Journal Watch

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

SECTION EDITOR

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A proposal to change the default *P*-value threshold

The one sentence summary of a paper signed by 72 statisticians was: "We propose to change the default *P*-value threshold for statistical significance for claims of new discoveries from 0.05 to 0.005".[1] The proposal is straightforward, but it must be correctly understood, as it targets new discoveries.

> *This simple step would immediately improve the reproducibility of scientific research in many fields. Results that would currently be called "significant" but do not meet the new threshold should instead be called 'suggestive'. They clarified that "We restrict our recommendation to claims of discovery of new effects. We do not address the appropriate threshold for confirmatory or contradictory replications of existing claims. We also restrict our recommendation to studies that conduct null hypothesis significance tests. We have diverse views about how best to improve reproducibility, and many of us believe that other ways of summarising the data, such as Bayes factors or other posterior summaries based on clearly articulated model assumptions, are preferable to P-values.*

Such a proposal could favour large studies and concentrate funding to few research groups.

In another report, *Nature* asked five influential statisticians their views on the role of statistics in poor reproducibility of results and to each recommend one change to improve interpretation of data.[2] The five answers concerned the researchers' practices rather than the use of statistics and can be summarised as:

"Adjust for human cognition."

– *Jeff Leek, Johns Hopkins Bloomberg School of Public Health in Baltimore, Maryland*

"Abandon statistical significance."

– *Blakeley B. McShane, Northwestern University, Evanston, Illinois, and Andrew Gelman, Columbia University, New York*

"State false-positive risk, too."

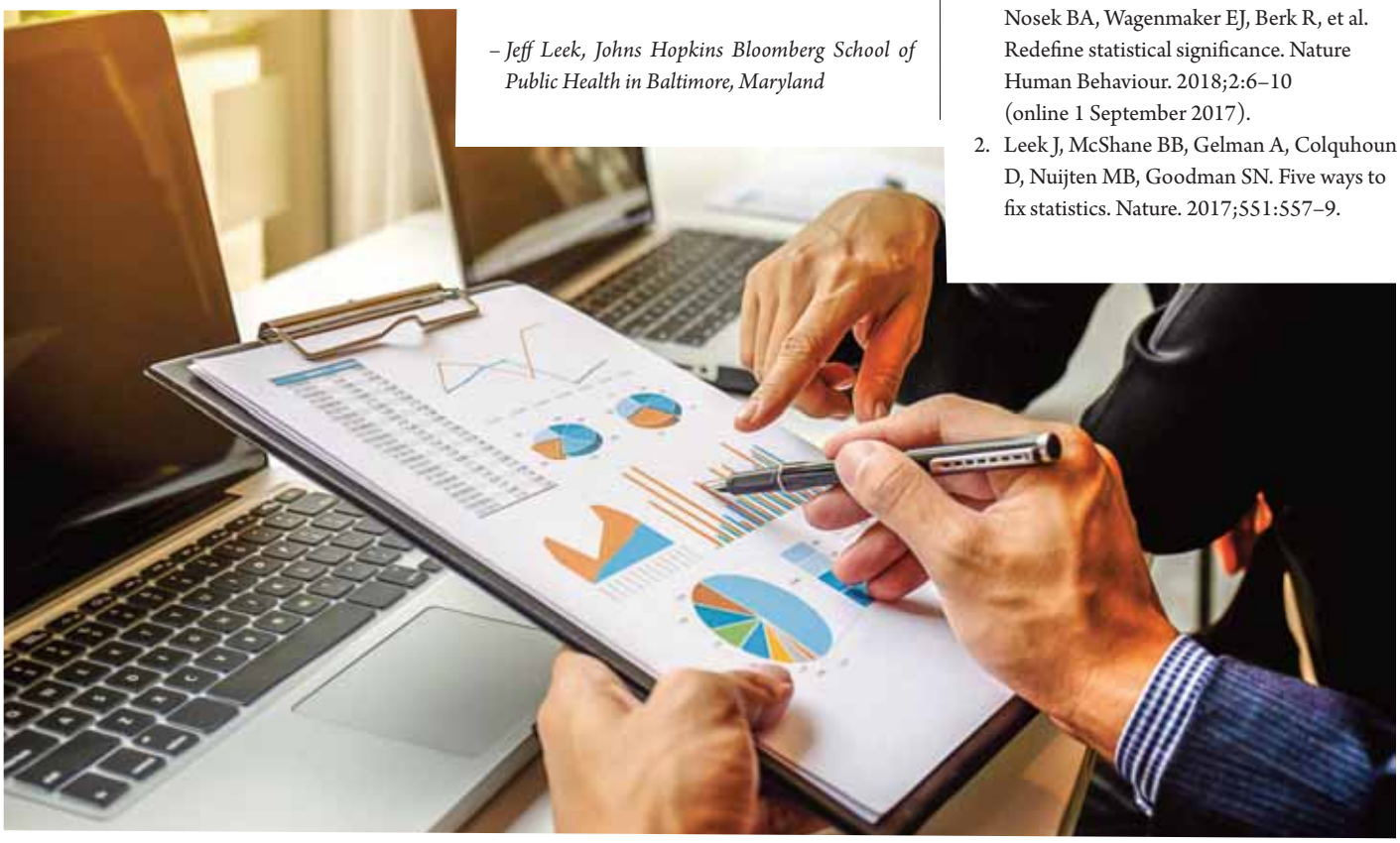
– *David Colquhum, University College London*

"Share analysis plans and results."

– *Michèle B. Nuijten, Tilburg University, the Netherlands*

"Change norms from within."

– *Steven Goodman, Stanford University, California*



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1. Benjamin DJ, Berger JO, Johannesson M, Nosek BA, Wagenmaker EJ, Berk R, et al. Redefine statistical significance. Nature Human Behaviour. 2018;2:6–10 (online 1 September 2017).
2. Leek J, McShane BB, Gelman A, Colquhoun D, Nuijten MB, Goodman SN. Five ways to fix statistics. Nature. 2017;551:557–9.

Guidelines for the content of statistical analysis plans in clinical trials

A group of experts has prepared, tested, and published a list of 55 items/sub-items as guidance for preparing a Statistical Analysis Plan (SAP) for clinical trials.[1] The researchers conducted a survey of current practice across trial units registered with the UK Clinical Research Collaboration and used a Delphi survey to collect information from 73 invited participants including statisticians, guidelines authors, and journal editors. This was followed by a consensus meeting. No existing guidance for SAP content was identified in their literature search or contacts with funders and regulators. The SAP is not a stand-alone document but rather should be read in conjunction with the clinical trial protocol; the protocol should be consistent with the principles of the SPIRIT (Standard Protocol Items: Recommendations for Interventional Trials) statement. According to ICH E9 (Statistical Principles for Clinical Trials), a SAP "contains a more technical and detailed elaboration of the principal features of the analysis described in the protocol, and includes detailed procedures for executing the statistical analysis of the primary and secondary variables and other data".

The 55 items/sub-items are listed under six sections: Title and Trial Registration; Introduction; Study Methods; Statistical Principles; Trial Population; and Analysis. The supplementary online content has additional information and examples for each item. Some journals, including *JAMA*, require the SAP to be submitted along with the report of a clinical trial for use within the peer-review process.[2]

References

1. Gamble C, Krishan A, Stocken D, Lewis S, Juszczak E, Doré C, et al. Guidelines for the content of statistical analysis plans in clinical trials. JAMA. 2017;318:2337–43.
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Authorship policies in an age of large research teams

A five-page editorial authored by *JAMA* editors explains their policy for maintaining integrity of authorship in team science.[1] Their concern is that as science has become increasingly collaborative, it is becoming more common for papers to have hundreds or even thousands of listed authors. They gave examples of papers on the sequencing of the human genome with 270 authors and 240 listed as collaborators. In their editorial, they have reproduced the JAMA Network journals authorship form. Authors must comply with the four ICMJE (International Committee of Medical Journal Editors) criteria. Individuals who do not meet authorship criteria but who have made important substantive contributions to the work should be acknowledged for their contributions and can be listed as collaborators. The main headings of the editorial are: author and research group designations; other authorship considerations (author contributions, shared author responsibilities, changes in authorship, resolving disagreements among authors). The following terms and definitions are listed:

- *Contributor:* Anyone, such as an author, a collaborator, or any other who has assisted or contributed in a meaningful way to the work.
- *Author:* A type of contributor who has participated sufficiently in the work to take public responsibility for the content, either all of the work or an important part of it, and meets defined criteria for authorship. Identification of authorship in a manuscript and published article can appear in two places: Byline author: Author name included in the article byline. Non-byline author: Author name not included in the article byline but listed elsewhere, typically in an acknowledgment or article Information section.
- *Group author:* A group of individuals, usually involving multicentre study investigators, members of working groups, and official or self-appointed expert boards, panels, or committees, who wish to display a group name to indicate authorship.
- *Collaborator:* Another type of contributor who is a non-author member of a formal group and who contributes significantly to the work but does not qualify for authorship. These individuals may be listed as collaborators in an Acknowledgment or Article Information section.
- *Other contributors:* Anyone else who contributed in some meaningful way and who is not an author or a non-author collaborator. These individuals can be listed under Additional Contributions in an Acknowledgment or Article Information section.

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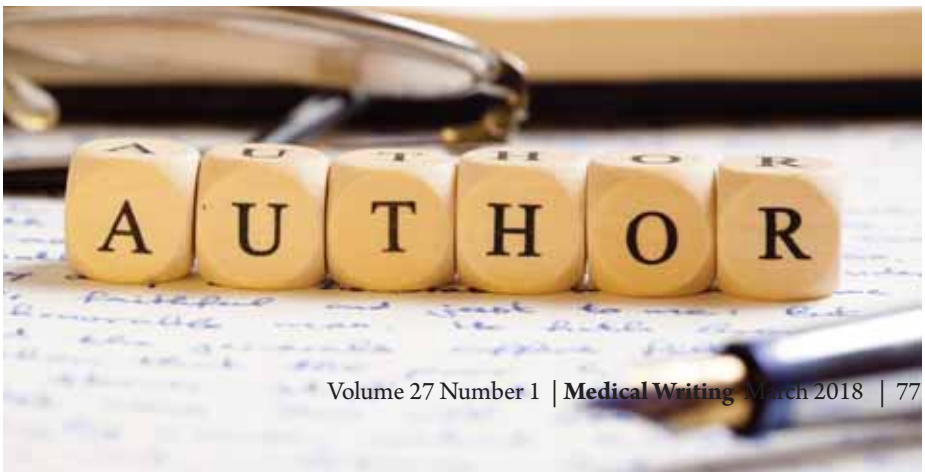
1. Fontanarosa P, Bauchner H, Flanagin A. Authorship and team science. JAMA. 2017;318:2433–7.



EQUATOR Oncology: Enhancing the quality and transparency of health research

The EQUATOR Network regularly updates a website with resources for authors and editors.[1] It contains a compilation of documents to help medical writers to write research papers using reporting guidelines. As of January 2018, there are 389 reporting guidelines and a collection of comprehensive resources developed per specialty. The first specialist-collection, "EQUATOR Oncology", compiles the information that are helpful to oncology researchers. The development of this cancer-specific project within the EQUATOR Network is funded by Cancer Research UK.

The first *EQUATOR Oncology Current Awareness Bulletin,* with a roundup of links to interesting publications and resources, was published in September 2017. The EQUATOR Oncology website has sections on the quality of reporting of randomised controlled trials in oncology; statistical controversies in clinical research; resources and references for oncology researchers; and a list of oncology-related organisations. Each section lists documents with the links to the original source. The series of 20 articles published in *Annals of Oncology* under the heading of "Statistical controversies in clinical research", is a major asset for oncology researchers. It comprises four articles published in 2015, six articles published in 2016, and 10 articles published in 2017. Most of these articles concern the poor quality of reporting research and the "beautification" practices of authors.

Reference

1. EQUATOR Network, http://www.equator-network.org/.

Researchers from wealthy nations contribute to Illegitimate predatory journals

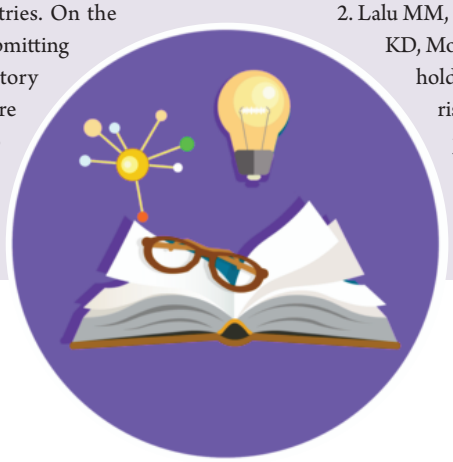
Two papers from the Ottawa-based research team Centre for Journalology (http://www.ohri.ca/journalology/) led by David Moher, are alarming the research community regarding a waste of human, animal, and funding resources.[1,2] Both articles relate to the matter of predatory journals, a global and growing problem contaminating all domains of science.

Although there is no universally accepted definition of predatory journals, the authors summed up criteria to identify them as those that

> *… lack scientific rigour, with a poor or non-existent peer-review process and little or no editorial oversight to facilitate rapid publication, thus ensuring receipt of their Article Processing Charge (APC) from authors. Predatory journals are usually not indexed in established bibliometric databases although they often claim legitimate indexing. They also do not indicate how their content will be archived in perpetuity — a key feature of standard online-only journals. They often have journal titles that mimic well-known authentic journals to confuse prospective authors. The APC for many of these journals is a magnitude cheaper than for legitimate open access journals.*

An analysis of 1,907 biomedical articles in predatory journals showed that among the top 10 countries to which the contributing authors belong were the United States, the United Kingdom, Japan, and China. In the past, we used to think that predatory journals concerned low and middle income countries. On the contrary, some authors submitting papers to these predatory journals know what they are doing. It is a way to enhance their curriculum vitae, to respond to the pressure to publish, and to please institutional administrators who do not take measures to stop this waste.

Predatory journals are a global and growing problem contaminating all domains of science. A coordinated response by all stakeholders (researchers, institutions, funders, regulators and patients) will be needed to stop the influence of these illegitimate journals.



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2. Lalu MM, Shamseer L, Cobey KD, Moher D. How stakeholders can respond to the rise of predatory journals. Nat Hum Behav. 2017;1:852–5.