What can a “traditional” journal do to improve published research?

EQUATOR symposium, World Conference on Research Integrity

31 May-4 June, Rio de Janeiro

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Head of Research, BMJ
& Editor-in-chief, BMJ Open
Competing interests

I’m editor in chief of BMJ Open and Head of Research at The BMJ, a wholly owned subsidiary of the BMA

BMJ (the company) receives revenues from drug & device manufacturers through advertising, reprint sales, & sponsorship

I receive a bonus based partly on the financial performance of The BMJ. Both The BMJ and BMJ Open publish all research with open access, supported by article publication fees

The BMJ was a co-founder of the Committee on Publication Ethics (COPE) and of the AllTrials campaign

The BMJ is campaigning for reproducible research
What I’ll cover

The BMJ can improve published research through:

Education

Editorial policies and peer review process

Advocacy and campaigning
Education

Research Methods and Reporting articles and series
Live outreach and workshops
eLearning: Research to Publication programme
What’s the problem?

What are the main reasons for journal editors to reject a research paper, even if it is well written and presented?

• the research question isn’t sufficiently new, interesting, or important

• the research question hasn’t been answered using the best study design

Investigators often lack training on research questions, study designs, and reporting research effectively – and this is why papers get rejected
Research Methods and Reporting: The BMJ’s free resource
Develop your clinical research skills
And learn how to write papers that get published

Courses & Modules

- How to Write & Publish a Study Protocol
  NOW OPEN

- How to Write a Paper

- What Editors and Peer Reviewers Look For

- Publication Ethics

- Designing Clinical Research

- Responsible Conduct of Research

- Introduction to Clinical Trials

Featured Module
The importance of research protocols

1. Your department has had a strategy meeting where it decided it would start a prospective cohort study, in which patients with type II diabetes will be followed up over one year and have, every two months, digital photography of their retinas. This is specifically for the purposes of the study and these patients would not normally be examined so frequently have been asked to write the research protocol.

Which is the most important reason for creating a research protocol?

- Having a protocol will make it easier to get funding for the study
- Making the protocol available to staff who will recruit patients into the study will make patient enrolment quicker
- The protocol could be published
- Writing a protocol is an ethical requirement
- You will benefit from the academic exercise of writing a protocol

The ethical requirement to have a protocol

Learn more about how international standards on research ethics require a protocol for any human study.

International standards on research ethics require a protocol for any human study

WMA Declaration of Helsinki 2013 requires that:

- the design and performance of each research study involving human subjects must be clearly described and justified in a research protocol
- the protocol should state the ethical considerations involved
- the protocol should include information regarding funding, sponsors, institutional affiliations, potential conflicts of interest, incentives for subjects and information regarding provisions for treating and/or compensating subjects who are harmed as a consequence of participation in the research study.

Further study

Below we have presented a copy of clause 22 from the World Medical Association’s Declaration of Helsinki. Read through this to understand why a protocol should describe and justify research involving human subjects.

You may also wish to read the full Declaration, last updated in 2013. [2]
Editorial policies and peer review process

Detailed resources for authors focusing on:

• ethical transparency

• scientific transparency

• open peer review
Ethics aspects of methods:

• what information before consenting?

• how much did study deviate from current normal practice?

• what burden was imposed?

• what risks & benefits for participants/others?

• how might society/future patients benefit in time?

• might publication reveal patients’ identities?
Altman DG, Moher D. Declaration of transparency for each research article. BMJ 2013;347:f4796
Comparative risk of gastrointestinal bleeding with dabigatran, rivaroxaban, and warfarin: population based cohort study


Cite this as: BMJ 2015;350:h1857

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1) Introduction: Consider using an alternative term to NOAC, since these agents are no longer "novel". Perhaps something like "target-specific oral anticoagulants (TSAOs)". Also, either mention all of the available agents in the 1st paragraph (vs only dab & riv), or just mention the drug classes as a whole.

2) Methods, Variables of Interest: Why were inducers/inhibitors of warfarin specifically mentioned, but not agents interacting with either dabigatran or rivaroxaban? Also, consider using the more universally recommended CHADS2-Vasc stroke risk score rather than the outdated CHADS2.

3) Results: I am not clear on why so many differences remained different between groups (particularly in the rivaroxaban non-AF patients) following propensity-score matching. Did the model that was used for matching not fit the data appropriately? Please provide the model diagnostics to support/refute this. Were too few variables used to match?

4) Results, Table 3: How do you explain why the hazard of GI bleeds was higher in the non-AF group with dabigatran vs. warfarin? This was not addressed anywhere in the discussion. While not statistically significant, the results are trending opposite of the AF cohort. Why might this be?

5) Results: When discussing the results of the rivaroxaban analyses, please keep in mind the consistent. Stating that there were numerically, albeit not statistically significant, fewer events with riv vs. warf in the AF cohort, while saying "similirc" of GIB when compared to warfarin" in the non-AF cohort is inconsistent. The non-AF cohort had confidence intervals much closer to statistical significance than the AF cohort.

6) Discussion: In the first paragraph, why was only the AF findings mentioned, and the non-AF findings ignored?

7) Discussion, Interpretation of Findings: When discussing the differences in age between your cohort & the clinical trials, you seem to suggest that the difference of 4 years in mean age could explain the differences in GIB rates. Please substantiate how this magnitude of age difference relates to significant GIB rates.

8) Discussion: Is there a mechanistic rationale for why one might expect differences in upper vs. lower GIB rates with these agents?

9) Figures 2 & 3: Consider adding the p-value for each comparison at the various timepoints to allow for easier interpretation of the data within the figures (same for those in the appendix).

Additional Questions:
Please enter your name: William L. Baker
Job Title: Assistant Professor
Institution: University of Connecticut School of Pharmacy

Reimbursement for attending a symposium?: No
A fee for speaking?: No
A fee for organising education?: No
Funds for research?: No
Funds for a member of staff?: No
Fees for consulting?: No
Promoting integrity in research publication

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COPE will be leading a workshop at the 4th World Conference on Research Integrity in Rio de Janeiro, Brazil, on publication ethics for editors, members of editorial boards and reviewers on Sunday May 31, 2015.

Read more

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All Latest | Latest Cases | Latest News | Upcoming Events

NEWS

COPE Workshop at 4th WCRI, Rio de Janeiro, Brazil, May 31–June 3, 2015

The BMJ's ethics committee meets three times a year and has the ability to communicate regularly by email. Collectively, the members have broad expertise including clinical medicine, research, journalism, bioethics, law, and medical editing.

The committee has six main roles:

Clarity, reviewing and developing editorial policies on issues such as:

- Material arising from the doctor patient relationship (Read our guidelines on consent to publication).
- Competing interests for authors, reviewers, editors, and ethics committee members.
- Prior disclosure of results to research participants.
- Editors' duty of confidentiality to authors

Formulating new editorial policies.
Advice and ethics questions that arise during routine editorial work. This includes scrutinising papers referred by editors or peer reviewers worried about some aspect of the conception, design, conduct, presentation, authorship, or peer review of the work described in those papers.

Advising editors on their moral duties and responsibilities to patients, research participants, authors, reviewers, publishers, other editors and readers.

Helping editors to enhance the coverage of bioethics in The BMJ.

Keeping editors informed of developments in research and publication ethics.
Advocacy and campaigning

AllTrials campaign

Open data campaign

Restoring Invisible and Abandoned Trials (RIAT)
Hundreds of thousands of people have taken part in clinical trials that have not published results.

Make their contributions count.

Sign the petition
AllTrial’s central call
To bring a high level of transparency to clinical trials for the benefit of everyone

| The main call of the campaign is that all clinical trials, past and present, are registered and all results are reported. | Greater scrutiny of trial design and findings, better drug design and clinical outcomes |
| Makes IPD available to Independent researchers and regulators, with rigorous confidentiality | Less research waste |
| | Evidence based decisions |
| | Fewer Rx-related harms, deaths |
| | Trial participants better assured of positive benefits for others |
2009
BMJ implements data sharing statements on all research papers

2012
BMJ publishes special issue on hidden clinical trial data and some authors deposit data in Dryad

2009

2010

2011

2012

2013

2011
BMJ Open launches and is first medical journal to integrate its submission process with the Dryad digital repository

2013
BMJ Open data campaign launches

The BMJ no longer publishes any trial of drugs or devices where the authors do not commit to making the relevant anonymised patient level data available
The BMJ mandates data sharing on request

Applies to any paper reporting main endpoints of an RCT of one or more drugs or medical devices in current use.

2012: 31 main reports of RCTs published. None about devices; 6 about drugs. 1 industry sponsored. 2 with datasets available from corresponding authors on request.

2013: Policy starts in January. 6 eligible trials published: all complied. None rejected because of policy.

2014: 5 eligible trials all complied.

July 2015: extending policy to all trials submitted to The BMJ

“They challenge medical researchers and funding agencies associated with unpublished or misreported trials to swiftly signal their intent to publish or correct these “abandoned” trials and then to act on this within a year. If no such intention is declared, or if a corrective paper has not been published within a year, they propose offering the opportunity to become “restorative authors” to other responsible researchers, who would restore the integrity of the reporting of the trials involved.”
Thanks...Obrigado
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