

# Publication Ethics: The dos and don'ts



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# Disclosures



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# Audience Participation



- Who here has published  $< 5$  peer-reviewed articles?
- Who here has published  $>5$ ?
- $>10$ ?
- $>20$ ?

Have you ever been unhappy/angry with the process?

Do you feel you understand the peer-review process?

Is it getting harder to publish (in peer-reviewed journals)?

Is it important??

# Agenda



- Describe the “process” at our journal
- Case-based learning. 4 examples of “problems” and how they might be dealt with
- Discussion of publication ethics from the perspectives of author, reviewer, and editor/journal
- Review of how this information applies to the 4 cases



# The Process

“continuously available”



- Conversion to an electronic editorial office (faster)
- Highly effective publications committee, and editorial board (associate editors)
- Statistical/methodologic review (now more sophisticated with 3 levels; at the outset, during the process, and just before final acceptance/rejection) usually in conjunction with content review
- Executive Editor (oversees day to day operations, interactions with the publisher, American Headache Society, authors, reviewers, associate editors, editor-in-chief)

# My Perspective as Editor



- Manuscript arrives: is it publishable? (guideline filled out, IRB approval, interesting, high quality, is the conclusion justified?).
- Options: immediate accept, immediate reject, or....send out for review.
- Review: choose an associate editor who then chooses reviewers. Their job is to ascertain if the manuscript should be published and if it needs changes.
- Results: recommendation to accept, minor or major revisions, or reject.
- I can overrule the recommendation but rarely do.

# First Concern



- The editor. “Editorial prerogative”. Potential bias.
- Immediate acceptance/rejection.
- Selection of associate editors (must know their interests, areas of expertise, friendships/affiliations): this will affect the review process outcome
- Conflicts of interest: best to avoid any real or even perceived conflicts. Role of publications committee, board of the journal’s society (e.g. the American Headache Society).
- The editor can be removed for cause.

# Goals



- High quality, rapid review.
- Fair and transparent
- Detect/deter plagiarism ( we have software that helps with this, as well as highly read and experienced expert reviewers)
- Content of high interest and educational value
- Time to initial decision < 30 days (we are there)
- Concerns regarding the Impact Factor, but content does trump the IF (in my opinion)

- “The impact factor is one of these; it is a measure of the frequency with which the "average article" in a journal has been cited in a particular year or period. The annual impact factor is a ratio between citations and recent citable items published. Thus, the impact factor of a journal is calculated by dividing the number of current year citations to the source items published in that journal during the previous two years.” TR



# Case #1



- A case report, in English, from Korea arrives at a competing journal for which I serve as an occasional reviewer. The report looked familiar as I had cause to do a literature search on this topic a year earlier ( an unusual parasitic infection causing headache with unique neurologic signs). On review, the same case had been published in Korean several years earlier (only the abstract was in English). The “new” case was identical except for having been translated into English entirely now.
- There was no mention of the prior publication anywhere in the “new” submission
- Is this a problem?

## Case #2



- A highly productive cardiology fellow in Boston was found by his colleagues to have fabricated data. His supervising attending conducted an (inadequate) internal investigation. Subsequently the NIH found a much larger extent of fraud and for the first time ever demanded funding be returned.
- Additionally, it was revealed that the respected supervising cardiology attending had provided inadequate supervision and was disturbingly unaware of the fellow's research activities
- How is this problem now mitigated regarding already published articles?

## Case #3



- An article submitted to the journal did not fare well in the review process. The reviewers and the Associate Editor recommended “rejection.”
- The editor found interesting material in the article and was unsatisfied with the recommendation. He acquiesced and rejected the article but contacted the author and stated if the manuscript was significantly revised, in fact made into 2 submissions, they would be given new, clean reviews.
- Is this acceptable? Or is it “corruption”?

## Case #4



- The journal editor was contacted by the Editor-in-Chief of the Cochrane Collaborative. An article published in the journal > 10 years earlier has been found to have problems. The sponsoring drug company was convicted of misrepresentation and fraud in matters involving the conduct of the study and in more widespread matters involving marketing of the study drug (gabapentin). He recommends “retracting” the article.
- What does this mean and what was done?

# Problems in Biomedical Publishing



- Publishing false positives.
- Exaggeration of results.
- Bias (conscious and unconscious)
- Failure to publish (negative) results

# Ethics



- Publication ethics apply to editors, associate editors, reviewers and authors.
- “the peer review system”
  - requires training to ensure quality of peer reviewers
  - handling author misconduct, and misconduct at other levels
  - managing conflicts of interest
  - managing bias: intentional and subconscious

# Safeguards Against Bias



- Some terms (acronyms)
- **CONSORT: Consolidated Standards of Reporting Trials.** CONSORT group formed in 1993, 30 experts (editors, clinical trialists, methodologists and epidemiologists) to deal with problems related to inadequate reporting of randomized controlled trials)
- **Similar: STARD, STROBE, PRISMA, COREQ**

more



- **The Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) Statement: guidelines for reporting observational studies**
- **Preferred Reporting Items for Systematic Reviews and Meta-Analyses: The PRISMA Statement**
- **Towards complete and accurate reporting of studies of diagnostic accuracy: the STARD initiative. Standards for Reporting of Diagnostic Accuracy**



## Yet more



- **Consolidated criteria for reporting qualitative research (COREQ): a 32-item checklist for interviews and focus groups**
- **The CARE Guidelines: Consensus-based Clinical Case Reporting Guideline Development**



- EQUATOR: <http://www.equator-network.org/>
- The EQUATOR Network works to improve the reliability and value of medical research literature by promoting transparent and accurate reporting of research
- Enhancing the QUAlity and Transparency Of health Research

# Publish or perish



- “perverse incentives in academia” may be one of the driving forces behind the publication of questionable studies
- Authors who are “suspiciously productive”. Roles of industry, “ghost writers”.
- Failures to disclose conflicts of interest
- Failures to publish negative results
- Benefits of registration of clinical trials, need to reproduce study results (confirmatory studies)

# Editorial Office Options



- For ethical failings
- Options: investigate. May lead to
- 1. letter to author, superiors, institution, society
- 2. Statement of concern regarding the publication
- 3. Retraction of the article

# Fundamentals of Publication Ethics



- Affect the design, conduct and reporting of research
- Require transparency and integrity
- Oversight at all levels
- For authors: must report who actually carried out the work (and what specific roles each contributed to, such as trial design, conduct of the trial, assembly of the manuscript), who funded the study, and potential conflicts.
- -also has the work been published (in part) before, and is it under consideration elsewhere
  - must protect the rights of research participants

# Authors' duties and responsibilities



- Use appropriate checklist/reporting guideline
- Declare sources of funding
- Define the role of each contributing author
- Acknowledge statisticians, translators
- Register clinical trials
- Protect participants (humans, animals)
  - --IRB approval
  - --anonymity of research participants
  - --Declaration of Helsinki, good clinical practice guidelines

# Authors



- Integrity: must not falsify, fabricate data, manipulate images, nor plagiarize (more on this particular issue to follow separately)

Plagiarism is widespread, and may be intentional or unintentional. It can destroy reputations, careers.

# Editors and Publishers' duties and responsibilities



- Should provide a peer review process that is efficient, transparent, protects confidentiality
- Peer reviewers: should declare conflicts of interest, provide objective, informed, unbiased, and prompt reviews.
- Should avoid personal attacks.
- Anonymity but with oversight. Sometimes the manuscript may become unblinded.



# Editors



- Should be independent. Ultimately editorial integrity is a highly personal issue. The editor may even feel compelled to resign if conflicts cannot be resolved.
- Not influenced by commercial, academic, personal or political factors.
- Ensure accuracy of published materials
- Encourage academic discourse and debate
- Manage due process to investigate author or peer reviewer misconduct

# Editor's responsibilities



- Breaches of ethics:
- Duplicate publication or submission
- Minor versus major. The author, their superior(s), and/or their institution may be informed
- Fabricated data: requires an investigation. May seek a second opinion. Raw data may be requested. The author should be given the opportunity to respond/explain. If cause for concern, the author's institution and regulatory bodies should be informed and investigate further.

# Plagiarism



- *www.merriam-webster.com/dictionary/plagiarize*
- to use the words or ideas of another person as if they were your own words or ideas. pla·gia·rizedpla·gia·riz·ing. Full **Definition** of **PLAGIARIZE**. transitive verb

# Plagiarism



- May be noted during review or subsequent to publication it may be detected, such as by the original author.
- One of our Associate Editors particularly liked a manuscript, until he realized large portions had been transcribed verbatim from one of his own papers!
- Anti-plagiarism software. “Ithenticate”
- Issues of publication in English. Cultural (emulation) and trying to use the language properly. Employ native speakers.

# Ethical problems with studies



- Fundamentals: lack of appropriate approvals or informed consent
- Unethical study design (failure of local institutional review board (IRB)/ethics committee): e.g. denial of best treatment such as use of placebo as opposed to effective treatment)
- Lack of consent, protection of anonymity for case reports
- Notify author and their institution

# Complaints against the journal/editor



- Mechanism for independent investigation
- Publications committee, the board of the relevant society
- Transparent
- Opportunity to present complaint publicly (letter to the editor)
- If no such “structure” then directly to the Publisher

# COPE



- Committee on Publication Ethics
- [Publicationethics.org](http://Publicationethics.org)
- Code of conduct and best practice guidelines for journal editors

## Back to our 4 cases



- Each case represents concerns for a possible breach of ethics
- All have/had a solution
- Obligation of the editor to ensure action is fair, timely and appropriate



## Case #1



- Koreans; re-submitting an article published originally in Korean in English as a “new” article
- Assessment: Self-plagiarism
- Not attributed/referenced. There are nearly 7,000 different languages. Does one suppose one can write an article, then get over 6,000 citations simply by re-translating?
- Action: I alerted the Associate Editor for the journal, the article was rejected with a warning letter to the authors. Relevant journal editors warned about this article and the authors.

## Case #2



- Famous case: Cardiology study with fabricated data.
  - Authors should not enhance their curriculum vitae with false assertions of participation in studies when they actually did not participate. This is fraud. Additionally the “senior” cardiologist did not adequately supervise his trainee.
  - Result: reported in the NEJM and elsewhere extensively and the reputation of the famous investigator and his institution was permanently and severely damaged.
- Relman, AS (1983). "Lessons from the Darsee affair". *The New England Journal of Medicine* **308** (23): 1415–7. [doi:10.1056/NEJM198306093082311](https://doi.org/10.1056/NEJM198306093082311). PMID 6843634.



- Editorial
- [Retraction: Darsee JR, Heymsfield SB, Nutter DO. Hypertrophic cardiomyopathy and human leukocyte antigen linkage: differentiation of two forms of hypertrophic cardiomyopathy. N Engl J Med 1979; 300:877-82.](#)
- To the Editor: In response to the announcement by Harvard University that John R. Darsee, M.D. had fabricated research data while serving as a research fellow in their school of medicine, we initiated an extensive investigation by both internal and external committees of Dr. Darsee's work at Emory...
- June 9, 1983 Nutter D.O. Heymsfield S.B. Glenn J.F.
- N Engl J Med 1983; 308:1400.
- Work at Emory, Notre Dame was fabricated as well
- Eventually lost his medical license

## Case #3



- Rejected manuscript, resubmitted at editor's request as 2 rewritten papers. And sent out for a new review by a new Associate Editor (AE).
- “Corruption”? The papers were accepted and published. The original AE noted this and made an inquiry. The situation was explained to his satisfaction. One original reviewer was unsatisfied.
- The new papers underwent new, blinded peer review and were accepted. They are now highly cited.
- Editorial prerogative ( making important new information available through guidance to authors)

## Case #4



- Old article published years ago on gabapentin for headache, found to have problems with fraud and misrepresentation by the sponsoring company.
- Issues: many authors were important members of the society including past presidents, respected authors, and friends of the editor!!
- Solution?: transparency! The involved parties were all contacted for response, as well as the publications committee and the president of the society. Dr. Sox gave me extensive useful advice as well.



# Case #4



- **From the Editorial Office**
- **Statement of Concern**
- **April issue 2014 Headache**

- **Special thanks to Dr. Harold Sox, Jr.**



# Statement of Concern



- As Editor-in-Chief of *Headache*, I want to alert the readers to some controversy surrounding this article and gabapentin studies in general. Dr. David Tovey, Editor-in-Chief of The Cochrane Library,
- contacted me (see his note below) about concerns regarding gabapentin studies previously reviewed by the Cochrane Collaborative. Legal inquiry has suggested that the sponsoring pharmaceutical company
- at the time may have suppressed certain negative results for gabapentin used to treat headaches. Specifically, regarding an article published in *Headache* and referred to by Dr. Tovey in his correspondence
- published below, the data analysis consisted of a posthoc modified intention-to-treat analysis performed on a study population from which some patients had been deleted rather than the pre-specified primary
- outcome measure, which was not reported.



- While these concerns cast doubt on some studies of gabapentin, the authors of this particular study published in *Headache* in 2001 (Mathew et al) do not wish to retract it and deny any misrepresentation on their part (see their note reproduced below).<sup>1</sup> Despite a good faith effort, I was not able to contact one author, Dr. Leslie Magnus, for comment. More recent information has suggested that there is no strong evidence-based support for the use of gabapentin as a migraine-preventive treatment and the journal suggests you review the most recent Cochrane review on the matter. Given the concerns, the journal makes a Statement of Concern regarding this article and directs interested parties to more recent studies and meta-analyses such as listed here.
- Thomas N. Ward MD





- Correspondence from Dr. Tovey
- “In an updated Cochrane review on ‘*Gabapentin or pregabalin for the prophylaxis of episodic migraine in adults*’ recently published in The Cochrane Library,<sup>2</sup> evidence has been cited that strongly indicates that a paper published in *Headache* in 2001 should be retracted as erroneous and misleading.”
- The paper in question (Mathew et al 2001)(1) was included in an earlier published version of the Cochrane review,(3 ) but excluded from the update
- because of information that came to light through the legal process in 2 US litigations against the manufacturer (Pfizer). The concerns are summarized in the published review by Linde et al (2013).<sup>2</sup> The relevant legal decision referenced in Saris 2014 found, unambiguously, that “the conclusions of the Mathew [2001] article were intentional misrepresentations” (p. 56).



- Correspondence from the Authors
- Dr. Ward, Editor-in-Chief of *Headache*, forwarded Dr. Tovey's letter to the authors of the Mathew et al's article, for review and comments.(1 ) We, the below-listed authors, did not misrepresent data from our carefully conducted clinical trial and find no compelling ethical or scientific reason to withdraw our publication. The manuscript was written with the prime intention of disseminating knowledge, and it was peer reviewed by *Headache* 14 years ago in accordance with contemporaneous publication standards. Legal information that appeared since the study was published indicated the pharmaceutical company that sponsored the trial may have withheld data and misrepresented the primary efficacy end point. Using the primary end point in the intention-to-treat analysis would indicate that gabapentin is ineffective for episodic migraine prevention. The per-protocol analysis at the intended dose demonstrated superiority of gabapentin over placebo



- Ninan Mathew, MD; Alan Rapoport, MD; Nabih Ramadan, MD, MBA; Joel Saper, MD; Brett Stacey, MD, Stewart Tepper, MD.
- **REFERENCES**
- 1. Mathew NT, Rapoport A, Saper J, et al. Efficacy of gabapentin in migraine prophylaxis. *Headache*. 2001; 41:119-128. doi: 10.1046/j.1526-4610.2001.111006119.
- x; [PMID: 11251695].
- 2. Linde M, Mulleners WM, Chronicle EP, McCrory DC. Gabapentin or pregabalin for the prophylaxis of episodic migraine in adults. *Cochrane Database Syst Rev*. 2013;(6):Art. No.: CD010609;doi: 10.1002/14651858.CD010609; [PMID: 23797675].
- 3. Chronicle EP, Mulleners WM. Anticonvulsant drugs for migraine prophylaxis. *Cochrane Database Syst Rev*. 2004;(3):Art. No.: CD003226;doi: 10.1002/14651858.CD003226.pub2; [PMID: 15266476].
- 4. Saris PUSDJ, Findings of fact and conclusions of law, In re Neurontin Marketing and Sales Practices
- Litigation. Civil Action no. 04-cv-10739-PBS, 2010 WL 4325225; 2010. Available at: <http://pacer.mad.uscourts.gov/dc/cgi-bin/recentops.pl?filename=saris/pdf/ucl%20opinion.pdf>. (accessed 30 September 2013).

# And more (? piling on) the following month



- **Letter to the Editor**
- **Cochrane, and the Truth About**
- **Gabapentin for Migraine**
- Timothy J. Steiner, MB, PhD;
- Mattias Linde, MD, PhD
- From the Department of Neuroscience,
- Norwegian University of Science and Technology,
- Trondheim, Norway;
- and Pain, Palliative and Supportive Care Group (PaPaS),
- Cochrane Collaboration, Oxford, UK (T.J. Steiner);
- Department of Neuroscience, Norwegian University of
- Science and Technology and Norwegian National
- Headache Centre, St Olavs Hospital,
- Trondheim, Norway (M. Linde)

## Suggested reading/ references



- Kuehn BM. Striving for a more perfect peer review: editors confront strengths, flaws of biomedical literature. *JAMA* 2013; 310(17): 1781-1783
- Cameron C, Zhao H, McHugh MK. Perspective: publication ethics and the emerging scientific workforce: understanding “plagiarism” in a global context. [Acad Med](#). 2012 Jan;87(1):51-4.
- Morton NS. *Paediatr Anaesth*. 2009; 19(10): 1011-1013
- Saper CB. Academic Publishing, Part I: Peering into the Review Process. *Ann Neurol* 2014; 75(2):175-177.

# Thank you



- Thank you for your attention
- Questions? Comments?
- [Thomas.N.Ward@hitchcock.org](mailto:Thomas.N.Ward@hitchcock.org)



The view from Lake Ward