWA and ISMPP are actively involved in and how these offering are promoting ethical and transparent medical communications

DISCLAIMER

- Information presented reflects the personal knowledge and opinion of the presenters and does not necessarily represent the position of their current or past employers or the position of ISMPP, AMWA and/or EMWA unless otherwise stated

GUIDELINES – WHAT YOU SHOULD KNOW

Wendy P. Battisti, PhD
Director Scientific & Medical Publications
Janssen Research & Development, LLC

INTRODUCTION

- **Faculty**: Wendy P. Battisti has nearly 30 years of experience in the medical sciences and scientific writing. Her Ph.D. is in neuroscience, from the Medical College of Pennsylvania, where she also worked for many years as an NIH-supported researcher, faculty member, and neuroscience course director for the medical school (Now: Drexel University School of Medicine). She also led graduate courses in scientific writing and presentation.

  Her academic career was followed by several years at a medical communication agency before joining Merck & Co. She has been supporting scientific and medical publications at Janssen Research & Development, LLC, for nearly 10 years. She has coauthored or assisted with numerous publications and presentations in the areas of neuroscience, neurology, pain, arthritis, respiratory, and cardiovascular, was a coauthor of GPP2, and is the lead author for GPP3. In addition, she has served two terms on the Certification Board for ISMPP and has given many presentations at scientific and professional meetings.

WHY ALL THE GUIDELINES?

- Peer reviewed publications impact research as well as our healthcare communities and patients, influencing treatment guidelines and physician decisions for their patients.
- The goals of publications are to help advance scientific and medical research, healthcare practice standards, and ultimately the quality of patients' lives
- Guidelines help establish or reinforce best practices for companies to achieve these goals
  - Develop unbiased, data-driven publications
  - Provide full transparency (data, as well as authorship and contributors)
  - Document that all activities are to the highest standard

Our goal must remain excellence in our publications: Advances in healthcare, and patients lives and safety, depend on it.

PRESSURES ON PHARMA

- Increased pressure to disclose all human data and as a result expansion of trial registration and data sharing:
  - Trial registry
  - Results posting
  - Posting of full protocols and study reports
  - Transparency and accountability (eg., open payment legislation)
- Public scrutiny of pharma
  - Competing interests and disclosures
  - Accusation of hiding data and inappropriately influencing clinicians and healthcare providers
  - “Noise” and marketing messages vs good science in publications

LANDMARKS IN PUBLICATIONS*

Publication organizations	Guidelines issued	Continuing to improve publication practices
1940 • American Medical Writers Association (AMWA) **1978** • Meeting of the "Vancouver group", later becomes International Committee of Medical Journal Editors (ICMJE) **1982** • European Association of Scientific Editors (EASE) **1989** • European Medical Writers' Association (EMWA) **1995** • World Association of Medical Editors (WAME) **2005** • International Society for Medical Publication Professionals (ISMPP) **2008** • Medical Publishing Insights and Practices (MPIP) initiative formed	**1979** • Uniform requirements for manuscripts submitted to biomedical journals (ICMJE) **1997, 2003, 2010, 2013** • Major revisions of ICMJE's uniform guidance **2003** • First GPP guidelines published • Recommendations for group authorship published by Council of Science Editors (CSE) **2005** • ICMJE's study registration requirements implemented • EMWA guidelines on role of medical writers • PhRMA principles and guidelines **2006** • Integrity in scientific journal publications white paper published by CSE	**2001** • Task force on contribution of medical writers to scientific publications formed by AMWA **2007** • FDA Amendments Act signed into law • ICMJE study registration requirements expanded • The International Publication Planning Association (TIPPA) established **2009** • GPP2 guidelines published • ICMJE's disclosure form for potential conflicts of interest published • Conflict of interest guidance added to AMWA policy • PhRMA principles and guidelines updated • CSE's white paper updated **2010** • Joint Position of Pharmaceutical Manufacturers Association published • ISMPP Code of Ethics **2014** • Principles for Responsible Clinical Trial Data Reporting (PhRMA, efpia) • EASE guidelines for scientific articles (and translations)

*Adapted from: Clark et al. (MPIP) *Int J Clin Prac*. 2010;64(8):1028–1023.

RESPONDING (STILL) TO THE CHANGING INDUSTRY

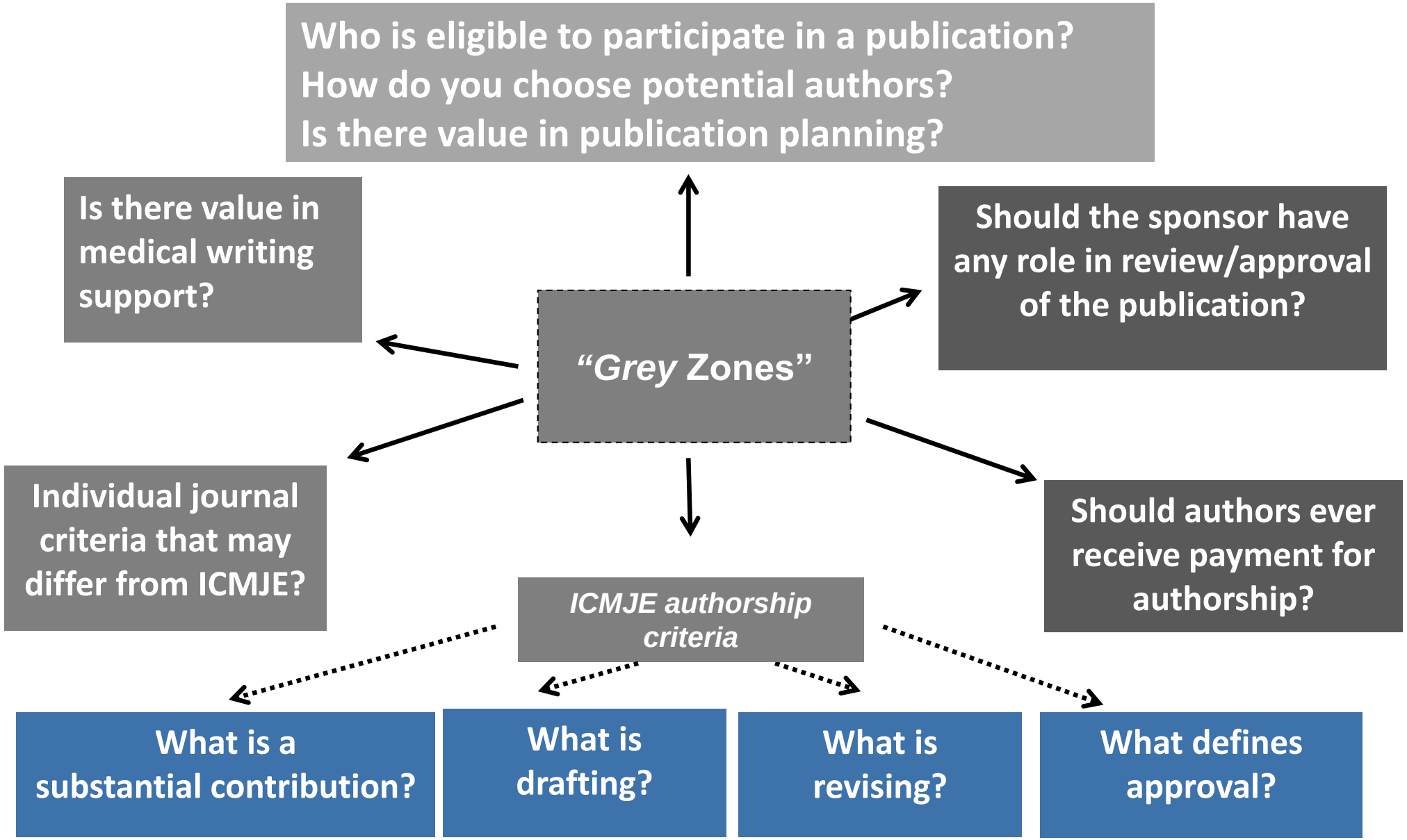
- Despite all the guidelines and increased legislation, public trust continues to erode.
- Pharmaism: the belief that people associated with pharmaceutical companies are more likely to be intellectually and morally dishonest than others
  - Citrome et al. "Pharmaism: A Tale of Two Perspectives." *Int J Clin Pract* 68, no. 6 (Jun 2014): 659-61.

SEE NO EVIL, HEAR NO EVIL, SPEAK NO EVIL, AND …

WHO NEEDS (MORE) GUIDELINES?

	ICMJE	GPP2	PhRMA (2009)	EMWA	AMWA
Authorship	X	X	X	X	
Funding disclosure	X	X		X	
Data access	X	X	X	X	
Professional writers		X		X	X
Duplicate publication	X	X	X		
Publication bias	X	X			
Sponsor right to review	X	X	X		

IT'S NOT ALL BLACK AND WHITE…



INTERNATIONAL COUNCIL OF MEDICAL JOURNAL EDITORS GUIDELINES (ICMJE)

"RECOMMENDATIONS FOR THE CONDUCT, REPORTING, EDITING, AND PUBLICATION OF SCHOLARLY WORK IN MEDICAL JOURNALS" (UPDATED DEC 2014)

THE EDITORS (N=14) HAVE SPOKEN…

- Goal – to standardize manuscript format and preparation across journals.
- Need for additional guidance on issues beyond manuscript preparation resulted in separate statements, eventually incorporated into the main document
- Multiple editions and revisions of this document
  - Uniform Requirements Manuscripts Submitted to Biomedical Journals ("URM" 1978; wholly revised 1997; section updates 1999, 2000, 2001; wholly revised and reorganized again 2003, 2010)
  - Recommendations for the Conduct, Reporting, Editing, and Publication of Scholarly Work in Medical Journals" (ICMJE Recommendations), 2013 (updated Dec 2014; annotated PDF is available at http://www.icmje.org/news-and-editorials/icmje-recommendations_annotated_dec14.pdf))
- Previous versions archived: "Archives" section of www.icmje .org.

JOINT POSITION STATEMENT FROM PHARMACEUTICAL MANUFACTURERS ASSOCIATIONS

PHRMA (US), EFPIA (EU), JPMA (JAPAN), AND IFPMA (INTERNATIONAL)

ISSUED JUNE 2010

JOINT POSITION STATEMENT

GUIDANCE ON PUBLICATION OF CLINICAL TRIAL RESULTS IN THE SCIENTIFIC LITERATURE

"The global pharmaceutical industry's joint position statement recognizes the important public health benefits associated with making clinical trial results widely available through publications and demonstrates a commitment to the transparency of clinical trials that are sponsored by its member companies."

Joint Position on the Disclosure of Clinical Trial Information via Clinical Trial Registries and Databases (www.ifpma.org/clinicaltrials)

JOINT POSITION STATEMENT:

COMMITMENT TO THE FOLLOWING:

Which Trials?

- All industry-sponsored clinical trials irrespective of whether the results are positive or negative.
  - results from all phase-3 clinical trials;
  - any trial results of significant medical importance;
  - investigational products whose development programs are discontinued.

When Submitted?

- Within 12 months and no later than 18 months of:
  - Clinical trial completion (marketed products), OR
  - Regulatory approval or decision to discontinue development (investigational products)
- Primary publication(s) (i.e. results from all centers) should be published before, or in parallel with, any secondary publications

Where?

- Peer-reviewed journals, preferably indexed by bibliographic databases (e.g., Medline)

COMMITMENT TO THE FOLLOWING (CONT.):

What Information?

- Authorship and Acknowledgments
  - ICMJE criteria or journal-specific guidelines
  - Writer or others (e.g., statisticians) acknowledged if he or she does not meet authorship criteria;
  - All funding sources, conflicts of interest, affiliations stated
  - All other support or assistance so acknowledged
- Disclosure
  - Sponsors should disclose their involvement in both research and development of publication (e.g., funding, review) and encourage external authors to fully disclose all relevant competing interests
- Content
  - Accurate and well-balanced (include AEs and relevant safety information)
  - Post hoc analyses described as such
  - Provide copies of protocols (and amendments) upon request


EQUATOR NETWORK
Enhancing the Quality And Transparency Of
Health Research

KEY REPORTING GUIDELINES

- CONSORT – randomized clinical trials
- STROBE – observational studies in epidemiology
- PRISMA – systematic reviews and meta-analyses (PRISMA- P – for related protocols)
- STARD – diagnostic accuracy
- SPIRIT – protocol standards
- CHEERS – health economic reporting
- STRICTA – acupuncture trials (extension of CONSORT)

A RESOURCE OF KEY GUIDELINES FOR SPECIFIC DATA TYPES AND ANALYSES

- Library - a comprehensive searchable database of reporting guidelines, with links to other relevant resources for reporting research. Includes wide variety of research types
- Toolkits for different user groups (authors, editors, guideline developers, librarians)
- Highlights (conferences, important publications) and News
- Videos (ex., “Rigour Mortis: How Bad Research is Killing Science.”)
- Translations available for many guidelines; Spanish language site

EVOLUTION OF THE GOOD PUBLICATION PRACTICES (‘GPP’) GUIDELINES

EVOLUTION OF GPP

2003 GPP

Current Medical Research Opinion

- First to describe standards for industry-based manuscripts
- Initiated at a meeting of academics, journal editors, and industry affiliates in 1998
- Five years in the planning and development

2009 GPP2

British Medical Journal

- More comprehensive than GPP
- More diverse input (reviewers)
- Additional topics since GPP

2015 GPP3

Annals of Internal Medicine

- More global steering committee
- Continue to focus on GPP and GPP2 core values:
  - Integrity,
  - Completeness,
  - Transparency,
  - Accountability,
  - Responsibility

GOOD PUBLICATION PRACTICE GUIDELINES "GPP" – THE EVOLUTION

Good Publication Practice for Pharmaceutical Companies. Wager, E, Field EA, and Grossman L. Curr Med Res Opin. 19 (2003): 149-54.

Good Publication Practice for Communicating Company-Sponsored Medical Research: The GPP2 guidelines. Graf, C, Battisti WP*, Bridges D, Bruce-Winkler V, Conaty JM, Ellison JM*, Field EA, Gurr JA, Marx M-E, Patel M, Sanes-Miller C, Yarker YE, for ISMPP. BMJ 339:b4330; (2009)

Good Publication Practice for Communicating Company-Sponsored Medical Research: GPP3. Battisti WP, Wager E, Baltzer L. Bridges D, Cairns A, Carswell CI, Citrome L, Gurr JA, Mooney LA, Moore BJ, Pena T, Sanes-Miller CH, Veitch K, Woolley KL, Yarker YE, for ISMPP **GPP3 (SUBMITTED 2015)**

WHAT'S NEW IN GPP3?

CAVEAT: Peer reviewer comments may result in changes.

- Reorganized from GPP2, to group similar or related topics together, for clarity and to reduce redundancy. Additional examples provided throughout to help clarify 'grey' areas
- No sections deleted, but several new sections added. Key ones:
  - Publication Principles
    - Ten principles summarize key best practices, provided at outset of guidelines
    - Provides more specifics to meet the key principles (transparency, completeness, etc) that were part of GPP2's checklist
  - Data Sharing
    - Recognizes the expanding and rapidly evolving guidelines and regulations on providing data, including patient-level data, to the public

WHAT'S NEW IN GPP3? (CONT.)

- Planning, registering, posting, and documenting. Reorganized under new heading: Publication Processes
  - Emphasis on need to include trial registration number in ALL publications and presentations, including meta-analyses, secondary publications
  - Plagiarism, including 'self-plagiarism' is discussed (NEW)
  - What should be published (NEW), currently left broad and referring to legislation – reorganized to new section above
- Role and Responsibilities
  - Written agreement – minor update
  - Access to data – minor update
  - Honoraria and reimbursement – removal of honoraria language and major changes from GPP2 to clarify when payment may be appropriate
  - Role of sponsor – revised section to highlight the overall duty of sponsor to take lead role in highlighting and ensuring ethical practices

WHAT'S NEW IN GPP3? (CONT.)

- Authorship
  - Substantial redrafting including reference to new ICMJE criteria
  - Two new tables added that provide guidance and interpretation to common authorship issues, including number of authors, sequence, addition or removal, and incapacity or death of an author.
- Professional medical writers
  - Peer-reviewed evidence included to strengthen the evidence base for appropriate role and responsibilities of writer.
- Contributorship and Acknowledgments
  - Clarification on the role of nonauthor contributors
  - Fuller explanation of what should be included in an acknowledgements section
  - How to acknowledge groups, such as a list of study investigators
  - More comprehensive examples of acknowledgment statements

WHAT'S NEW IN GPP3? (CONT.)

- Disclosures (Formerly ' Conflict of Interest')
  - Renamed "Conflicts of Interest" to "Disclosures", along with the rationale for this.
  - The extent of the recommended disclosures is now made explicit.
- Recommendations for specific types of articles
  - Duplicate publication section moved to Publication Process section
  - Definition added for primary and secondary publication.
- Steering Committees
  - Section moved into Publication Process section
  - Composition and role clarified, authorship writing group defined (aligned with MPIP authorship framework publication*)

* Marušić et al. Five-step authorship framework to improve transparency in disclosing contributors to industry-sponsored clinical trial publications. BMC Medicine. 2014;12(1):197.

SO MANY GUIDELINES…SO LITTLE TIME

- Follow the local legislation as it applies to your company
- Follow reporting standards relevant to your dataset
- Review ethics statements standards issued from professional organizations
- Commit to memory ICMJE, GPP
- There will always be ‘grey’ areas – guidance that is open to interpretation, or lack of guidance for a particular situation. Let the following goals guide you:
  - Integrity
  - Completeness
  - Transparency
  - Accountability
  - Responsibility

Good publication practice helps advance science and medicine and demonstrates our commitment to patients, scientists, and healthcare professionals.

PUBLICATION STANDARDS: ONE SIZE FITS ALL?

Art Gertel
President and Principal Consultant
MedSciCom, LLC
&
Senior Research Fellow
Centre for Innovation in Regulatory Science (CIRS)

INTRODUCTION

- Faculty: Art Gertel has nearly 40 years of experience in many of the phases of drug research and development, with particular expertise in global regulatory strategy, medical writing, and bioethics. He has held management positions in large, multinational pharmaceutical companies (Hoffmann-LaRoche and Schering-Plough), CROs (Quintiles and TFS); and an eDC innovator (iKnowMed). He has recently established an independent strategic regulatory and medical writing consultancy and currently serves as a Senior Research Fellow at the Centre for Innovation in Regulatory Science (CIRS), a London-based "Think-Tank" dedicated to improving the quality of decision-making in new medicines research, development, review, and approval. He holds BS (Biology) and BA (Psychology) degrees from the University of Pennsylvania, an MS in Neurophysiology and Behavioral Medicine from New York Medical College, and completed doctoral coursework in Pharmaceutics at Temple University.

  Art has also been active in numerous professional organizations, including AMWA (President and Fellow), EMWA (Fellow), DIA, ISMPP, and TIPPA (Advisory Board). Art has a strong interest in Biomedical Ethics, serving on an IRB Advisory Board, and co-chairing the Alliance for Clinical Research Excellence and Safety (ACRES) Global Ethical and Regulatory Innovation (GERI) Steering Committee. He has been active in the establishment of standards of authorship for AMWA, EMWA, and ISMPP, as well as data transformation standards for protocols, registries, and health records, under the auspices of CDISC, chairing the CDISC Glossary Group, and is a charter member of the CDISC Protocol Representation Group. He is a founding member of the Global Alliance of Publication Professionals (GAPP), with a remit to clarify authorship standards.

Standards!...Standards!

We Don’t Need No Stinkin’ Standards!

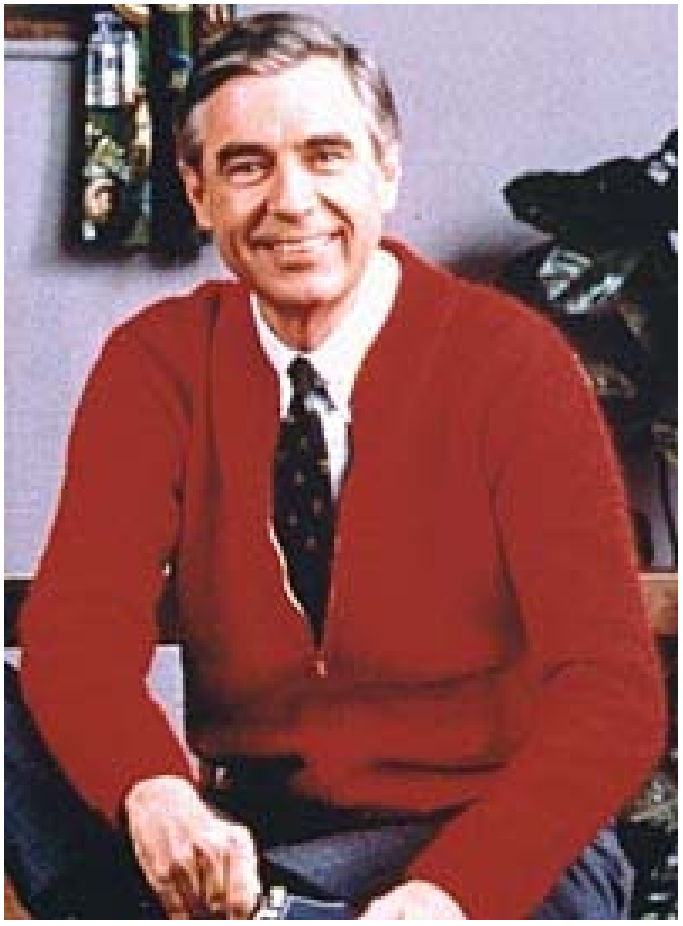
WHAT ARE REPORTING GUIDELINES?

- Statements that provide advice on how to report research methods and findings
- Specify a minimum set of items required, discussing particular issues that might introduce bias
- Most widely recognized guidelines are based on the available evidence and reflect consensus opinion of experts in a particular field

GUIDELINES, STANDARDS, PRACTICES

- **Guidelines**: General principles agreed upon by a group of experts, to be followed as an indication or outline of policy or conduct.
- **Standards**: Usually developed by a Standards Committee (eg, ISO, NISO, ANSI), subject to rigorous control and approval process, including peer review.
- **Practices**: How organizations and individuals interpret Guidelines and Standards and codify their implementation (via SOPs).

STANDARDS VS. GUIDELINES



WHY WRITING GUIDELINES?

Research is guided by

GCPs, GLPs, GSPs, GMPs,...

Why not GWPs?

A *UNIFIED THEORY* OF GOOD PUBLICATION PRACTICES?

UNIFIED THEORY?

Publication and authorship standards have many source-points, yet they have evolved from a succession of predecessors to represent a fairly uniform set of expectations, most of which are codified in ICMJE.

WHAT ARE THE BASIC REQUIREMENTS FOR REPORTING HEALTH RESEARCH?

- Most **biomedical journals** require authors to comply with the Uniform Requirements for Manuscripts Submitted to Biomedical Journals prepared by the International Committee of Medical Journal Editors (ICMJE).
  - ethical principles in the conduct and reporting of research
  - recommendations relating to specific elements of editing and writing.
- The Grey Literature International Steering Committee (GLISC) adapted the ICMJE requirements and created Guidelines for the Production of **Scientific and Technical Reports.**
  - Ethical considerations
  - Publishing and editorial issues
  - Report preparation.
- **Health authorities** have developed standards for reporting the final results of clinical trials (ICH E3)

ICMJE

*www.**icmje**.org*

UNIFIED THEORY?

However…

- Congesses and journals don’t use the same standards
- High number and variability of editors’ instructions
- Guidelines are continuously developing
- Guidelines for publishing various types of research are different

GUIDELINES: WHERE?

www.equator-network.org/

equator network

Search: Go

Enhancing the QUAlity and Transparency Of health Research

Home | About EQUATOR | Resource Centre | Courses Events | Research Projects | Contact | News | Forum

Welcome to the EQUATOR Network website – the resource centre for good reporting of health research studies

Too often, good research evidence is undermined by poor quality reporting.

The EQUATOR Network is an international initiative that seeks to improve reliability and value of medical research literature by promoting transparent and accurate reporting of research studies.

Highlights

EQUATOR Spanish website
New site launched on 16 July 2010 in collaboration with the Pan American Health Organization (PAHO). Find out more and visit the site

Promote good reporting
Print and display EQUATOR leaflets

EQUATOR Newsletter
New reporting guidelines, events, and other news. Subscribe now

Latest news more news

Warm welcome to Professor Ana Marusic

Ana Marusic joins the EQUATOR Steering Group bringing with her extensive experience in research methodology and scientific publishing.

Read the full story

Reporting guidelines

Library for Health Research Reporting

Authors

Information for authors of research reports

Editors

Resources for journal editors and peer reviewers

Developers

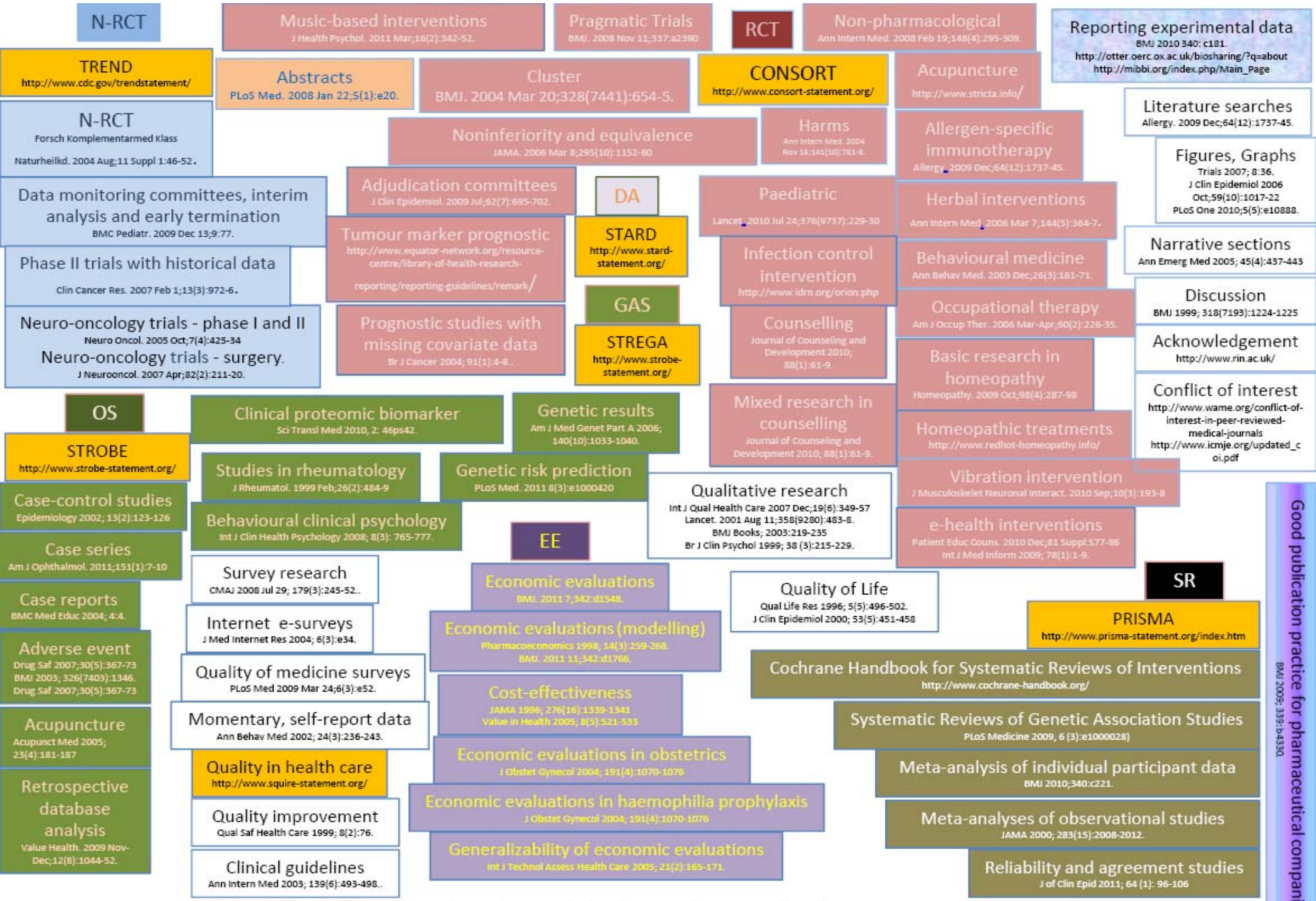
Resources for developers of reporting guidelines

WHAT GUIDANCE IS AVAILABLE FOR REPORTING RESEARCH STUDIES?

Medical journals often require compliance to all or some of the following guidelines:

- CONSORT Statement (reporting of randomized controlled trials)
- STARD (reporting of diagnostic accuracy studies)
- STROBE (reporting of observational studies in epidemiology)
- PRISMA (reporting of systematic reviews), which replaced QUOROM
- MOOSE (reporting of meta-analyses of observational studies)

However…



N- RCT=Non-Randomized Controlled Studies ;RCT=Randomized Controlled Studies; OS=Observational Studies; GAS=Genetic association studies; DA=Diagnostic accuracy; SR=Systematic Reviews & Meta-analysis; EE=Economic Evaluations

RCT
RANDOMIZED CONTROLLED STUDIES

Noninferiority and equivalence
JAMA. 2006 Mar 8;295(10):1152-60

CONSORT
http://www.consort-statement.org/

Non-pharmacological
Ann Intern Med. 2008 Feb 19;148(4):295-309.

Pragmatic Trials
BMJ. 2008 Nov 11;337:a2390

Pediatric
Lancet. 2010 Jul 24;376(9737):229-30

Basic research in homeopathy
Homeopathy. 2009 Oct;98(4):287-98

Prognostic studies with missing covariate data
Br J Cancer 2004; 91(1):4-8..

Behavioral medicine
Ann Behav Med. 2003 Dec;26(3):161-71.

Homeopathic treatments
http://www.redhot-homeopathy.info/

Cluster
BMJ. 2004 Mar 20;328(7441):654-5.

Allergen-specific immunotherapy
Allergy. 2009 Dec;64(12):1737-45.

Herbal interventions
Ann Intern Med. 2006 Mar 7;144(5):364-7.

Music-based interventions
J Health Psychol. 2011 Mar;16(2):342-52.

e-health interventions
Patient Educ Couns. 2010 Dec;81 Suppl:S77-86
Int J Med Inform 2009; 78(1):1-9.

Infection control intervention
http://www.idrn.org/orion.php

Acupuncture
http://www.stricta.info/

Vibration intervention
J Musculoskelet Neuronal Interact. 2010 Sep;10(3):193-8

Abstracts
PLoS Med. 2008 Jan 22;5(1):e20.

Tumor marker prognostic
http://www.equator-network.org/resource-centre/library-of-health-research-reporting/reporting-guidelines/remark/

Occupational therapy
Am J Occup Ther. 2006 Mar-Apr;60(2):226-35.

Counseling
Journal of Counseling and Development 2010; 88(1):61-9.

Quality of Life
Qual Life Res 1996; 5(5):496-502.
J Clin Epidemiol 2000; 53(5):451-458

Adjudication committees
J Clin Epidemiol. 2009 Jul;62(7):695-702.

Harms
Ann Intern Med. 2004 Nov 16;141(10):781-8.

Mixed research in counseling
Journal of Counseling and Development 2010; 88(1):61-9.

Thanks to Andrea Rossi – used with permission

N-RCT
NON-RANDOMIZED CONTROLLED STUDIES

TREND
http://www.cdc.gov/trendstatement/

N-RCT

Forsch Komplementarmed Klass Naturheilkd. 2004 Aug;11 Suppl 1:46-52.

Data monitoring committees, interim analysis and early termination
BMC Pediatr. 2009 Dec 13;9:77.

Phase II trials with historical data
Clin Cancer Res. 2007 Feb 1;13(3):972-6.

Neuro-oncology trials - phase I and II
Neuro Oncol. 2005 Oct;7(4):425-34.

Neuro-oncology trials - surgery
J Neurooncol. 2007 Apr;82(2):211-20.

DA
DIAGNOSTIC ACCURACY

STARD
http://www.stard-statement.org/

Pragmatic Trials
BMJ. 2008 Nov 11;337:a2390.

Cluster
BMJ. 2004 Mar 20;328(7441):654-5.

Noninferiority and equivalence
JAMA. 2006 Mar 8;295(10):1152-60.

Adjudication committees
J Clin Epidemiol. 2009 Jul;62(7):695-702.

Prognostic studies with missing covariate data
Br J Cancer 2004; 91(1):4-8.

Tumour marker prognostic
http://www.equator-network.org/resource-centre/library-of-health-research-reporting/reporting-guidelines/remark.

Abstracts
PLoS Med. 2008 Jan 22;5(1):e20.

OS
OBSERVATIONAL STUDIES

STROBE
http://www.strobe-statement.org/

GAS
Genetic association studies

Case-control studies
Epidemiology 2002; 13(2):123-126.

Case series
Am J Ophthalmol. 2011;151(1):7-10.

Clinical proteomic biomarker
Sci Transl Med 2010, 2: 46ps42.

STREGA
http://www.strobe-statement.org/

Case reports
BMC Med Educ 2004; 4:4.

Studies in rheumatology
J Rheumatol. 1999 Feb;26(2):484-9.

Genetic results
Am J Med Genet Part A 2006; 140(10):1033-1040.

Retrospective database analysis
Value Health. 2009 Nov-Dec;12(8):1044-52.

Behavioural clinical psychology
Int J Clin Health Psychology 2008; 8(3): 765-777.

Genetic risk prediction
PLoS Med. 2011 8(3):e1000420.

Acupuncture
Acupunct Med 2005; 23(4):181-187.

Adverse event
Drug Saf 2007;30(5):367-73.
BMJ 2003; 326(7403):1346.
Drug Saf 2007;30(5):367-73.

EE
ECONOMIC EVALUATIONS

Economic evaluations
BMJ. 2011 7;342:d1548.

Economic evaluations (modelling)
Pharmacoeconomics 1998; 14(3):259-268.
BMJ. 2011 11;342:d1766.

Cost-effectiveness
JAMA 1996; 276(16):1339-1341.
Value in Health 2005; 8(5):521-533.

Abstracts
PLoS Med. 2008 Jan 22;5(1):e20.

Economic evaluations in obstetrics
J Obstet Gynecol 2004; 191(4):1070-1076.

Economic evaluations in haemophilia prophylaxis
J Obstet Gynecol 2004; 191(4):1070-1076.

Generalizability of economic evaluations
Int J Technol Assess Health Care 2005; 21(2):165-171.

Quality of Life
Qual Life Res 1996; 5(5):496-502.
J Clin Epidemiol 2000; 53(5):451-458.

SR

SYSTEMATIC REVIEWS & META-ANALYSES

PRISMA
http://www.prisma-statement.org/index.htm

Cochrane Handbook for Systematic Reviews of Interventions
http://www.cochrane-handbook.org/

Meta-analysis of individual participant data
BMJ 2010;340:c221.

Systematic Reviews of Genetic Association Studies
PLoS Medicine 2009, 6 (3):e1000028).

Reliability and agreement studies
J of Clin Epid 2011; 64 (1): 96-106.

Meta-analyses of observational studies
JAMA 2000; 283(15):2008-2012.

Abstracts
PLoS Med. 2008 Jan 22;5(1):e20.

ALSO…

Reporting experimental data
BMJ 2010 340: c181.
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WEBSITES AND REFERENCES

- ICMJE: "Recommendations for the Conduct, Reporting, Editing, and Publication of Scholarly Work in Medical Journals" (Updated Dec 2014)
  - http://www.icmje.org/
- EQUATOR Network
  - http://www.equator-network.org/
- Good Publication Practice (Graf et al):
  - http://www.ncbi.nlm.nih.gov/entrez/query.fcgi?cmd=Retrieve&db=PubMed&dopt=Citation&list_uids=19946142
- Joint Position on the Publication of Clinical Trials Results in the Scientific Literature
  - http://www.ifpma.org/fileadmin/content/Ethics/Clinical_Trials/June2010_Joint_Position_CT_Data_Publication-scientific_literature.pdf

ETHICS

DECLARATION OF HELSINKI

WORLD MEDICAL ASSOCIATION DECLARATION OF HELSINKI
Ethical Principles for Medical Research Involving Human Subjects

Adopted by 18th WMA General Assembly, Helsinki, Finland, June 1964

Amended by the:
29th WMA General Assembly, Tokyo, Japan, October 1975
35th WMA General Assembly, Venice, Italy, October 1983
41st WMA General Assembly, Hong Kong, September 1989
48th WMA General Assembly, Somerset West, Republic of South Africa, October 1996
52nd WMA General Assembly, Edinburgh, Scotland, October 2000
53th WMA General Assembly, Washington 2002 (Note of Clarification on paragraph 29 added)
55th WMA General Assembly, Tokyo 2004 (Note of Clarification on Paragraph 30 added)
59th WMA General Assembly, Seoul, October 2008
64th WMA General Assembly, Fortaleza, Brazil, October 2013

OF SPECIAL INTEREST…

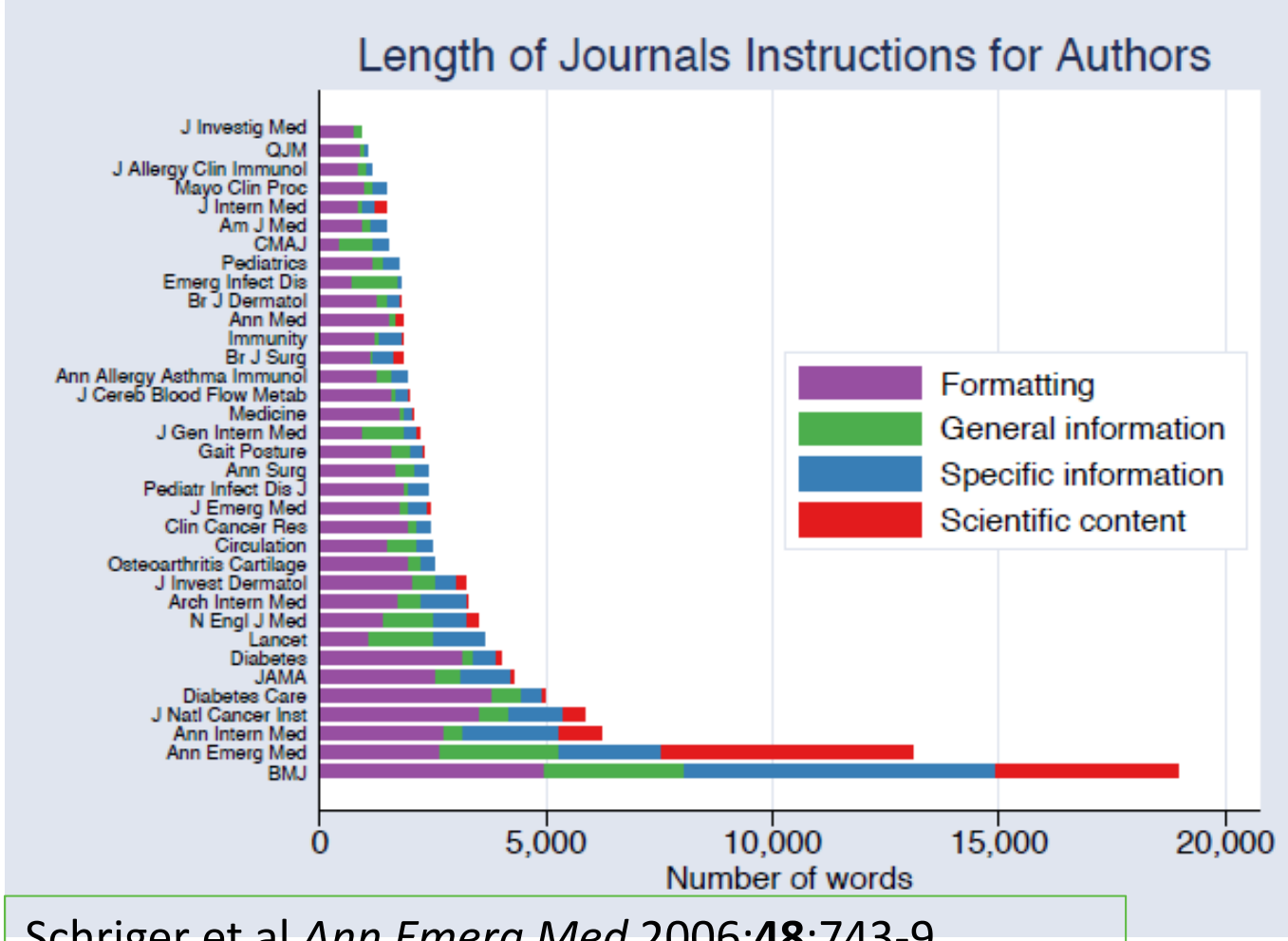
20. Authors, editors and publishers all have ethical obligations with regard to the publication of the results of research. Authors have a duty to make publicly available the results of their research on human subjects and are accountable for the completeness and accuracy of their reports. They should 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.

HOW HELPFUL ARE JOURNAL INSTRUCTIONS? (EVEN TO AUTHORS WHO WANT TO FOLLOW THEM)

- 100/122 (82%) did not publish a retraction policy
  (Atlas *J Med Libr Assoc* 2004;92:242-50)

- 100/234 (43%) had no guidance on authorship
  (Wager *Medscape Gen Med* 2007;9:16)

MOST INSTRUCTIONS ARE ABOUT FORMATTING



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WE CAN CHANGE THE WORLD

"WE HAVE MET THE ENEMY AND HE IS US"

POGO

While standards are fine, in and of themselves, they are aspirational.

We must effect behavioral change in order to make a difference.

ALLIANCES

Despair, Inc

ALLIANCES – WE ARE A GLOBAL PROFESSION

- Global Alliance of Publication Professionals (GAPP)
  gappteam.org
- (Clarity and Openness in Reporting: E3-based) Guidance (CORE)
- AMWA-DIA Joint Tutorials
- EMWA-AMWA Collaboration
- ISMPP – Global Collaboration

QUESTIONS.....

To ask a question, please type your query into the ‘Q&A’ chat box at the bottom left of your screen. Every attempt will be made to answer all questions.

AMERICAN MEDICAL WRITERS ASSOCIATION (AMWA)

Cindy W. Hamilton, PharmD

AMWA President, 2008–2009

INTRODUCTION

- **Faculty:** Cindy W. Hamilton is principal of Hamilton House, a medical communication firm founded in 1990 and located in Virginia Beach, Virginia. A past president of the American Medical Writers Association (AMWA), she is also active in ISMPP and is a founding member of the Global Alliance of Publication Professionals (GAPP). She has advocated ethical standards for publication professionals for decades, developed and taught AMWA ethics workshops, and conducted research in this area.

  Cindy holds a Doctor of Pharmacy degree from the University of the Sciences in Philadelphia and a Bachelor of Science degree in pharmacy from the University of North Carolina at Chapel Hill. Before becoming a medical writer, she was a clinical pharmacist, taught pharmacy, and was a clinical research scientist at a pharmaceutical company.

ABOUT AMWA

- Mission: to promote excellence in medical communication and to provide educational resources in support of that goal.
- Membership: ~5000 medical writers, editors, and other medical communicators working in the US, Canada, and 30 other countries and providing services to pharmaceutical companies, universities and medical schools, hospitals, nonprofit organizations, government agencies, journals, and many other businesses and organizations

www.amwa.org

AMERICAN MEDICAL WRITERS ASSOCIATION
The Resource for Medical Communicators
LEADING MEDICAL WRITING FOR 75 YEARS
75 YEARS

WHAT'S NEW? CERTIFICATION

- Eligibility for certification: Professional medical writers (PMWs) who have a bachelor's degree and have worked as medical communicators for at least 2 years may pursue the credential.
- Definition: PMWs write, edit, and develop materials about medicine and health by gathering, evaluating, organizing, interpreting, and presenting information in a manner appropriate for the target audience. PMWs have communication expertise, awareness of ethical standards, and health care knowledge.
- Examination dates
  - September 30, 2015 at the AMWA conference
  - Spring 2016 at the DIA meeting

MEDICAL WRITER CERTIFIED

STEPS FOR TACKLING THE GHOSTWRITING CONTROVERSY

2001
- Appoint a task force.
- Research the controversy.

2002
- Develop a position statement.

2003
- Expand educational resources.

2005
- Survey members every 3 years.

AMWA CODE OF ETHICS

- Preamble: AMWA “is an educational organization that promotes advances and challenges in biomedical communication by recommending principles of conduct for its members.”
- Principle 1 of 8: “Medical communicators should recognize and observe statutes and regulations pertaining to the materials they write, edit, or otherwise develop.”

AMWA POSITION STATEMENT

- AMWA recognizes the valuable contributions of biomedical communicators to the publication team.
- Biomedical communicators who contribute substantially to the writing or editing of a manuscript should be acknowledged
  - with their permission and
  - with disclosure of any pertinent professional or financial relationships.
- In all aspects of the publication process, biomedical communicators should adhere to the AMWA code of ethics.

Adopted 2002.

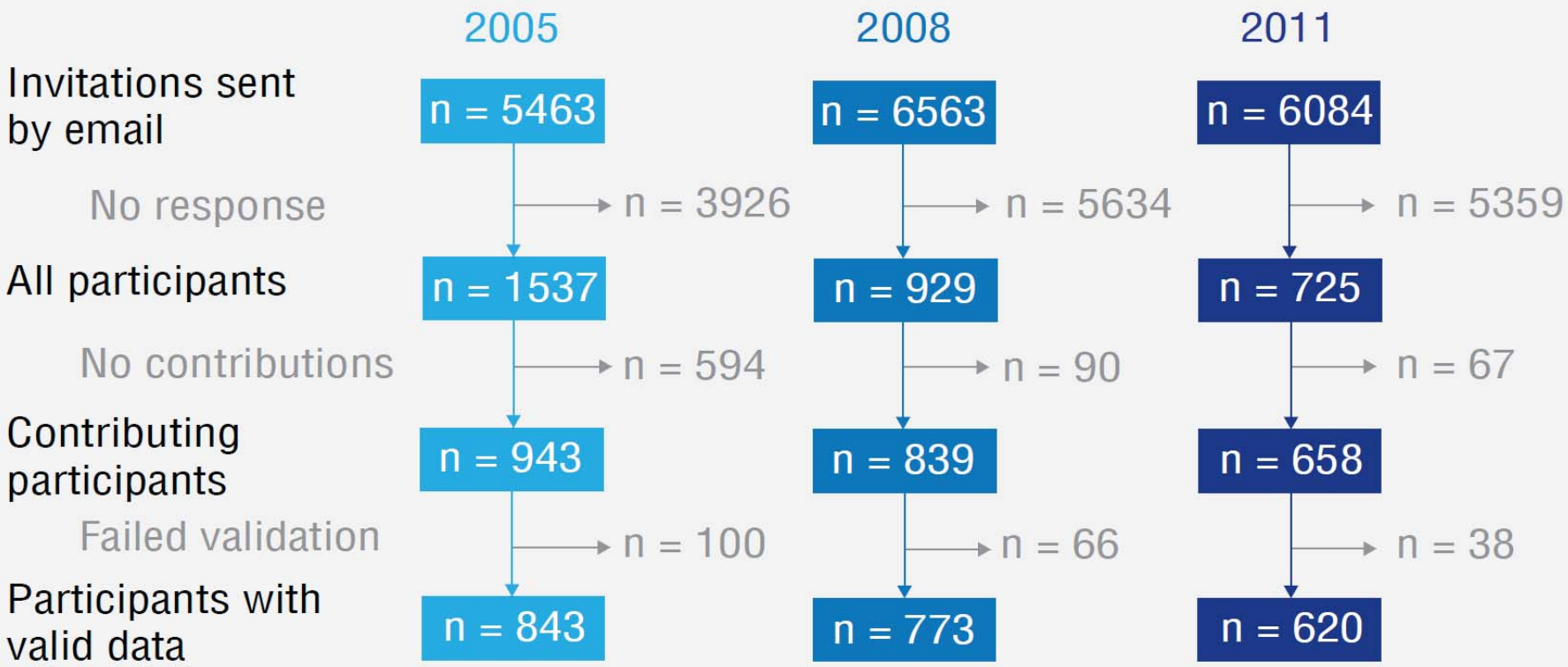
GHOSTWRITING SURVEY

- Rationale: perception that ghostwriting is widespread
- Objectives
  - Primary: to determine the prevalence of ghostwritten manuscripts among AMWA and EMWA members
  - Secondary: to determine the prevalence of medical communicators' requests for disclosure and predictors for requests

GHOSTWRITING SURVEY: METHODS

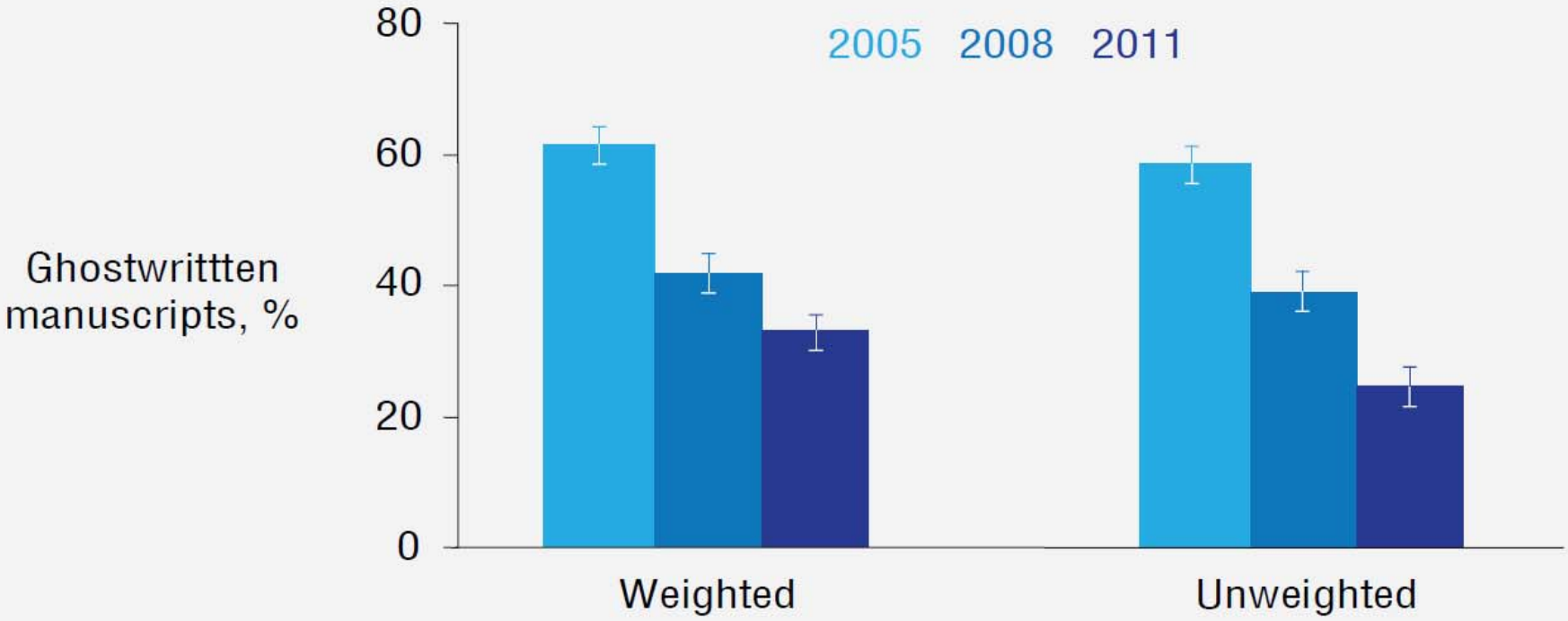
- Self-administered, confidential survey of AMWA and EMWA members in 2005, 2008, 2011, and 2014
- E-mail invitation to all AMWA and EMWA members, with 1 reminder and no incentives
- Survey with 14 multiple-choice questions about medical communicators and their contributions to manuscripts for submission to medical journals
- Internal validation of responses
- Statistical analyses

GHOSTWRITING SURVEY: PARTICIPANTS



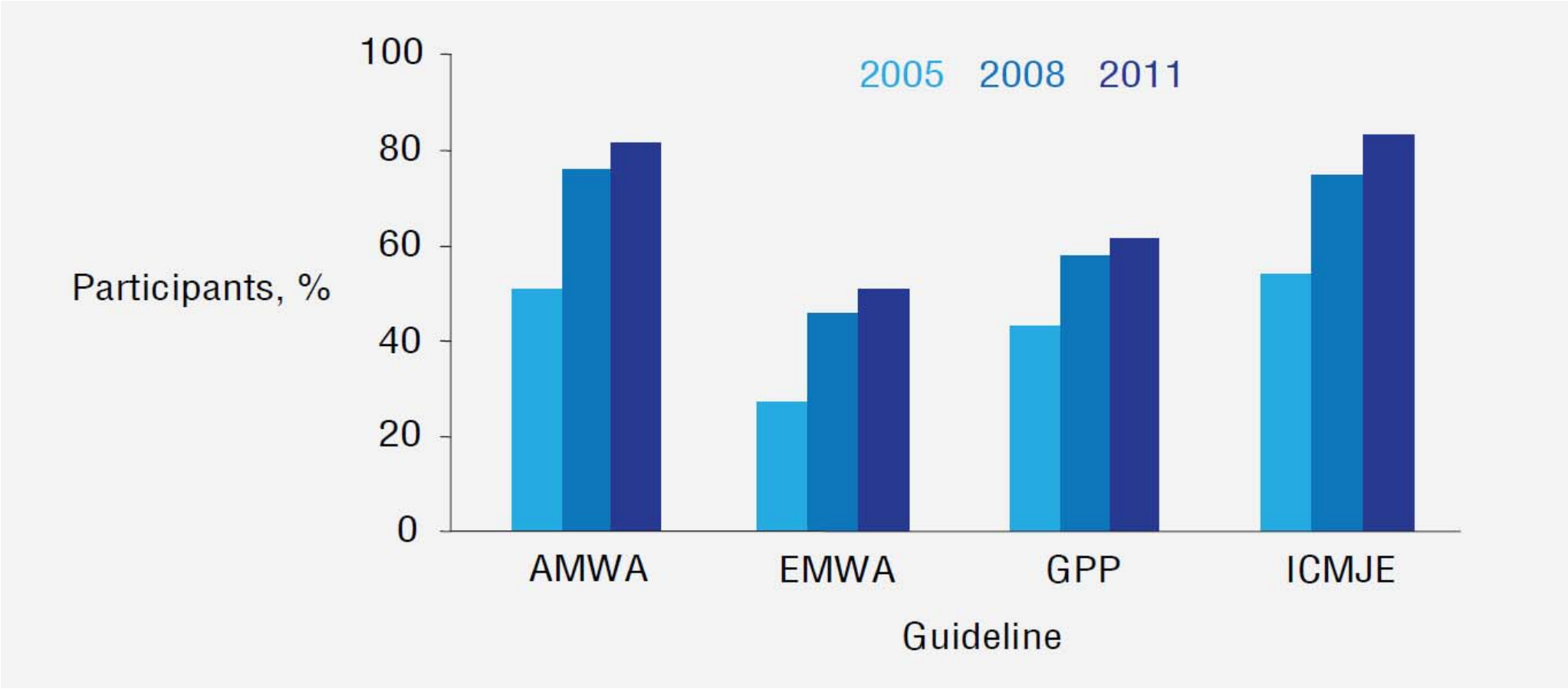
Hamilton CW, Jacobs A. Poster. AMWA AC Oct 4-6, 2012. Sacramento CA.

GHOSTWRITING SURVEY: RESULTS



Hamilton CW, Jacobs A. Poster. AMWA AC Oct 4-6, 2012. Sacramento CA.

GHOSTWRITING: FAMILIARITY WITH GUIDELINES



Hamilton CW, Jacobs A. Poster. AMWA AC Oct 4-6, 2012. Sacramento CA.

GHOSTWRITING SURVEY: EXPERIENCE OF AND PRACTICE IN REQUESTING ACKNOWLEDGMENT

Type of experience or practice	Number (%)		
	2005	2008	2011
Change in prevalence of ghostwriting in last 5 years	N = 688	N = 651	N = 526
Decreased to none	20 (3)	72 (11)	95 (18)
Decreased but still occurs	250 (36)	340 (52)	275 (52)
No change	360 (52)	198 (30)	137 (26)
Increased	58 (8)	41 (6)	19 (4)
Request disclosure of contributions	N = 747	N = 665	N = 533
Always	187 (25)	288 (43)	309 (58)
Usually	183 (24)	168 (25)	118 (22)
Rarely or never	377 (50)	209 (32)	106 (20)
Requests for disclosure granted	N = 365	N = 466	N = 424
Always	127 (35)	224 (48)	257 (61)
Usually	177 (48)	185 (40)	142 (34)
Rarely or never	61 (17)	57 (12)	25 (6)

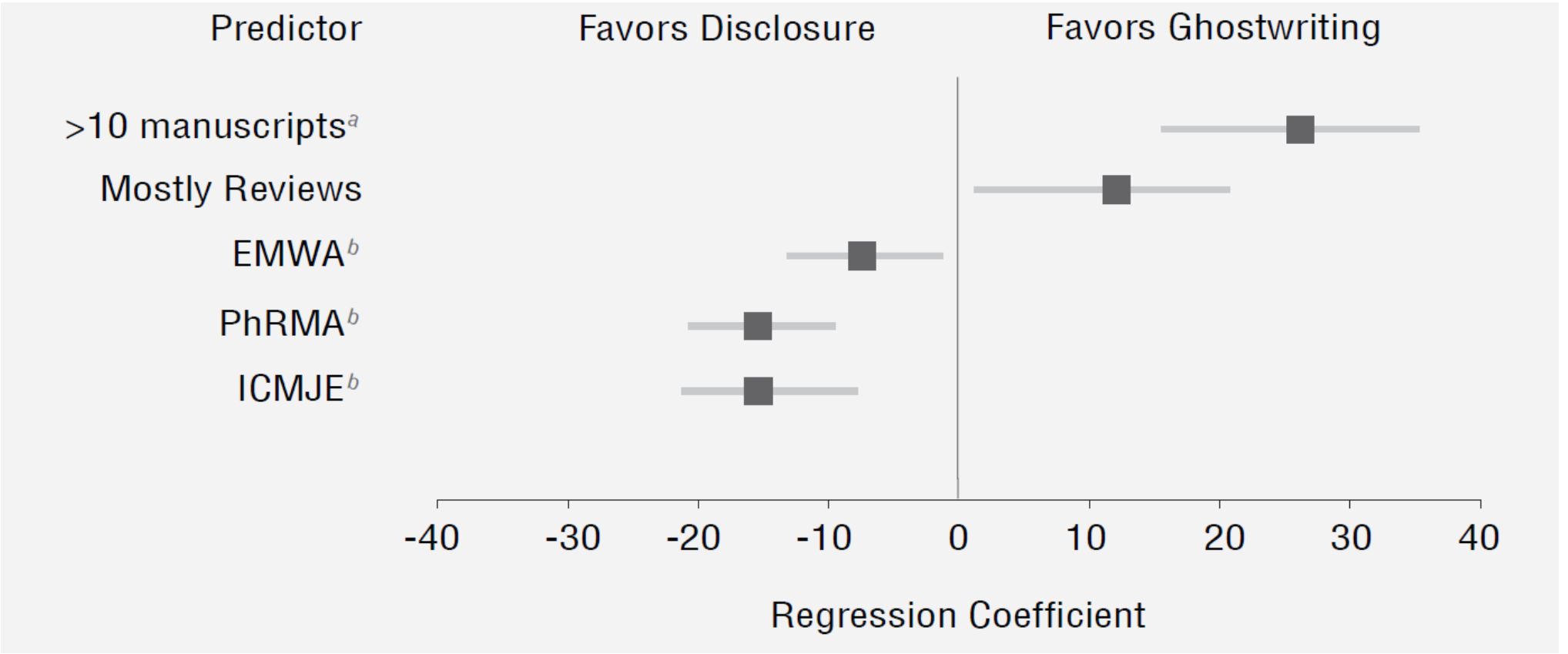
Hamilton CW, Jacobs A. Poster. AMWA AC Oct 4-6, 2012. Sacramento CA.

GHOSTWRITING SURVEY: UNIVARIATE ANALYSIS

- Participants familiar with more guidelines were less likely to have their contributions unacknowledged.
  - Regression coefficient for number of guidelines from univariate analysis, –7.68
  - 95% CI, –9.54 to –5.82
  - $P < .001$

Hamilton CW, Jacobs A. Poster. AMWA AC Oct 4-6, 2012. Sacramento CA.

GHOSTWRITING SURVEY: MULTIVARIATE REGRESSION ANALYSIS



Hamilton CW, Jacobs A. Poster. AMWA AC Oct 4-6, 2012. Sacramento CA.

[a] Number of manuscripts/year relative to 1 to 2; [b] familiarity with specific guideline.

WHERE DO WE GO FROM HERE?

EUROPEAN MEDICAL WRITERS ASSOCIATION (EMWA)

Julia Donnelly BPharm PhD

EMWA President, 2014–2015

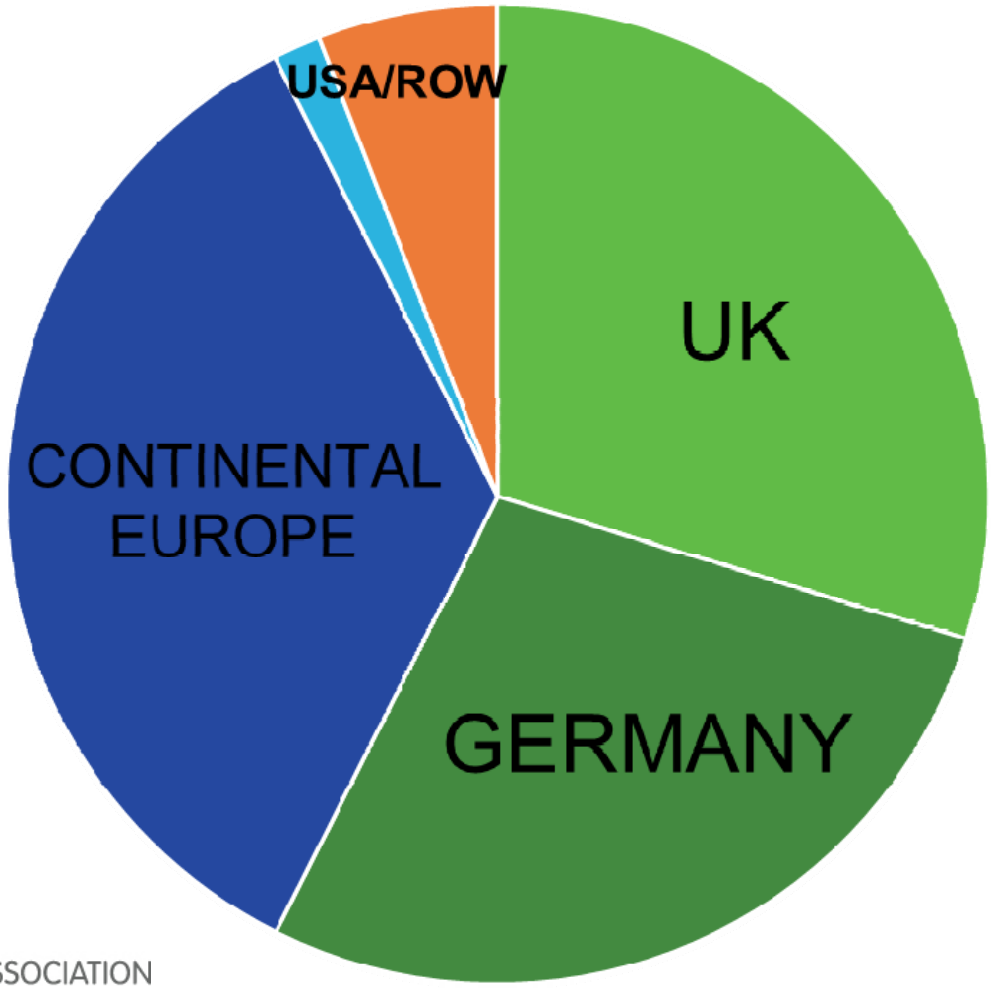
INTRODUCTION

- **Faculty:** Julia Donnelly has run her own medical communication company (Julia Donnelly Solutions Limited) since 2003 and works predominantly for pharmaceutical industry clients. Previously she has worked as a medical writer, project leader, editorial director, technical director and global resource, training and development director in international medical communications. Julia also worked within medical information and hospital pharmacy. She is an experienced medical writer and publication manager (both in-house and out-contracted) and has developed over 40 publication plans in diverse therapeutic areas. Julia is an accomplished trainer, running six EMWA workshops, a post-graduate module on Medical Writing for the University of Manchester Pharmaceutical Industry Advanced Training programme and bespoke in-house courses. Julia is the serving President of EMWA (May 2014-2015).

ABOUT EMWA

- Mission: to represent, support and train medical writing professionals
- Membership: ~1000 medical writing professionals who are involved in any aspect of medical writing (writing, editing, translation, project or publication management)
- Regulatory or medical communications

GEOGRAPHIC DISTRIBUTION OF MEMBERS



EUROPEAN MEDICAL WRITERS ASSOCIATION

OBJECTIVES

EUROPEAN MEDICAL WRITERS ASSOCIATION

RECOMMENDATIONS and GUIDELINES

Ethics should be paramount for all of our members

- Awareness
- Education
- Sharing experience
- Identifying gaps
- Collaborating with fellow professionals
- Developing guidelines and tools

INITIATIVES

- EMWA Professional Development Programme (80+ topics)
- Bespoke journal (*Medical Writing*)
- Spring and Autumn conferences
- Symposia days
  - 2014 Transparency of clinical trial data – where does medical writing fit in?
  - 2015 Risk management and risk-benefit evaluation – a 360° perspective
- EMWA Guidelines (Wager & Jacobs 2005)

NEW INITIATIVES

- Webinar program
- E-learning
- Expert seminar series
- Webeditorials

EMWA-AMWA JOINT ALL-NEW CORE (CLARITY AND OPENNESS IN REPORTING: E3-BASED) REFERENCE

- The CORE Reference project began as a detailed review and recommendation project on ICH E3, led by the EMWA Budapest Working Group (BWG).
- Final output will be a manual intended to:
  - Assist authors of clinical study reports
  - Complement existing 1995 ICH E3 guidance and 2012 ICH E3 Q&A update
- Being developed in close collaboration with all relevant stakeholders, including medical establishment, patient advocates, industry and regulators
- Scheduled for mid-2016

INTERNATIONAL SOCIETY FOR MEDICAL PUBLICATION PROFESSIONALS (ISMPP)

Al Weigel, MEd, CMPP

President and COO, ISMPP

INTRODUCTION

- **Faculty:** Al Weigel is President and COO for the International Society for Medical Publication Professionals (ISMPP). Al joined ISMPP in November of 2013 with primary responsibility for implementing the strategic goals and vision of the Society, in addition to ensuring the Society meets established milestones foaweigel@ismpp.orgr ongoing development, growth and success. Prior to joining ISMPP, Al led cross-therapeutic medical publication and scientific communication teams at sanofi-aventis, Boehringer-Ingelheim and Celgene Corporation.

  Al earned his Masters of Education at the University of the Arizona and is a ISMPP Certified Medical Publication Professional (CMPP).

VISION AND MISSION

Vision

To become the leading global authority on the ethical and effective publication of medical research to inform treatment decisions.

Mission

Advance the medical publication profession globally through:

- enhanced integrity and transparency in medical publications
- improved standards and best practices
- education, advocacy, and professional collaborations

ISMPP CODE OF ETHICS

ISMPP CODE OF ETHICS (CoE)

- First released in 2007 to address the need for ISMPP to establish ethical principles that guide our professional conduct
- Updated in 2011 to reflect changes in the external environment and ISMPP's continued commitment to ethical principles
- Provided a stronger foundation for our advocacy initiatives
- More positive tone, more definitive wording, and focused on "principles"
- The positive tone of the CoE emphasizes the value of our professional expertise – we are experts at doing things right and don't just mitigate risk
- CoE Case Studies series issued in 2014 to emphasize ISMPP's commitment to ethical practices

ISMPP CODE OF CONDUCT

ISMPP CODE OF CONDUCT

- Published on July 7, 2014
- Outlines appropriate and expected standards of professional behavior of CMPP applicants and certificants
- ISMPP core value – promotion of ethical and transparent publication practices

INTERNATIONAL SOCIETY FOR MEDICAL PUBLICATION PROFESSIONALS, INC. (ISMPP)

CERTIFICATION PROGRAM
CODE OF CONDUCT

Introduction

The International Society for Medical Publication Professionals, Inc. (ISMPP) is a non-profit, professional association dedicated to: advancing the practice of medical publication planning and development; supporting medical publication professionals; and, promoting ethical medical publication practices. The ISMPP Certified Medical Publication Professional (CMPP) Certification Program (Certification Program) credentials medical publication professionals who have met the professional standards established by the ISMPP Certification Board.

The Certification Program Code of Conduct (Code) establishes the core ethical standards for the professional behavior of CMPP applicants and certificants. The Code is designed to provide enforceable standards of conduct. Conduct matters related to this Code will be reviewed and processed consistent with the Certification Program Conduct Case Procedures.

General Conduct Standards

CMPP applicants and certificants provide quality, professional services in a manner that promotes integrity and transparency; and reflects positively on the profession, consistent with accepted ethical and legal standards.

CMPP applicants and certificants pledge and agree to: act with integrity and transparency; practice with fairness and honesty; act consistent with established standards of professional conduct; accept responsibility for their actions; continually seek to enhance their professional capabilities; and encourage others to act in an appropriate professional manner, consistent with all ISMPP certification standards and the conduct principles set forth below.

http://www.ismpp.org/code-of-conduct

DOES ISMPP CODE OF CONDUCT DIFFER FROM THE ISMPP CODE OF ETHICS?

- ISMPP Code of Ethics
  - A voluntary, professional resource for ISMPP members
- ISMPP Code of Conduct
  - Developed specifically for CMPP applicants and certificants
  - Formalizes the obligation to work to acceptable standards of professional ethics and practices
  - Enforceable: Conduct Case Procedures for complaints regarding professional conduct and structured appeals process

ISMPP: GPP SPONSORSHIP

- Development of the GPP2 and GPP3 guidelines was initiated and sponsored by ISMPP
- ISMPP provided the resources to help the GPP2/3 Steering Committee:
  - ISMPP mailing list
  - managing database of respondents
  - setting up reviewer website
  - creating/updating GPP website
  - translating the guidelines

BROADENING OUR GLOBAL PRESENCE AND OUTREACH

Asia-Pacific

- 2014
  - A-P specific ISMPP U's
  - Two successful Leadership Summit meetings in China and Japan

  Goal: Enhance ethical publication practices in the AP region by bringing together leaders from government, academia, medical publishing, and the healthcare industry to identify opportunities to collaborate on awareness, education, and advocacy initiatives
- 2015
  - Continue with A-P specific ISMPP U's
  - A number of educational activities that in some cases will be in partnership with local country associations/societies
  - Two live one-day educational meetings in China and Japan

BROADENING OUR GLOBAL PRESENCE AND OUTREACH

India

- 2015 Goals: further explore the needs and requirements of medical writers and publication professionals in India and consider possible collaboration with other associations/societies
- Contacts identified for initial outreach:
  - All India Medical Writer's Association
  - Indian Society for Clinical research (ISCR)
  - Indian Association of Medical Journal Editors (IAMJE)

Latin America/South America

- Initial efforts on understanding issues and countries to focus on


COLLABORATIONS

ESTABLISHED RELATIONSHIPS

- AMWA
- Coalition for Healthcare Communication (CHC)
- EMWA
- GAPP
- MPIP

DEVELOPING RELATIONSHIPS

Co-promotion of activities occurring; pursuing collaborations on content and other member benefits:

- Committee On Publication Ethics (COPE)
- Council of Science Editors (CSE)
- Drug Information Association (DIA)
- Society for Technical Communications (STC)
- European Association of Science Editors (EASE)
- EQUATOR NETWORK

OTHER COLLABORATIONS

- Task Force: goal of conducting a needs assessment around collaboration with select external organizations
- Successful presentation by ASCO at 2014 Annual Meeting
  - Assessing continued areas of collaboration
- Presentation scheduled at *Society of University Urologists* and *American Urological Association* Annual Meeting
  - May 15, 2015
  - Focus: Academic/Industry Publication Practices

UNIFIED GOALS

- There remains many challenges in foreseeable future
- Time for more formalized collaborations among organizations with common goals:
  - integrity and transparency in medical publications
  - improved standards and best practices
  - education and advocacy for our profession
- Time for more evidence-based research in our field *and publication of research results*

BROADER FUTURE COLLABORATION

- Others?
  - AAMC
  - ABPI
  - IFPMA
  - PhRMA

Competition makes us faster; Collaboration makes us better!

QUESTIONS.....

To ask a question, please type your query into the ‘Q&A’ chat box at the bottom left of your screen. Every attempt will be made to answer all questions.

UPCOMING ISMPP U WEBINARS

- Wednesday, February 25, 2015
  - Topic: MPIP Introduces “Five-step Authorship Framework” to Improve Transparency in Disclosing Contributors to Industry-Sponsored Publications

THANK YOU FOR ATTENDING!

We hope you enjoyed today's presentation.

Please take a moment to click on the link that will be provided and complete the survey. We depend on your valuable feedback as we develop future educational offerings.