

Journal Watch

Journal Watch is based on the French-language blog *Rédaction Médicale et Scientifique*, by Hervé Maisonneuve available at <http://www.redactionmedicale.fr>.

SECTION EDITOR



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We need more recommendations to report adverse events in publications

Reporting guidelines, such as Consolidated Standards of Reporting Trials (CONSORT) Harms Extension exist, but the overall communication of adverse event data in publications is suboptimal. Data was collected via in-depth phone interviews with 28 experts (18 industry experts, 6 journal editors, 4 clinical investigators) by medical publication professionals and journal researchers. After analysis of the data, the authors have made five recommendations to improve the quality of adverse events reporting in clinical research publications:

1. Identify and communicate the most clinically relevant drug adverse event data as part of a comprehensive safety profile;
2. Report timing, frequency, duration, and other potentially relevant descriptors when clinically appropriate;
3. Use statistical analysis for clinically relevant adverse events (where appropriate);
4. Avoid use of overly general text descriptions for adverse events, including in abstracts;
5. Discuss adverse events findings in the broader context of available evidence and maintain consistency of data across different public reports. These are intended to supplement



existing guidelines for reporting adverse event data.

Reference: Lineberry N, Berlin JA, Mansi B, Glasser S, Berkwits M, Klme C et al.

Recommendations to improve adverse event reporting in clinical trial publications: a joint pharmaceutical industry/journal editor perspective. *BMJ*. 2016;355:i5078

Online service identifies sponsors who have failed in their duty to make results of clinical trials available



Based on data uploaded on <https://clinicaltrials.gov>, the TrialsTracker tool was successfully built and is now running online at <https://trialstracker.ebmdatalab.net> with the title "Who's not sharing their results?". Users can rank sponsors by number of trials missing, number of trials conducted, and proportion of trials missing. Users can click on a sponsor name to examine the number and proportion of trials completed and reported from each year for that sponsor.

Reference: Powell-Smith A, Goldacre B. The TrialsTracker: Automated ongoing monitoring of failure to share clinical trial results by all major companies and research institutions [version 1; referees: 2 approved]. *F1000Research* 2016, 5:2629.

Plagiarism! Plagiarism!



Three recent articles have discussed plagiarism in scientific/medical literature:

- *Genetics in Medicine* has published its data, and the core results were: *In 400 consecutively submitted manuscripts, 17% of submissions contained unacceptable levels of plagiarised material with 82% of plagiarised manuscripts submitted from countries where English was not an official language. Using the most commonly employed commercial plagiarism detection software, sensitivity and specificity were studied*

with regard to the generated plagiarism score. The cutoff score maximising both sensitivity and specificity was 15% (sensitivity 84.8% and specificity 80.5%). As usual, titles, abstracts, methods and references were not included in the software search for plagiarism.

- A reviewer stole and published data of a paper he rejected for the *Annals of Internal Medicine*. The plagiarised author's letter entitled "Dear plagiarist" is revealing.
- The Office of Research Integrity (USA) has

updated its guide on ethical writing: an excellent resource for teaching, with 28 recommendations. It's a revised edition of a popular learning module. The new edition includes revision throughout and adds cultural linguistic issues.

References:

- Higgins JR, Lin FC, Evans JP. Plagiarism in submitted manuscripts: incidence, characteristics and optimization of screening—case study in a major specialty medical journal. *Res Integr Peer Rev*. 2016;1:13.
- Dansinger M. Dear plagiarist: a letter to a peer reviewer who stole and published our manuscript as his own. *Ann Intern Med*. 2016, December 13 doi: 10.7326/M16-2551.
- Roig M. Avoiding plagiarism, self-plagiarism, and other questionable writing practices: A guide to ethical writing. Office of Research Integrity. November 7, 2016 <https://ori.hhs.gov/avoiding-plagiarism-self-plagiarism-and-other-questionable-writing-practices-guide-ethical-writing>.

Series of articles on "The Changing Face of Clinical Trials"

In June 2016 the *New England Journal of Medicine* inaugurated a series of articles with the aim to examine the current challenges in the design, performance, and interpretation of clinical trials. The series deals with contemporary challenges that affect clinical trialists. It is not meant to be a course in clinical trial performance, rather to stimulate thought and discussion. The NEJM already covered 12 topics that are accessible at <http://www.nejm.org/page/clinical-trials-series>: Comparative effectiveness studies and patient care (June 2, 2016); Adaptive designs for clinical trials (July 7, 2016); Pragmatic Trials (August 4, 2016); The primary outcome fails – What next? (September 1, 2016); Considerations when the primary outcome is positive (September 8, 2016); Data monitoring committees – Expect the unexpected (October 6, 2016); Lessons from clinical

trials involving hypertension (November 3, 2016); Geographic variations in randomised, controlled trials (December 8, 2016); The large pharmaceutical company perspective (January 5, 2017); Drug-development challenges for small companies (February 2, 2017); Informed consent (March 2, 2017); An FDA viewpoint on medical-device clinical trials (April 6, 2017); and there's more to come...

Reference: Woodcock J, Ware JH, Miller PW, McMurray JJV, Harrington DP, Drazen JM. Clinical trials series. *N Engl J Med*. 2016;374:2167.



Ensuring scientific integrity in the age of Trump

There are indications that the Trump administration plans to distort or disregard science and evidence. Most of the leading scientific journals have published papers warning scientists in all domains. For example, the anti-vaccine lobbies were acclaimed by Trump who invited Andrew Wakefield (the fraudulent 1998 research paper suggesting a link MMR/autism). If you enter the key-word "Trump" in journals' search engine (April 10, 2017), you get 733 results for the *BMJ*, 186 for the *New England Journal of Medicine*, 426 for *Nature*, and even more for *Science*. All journals describe the perils of Trumping science. The Journal of Alternative Facts has been launched with Trump as chief editor, with the mission: "the greatest scientific research peer reviewed by politicians and approved by public relations/ submissions via tweet" (<https://twitter.com/journalaltfacts>).

Reference: The above title was copied from a *Science* paper (17 Feb 2017; vol 355, issue, 6326, page 696-698).

Relative Citation Ratio: A new bibliometric indicator

Researchers at the National Institutes of Health (NIH), USA, have described an improved method to quantify the influence of a research article by making novel use of its co-citation network. A Relative Citation Ratio (RCR) is calculated, which is an alternative to using journal impact factor to identify influential papers. RCR can provide valuable supplemental information, either to decision makers at funding agencies or to others who seek to understand the relative outcomes of different groups of research investments. A web tool for RCR calculation is

available at *iCite*, <https://icite.od.nih.gov/>. It “provides access to a dashboard of bibliometrics for papers associated with a portfolio. Users upload the PubMed IDs of articles of interest (from SPIRES or PubMed), optionally grouping them for comparison. *iCite* then displays the number of articles, articles per year, citations per year, and Relative Citation Ratio (a field-normalised metric that shows the citation impact of one or more articles relative to the average NIH-funded paper). A range of years can be selected, as well as article type (all, or only

research articles), and individual articles can be toggled on and off. Users can download a report table with the article-level detail for later use or further visualisation.”

Reference: Hutchins BI, Yuan X, Anderson JM, Santangelo GM. Relative citation ratio (RCR): a new metric that uses citation rates to measure influence at the article level. *PLoS Biol.* 2016;14(9): e1002541.

Experts in research integrity are more concerned about sloppy science than scientific fraud

A survey was conducted among attendees of international research integrity conferences. They were asked to score on a five-point scale, 60 research misbehaviours according to their personal assessment of: frequency of occurrence, preventability, impact on truth (validity), and impact on trust between scientists. Two hundred and twenty-seven participants completed the survey. The rankings suggest that selective reporting, selective citing, and flaws in quality assurance and mentoring are viewed as the major problems of modern research. The “deadly sins” of fabrication and falsification ranked highest on the impact on truth but low to moderate on aggregate level impact on truth, due to their low estimated frequency. Plagiarism is thought to be common but to have little impact on truth although it ranked high on aggregate level impact on trust. The top 5 misbehaviours according to frequency were:

1. Selectively cite to enhance your own findings or convictions;
2. Insufficiently supervise or mentor junior co-workers;



3. Not publish a valid “negative” study;
4. Demand or accept an authorship for which one does not qualify;
5. Selectively cite to please editors, reviewers, or colleagues.

Reference: Bouter LM, Tijdink J, Axelsen N, Martinson BC, Riet G. Ranking major and minor research misbehaviors: results from a survey among participants of four World Conferences on Research Integrity. *Res Integr Peer Rev*, 2016;1:17.

Academic spam invitations are common and irritating, with 2.1 invitations received daily by each investigator

Predatory journals use robots to generate spam academic invitations to publish research. Five Auckland academics (endocrinology, rheumatology, biostatistics, and women’s health specialist) with 10 to 24 years of professional experience analysed all the spams received between February and April 2014: 312 spams per month for the 5 researchers, or 2.1 spams per day per researcher, including weekends!

Spam invitations were characterised by inventive language, flattery, and exuberance, and were sometimes baffling and amusing. The origins of these spams were: Bentham Science, Herbert Publishing, Jacobs Publishers, OMICS Group, Open Access Publications, and Science Domain. The incidence of spam invitations was modestly reduced in the first month after unsubscription and the effect waned after 1 year; 16% of spam

invitations were duplicates and 83% were of little relevance to the recipient.

Reference: Grey A, Bolland MJ, Dalbeth N, Gamble G, Sadler L. We read spam a lot: Prospective cohort study of unsolicited and unwanted academic invitations. *BMJ.* 2016;355:i5383.

Misspellings of drug names impede searches for published literature

When researchers perform literature searches, they should include misspelling among their search terms. Drug names are frequently misspelt by healthcare professionals, and spelling errors are common in databases such as Medline/ Pubmed. This study published in the Christmas issue of the British Medical Journal (BMJ) was correctly done. The authors performed searches with gentamicin, amitriptyline, and other drugs commonly misspelt. In these cases, professionals use y instead of i and vice versa. This study confirmed that spelling errors must be considered when searching the literature: “For example, 18 variants of amitriptyline returned 179 hits that would have been hidden using only the standard name.” The paper advises using truncated search terms: “The textword

“am#tr#pt#l*.af.” truncated at the letter l uncovers variants of the last few letters (for example, ending in “lin,” “line,” “llin,” “lline”) without sacrificing specificity, and gives further hits.”

Reference: Ferner RE, Aronson JK. Nominal ISOMERS (Incorrect Spelling Of Medicines Eluding Researchers) – variants in the spellings of drug names in PubMed: a database review. *BMJ* 2016;355:e4854.



Publication bias in animal research, its extent, its predictors, and its potential countermeasures are increasingly discussed in the literature.

PLOS Biology has published papers on the poor quality and waste in animal research. Three papers contribute to the debate with new proposals:

- Recent reports and conferences highlight the potential strengths of animal study registries (ASRs). A literature review and 21 international key-informant interviews were used to identify 130 ASR-related strengths, weaknesses, facilitators, and barriers. All stakeholder groups agreed that ASRs could in various ways improve the quality and refinement of animal studies while allowing their number to be reduced, as well as supporting meta-research on animal studies. The comprehensive information gathered could help to guide a more evidence-based debate and to design pilot tests for ASRs.
- That most animal research undergoes peer review or ethical review would offer the possibility to detect risks of bias at an earlier stage, before the research has been conducted. For example, in Switzerland, animal experiments are licensed based on a detailed description of the study protocol and a harm-benefit analysis. Similar to manuscripts getting accepted for publication despite poor reporting of measures against bias, applications for animal experiments may often be approved based on implicit confidence rather than explicit evidence of scientific rigor.
- There is surplus material remaining that is frequently never revisited but could be put to

good use by other scientists. Recognising that most scientists are willing to share this material on a collaborative basis, it makes economic, ethical, and academic sense to explore the option to utilise this precious resource before generating new/additional animal models and associated samples. To bring together those requiring animal tissue and those holding this type of archival material, a framework called Sharing Experimental Animal Resources, Coordinating Holdings (SEARCH) was devised with the aim of making remaining material derived from animal studies in biomedical research more visible and accessible to the scientific community.

References:

- Vogt L, Reichlin TS, Nathues C, Würbel H. Authorisation of Animal Experiments Is Based on Confidence Rather than Evidence of Scientific Rigor. *PLoS Biol.* 2016;14(12): e2000598.
- Wieschowski S, Silva DS, Strech D. Animal Study Registries: Results from a Stakeholder Analysis on Potential Strengths, Weaknesses, Facilitators, and Barriers. *PLoS Biol.* 2016;14(11): e2000391.
- Morrissey B, Blyth K, Carter P, Chelala C, Jones L, Hohen I, et al. The Sharing Experimental Animal Resources, Coordinating Holdings (SEARCH) Framework: Encouraging Reduction, Replacement, and Refinement in Animal Research. *PLoS Biol.* 2017;15(1): e2000719.

