Publication ethics in medicine
What happened in publication ethics in biomedicine since 1970?

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JA – KAGB – Symposium Changing publication practices
Palace of the Academies, Brussels

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Declaration of interests

No competing interests

1979 – 2007 Reproductive medicine researcher
2013 – 2021 President of VCWI

Thanks to

Alan N. Schechter (NIH)  Henri Vis (VUB)

Lecture set up together with Bert Seghers
The negative story
- Research misconduct
- Ethics breaches
- Unethical publication practices

Misbehaviour & conflict

The positive story
- Open Access, Plan S
- Open data, repositories
- Preregistration
- Open peer review

Open Science
Misbehaviour & conflict

Ombudspeople
Mediators
Research integrity commissions
Research ethics committees
April 1997

Nov 1997  25 journal editors (medical)
1999     Guidelines report
2000     90 members, statutes
2007     1st WCRI
2008     Charity
2020     12 000+ members, all fields

Committee On Publication Ethics
“Promoting integrity in research”
www.publicationethics.org
committed to educate and support editors and publishers, moving the culture of publishing towards more ethical practices.

Authority: leadership in publication ethics

COPE cases database (600+ documented)

COPE editors discussion forum (individual case advice)

COPE education (e-learning programme for editors)

COPE flowcharts (36) & guidelines (12)
What to do if you suspect image manipulation in a published article

What to do if a reviewer suspects undisclosed conflict of interest in a submitted manuscript

Request for addition of extra author after publication

Suspected plagiarism in a published manuscript

Responding to Whistleblowers
Concerns raised via social media
Clarify reason for change in authorship

Check that all authors consent to addition of extra author

- All authors agree
  - Publish correction
- Authors do not agree
  - Explain that you will not change the authorship until you have written agreement from all authors. Provide authorship guidelines but do not enter into dispute
    - All authors agree
      - Publish correction if needed
    - Authors still cannot agree
      - Refer case to authors’ institution(s) and ask it/them to adjudicate
      - Publish correction if required by institution(s)

Ask why author was omitted from original list – ideally, refer to journal guidelines or authorship declaration which should state that all authors meet appropriate criteria and that no deserving authors have been omitted

To prevent future problems:
1. Before publication, get authors to sign statement that all listed authors meet authorship criteria and that no others meeting the criteria have been omitted
2. Publish details of each person’s contribution to their research and publication
What to do if you suspect fabricated data

(a) Suspected fabricated data in a submitted manuscript

1. Reviewer expresses suspicion of fabricated data
2. Thank reviewer, ask for evidence (that already provided and data plans to investigate)
3. Consider getting a 2nd opinion from another reviewer
4. Contact author to explain concern but do not make direct accusation

- Author responds
- Un satisfactory response
- Author agrees
- Contact author’s institution requesting your concern is passed to author’s superior and/or person responsible for research governance
- No response
- No response
- Author accepts
- Author benefits
- No or unsatisfactory response
- Author injured
- Author refuses
- Author proceeds with peer review
- No response
- Contact regulatory body
- No or unsatisfactory response
- Author refuses
- Author proceeds with peer review
- No response
- Contact regulatory body
- No or unsatisfactory response
- Author proceeds with peer review
- No response
- Contact regulatory body
- No or unsatisfactory response
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C O P E

Misbehaviour & conflict

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Open Science
Registered Reports

1. Design → Conduct → Analysis → Write → Publish

Peer Review
Registered Reports

Design → Conduct → Analysis → Write → Publish

Peer Review

Revision

Accepted: approved for publication (in principle)

Rejection
Registered Reports

225 journals mostly in social psychology

Psychological Science
Nature Human Behaviour
European Journal of Personality
...

Scientific value align Research practice

Questions Methods Results

Publication bias Reviewer incentive

Data dredging Data quality

p-harking Review design suggestions
# (Pre)registration practices

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<th><strong>Registration of clinical trials</strong></th>
<th><strong>Preregistration</strong></th>
<th><strong>Registered reports</strong></th>
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<tbody>
<tr>
<td>Summary of study + medical information</td>
<td>Detailed record of study + analysis plan</td>
<td>Detailed record of study + analysis plan</td>
</tr>
<tr>
<td>Registered in public database (register)</td>
<td>Published (= time-stamped, non-modifiable)</td>
<td><em>Peer-reviewed</em></td>
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<tr>
<td>(before study)</td>
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<td>(before study)</td>
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Registration of clinical trials

Summary about a study protocol:
• disease
• intervention (medical product)
• study description & design
• patient criteria
• location
• contact information
• links

Clinical trial registry:
• online, publicly accessible
• searchable by …

ClinicalTrials.gov

JAPAN PRIMARY REGISTRIES NETWORK

EU Clinical Trials Register
Registration of clinical trials

“Registration of all interventional trials is considered to be a scientific, ethical and moral responsibility because”

- Evidence-based decisions, without publication bias or selective reporting
- Declaration of Helsinki (medical ethics)
- Avoid duplication
- Identify gaps
- May facilitate recruitment
- Collaboration among researchers
- Quality improvement by early problem identification

Our journals will not publish results unless trials registered.
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Misbehaviour & conflict
Open peer review

Open identities: Authors and reviewers are aware of each other’s identity.

Open reports: Review reports are published alongside the relevant article.

Open participation: The wider community is able to contribute to the review process.

Open interaction: Direct reciprocal discussion between author(s) and reviewers, and/or between reviewers, is allowed and encouraged.

Open pre-review manuscripts: Manuscripts are made immediately available (e.g., via pre-print servers like ArXiv) in advance of any formal peer review procedures.

Open final-version commenting: Review or commenting on final “version of record” publications.

Open platforms: Review is de-coupled from publishing in that it is facilitated by a different organizational entity than the venue of publication.