Selective publication and the replicability crisis

Arjan Polderman
Pharmaceutisch Weekblad, Royal Dutch Association for the Advancement of Pharmacy; a.k.s.polderman@pw.nl

At the 13th EASE Conference in Strasbourg professor Lex Bouter, chairman of the 5th World Conference on Research Integrity (WCRI) will give a plenary lecture on Selective publication and the replicability crisis. We interviewed him on this subject and research integrity in general.

How did you become involved in integrity issues?
Epidemiologists are the guardians of methodology and quality control in clinical research. From 1992 I took part in the development of standard operating procedures and internal audits for primary care and public health research. Later, in the Central Committee on Research involving Human Subjects (CCMO, the Dutch institution that supervises medical research ethics committees), medical ethics and conflicts of interest came my way.

As the rector magnificus of the Vrije Universiteit Amsterdam I also had to deal with allegations of scientific misconduct. Not very serious cases, but still I faced the dilemma of either defending the university reputation or starting a thorough investigation. Not all allegations really have to do with scientific misconduct. Sometimes the problem is an ordinary workplace conflict or discordant scientific convictions.

Certainly, conflicts of interest do occur. In several cases the CCMO found that interests of trial sponsors [commonly pharmaceutical companies – AP] led to publication vetoes or inappropriate stopping rules.

An infamous Dutch example of scientific fraud is psychologist Stapel, who fabricated numerous data sets for his PhD students. Stapel's successor as the dean of Tilburg University was eager to apply the economists' motto 'never waste a good crisis' and implemented rigorous measures, including internal audits and data repositories.

What are the main problems in scientific integrity?
Data falsification and fabrication is the most disruptive threat to scientific integrity, but it is relatively rare. Another major problem is plagiarism: widespread and disastrous for mutual trust, but it does not really hamper the progress of science. Combining frequency and impact if it occurs, sloppy science is the more important issue.

By far the most worrying problem is publication bias due to not reporting negative results. This practice is widespread and it distorts scientific knowledge. That makes it hard to replicate results, in biomedicine but also in psychology, ecology, economics and other disciplines. Only 10-40% of reported studies can be replicated with similar results, probably because the published positive results are often coincidental findings. This is the replicability crisis I will discuss at the EASE Conference.

Journals are seeking to publish papers with spectacular results, or at least significant findings This exaggerates the true effect of an intervention, leading to biased systematic reviews and meta-analyses. Page limitations play no role any more in digital outlets, so this can be no reason to reject papers with negative outcomes.

Editors face an awkward predicament between science integrity and the commercial interests of the publisher. They do not always do what they can do. For example, editors are often reluctant to retract papers, because it takes too much trouble. Disgraceful is the practice to ask for additional references that will boost the journal's impact factor.
Authors do often not appreciate editorial interference, even when improving the quality of reporting. Especially statistical editors are considered a nuisance.

What measures can be taken to reduce the problem?
The first step is to increase transparency. Transparency in itself this does not cure selective reporting, but it identifies the trouble. Consider a trial protocol that mentions two primary outcome measures and five secondary outcomes. If the eventual publications presents only three of the secondary outcomes, you have a clear example of selective reporting. You can be pretty sure that there were no significant differences in the two primary outcomes. But this should be reported as well to give an unbiased contribution to scientific knowledge.

Transparency starts with registering research projects and their protocols. This has been advocated for clinical trials long ago but serious implementation started only around 2000. A further step is to deposit all protocol changes, laboratory journals, data analysis plans, data sets, etcetera. This can easily be done in the digital era and will further prevent selective publication.

Which parties should take the lead in addressing the problem?
The fundamental solution is that desirable behaviour is demanded and facilitated. Funding agencies and research ethics committees can do this by requiring that all findings are published and all data are made available through repositories. If a researcher receives the last 10% of the funding only after complying with the transparency rules, he has a strong incentive to do so. A large Dutch national funding agency requires a detailed data management plan. The major Irish funding agency has recently started research integrity audits.

The academic reward system does not stimulate transparency. This system is mainly based on citations and thus favours publication of positive and spectacular results. Researchers will think that citations are the only thing that counts and will feel discouraged to archive their data, share them with fellow researchers et cetera.

What would be the role of editors?
A 30-year old idea, that only now is being implemented, is that results are not taken into account when deciding about acceptance for publication. This practice is now gaining ground in neurosciences and psychology. Registered Reports is a two-step process in which first the introduction and methods sections plus the data analysis plan are judged. After acceptance the authors send in the results an discussion sections, which are judged against the accepted manuscript of step one.

Many websites and some journals like *BMJ Open* are willing to publish study protocols. Leading journals offer the option to peer review trial protocols. If accepted these journals are committed to seriously consider manuscripts describing the findings of the study. *The Lancet* has launched the REWARD campaign (REduce research Waste And Reward Diligence), which is already endorsed by many medical institutions. The shocking background is that up to 85% of clinical research may be useless waste. If this initiative gains ground, trial data will not remain invisible and both the relevance and quality of clinical research will increase.

The TOP Guidelines (Transparency and Openness Promotion), comprising 8 aspects with 4 levels each, enable journals to decide how far they want to go. For example, a journal can adopt the guideline that a manuscript will only be considered when data are deposited in a public repository or when the authors promise to make them available on request.

Open peer review is gaining momentum. Many journals already have all versions of a manuscript, all reviews and all author responses on their website. Recently some journals started publishing the initial manuscript before peer review and/or add post-peer review comments after acceptance.

How did you come to chair the next WCRI?
As yet, it's a small world. When I studied the subject during my sabbatical, colleagues in my new network thought that a methodologist with experience as a university rector would be an interesting speaker at the 4th WCRI (Rio de Janeiro, 31 May-3 June 2015). Only later I found that this came with the idea that I should organise the next conference. Well, I feel honoured by this task and it is good to have the conference back in Europe again.

At the 5th WCRI I see many opportunities for editors to participate. They could also play a role in drafting the closing declaration. I envisage a one-page document with 3 or 4 main statements. These might include that editors are urged to publish studies irrespective of its results. And also that they need to endorse a minimum level of transparency. We would also appreciate abstracts from editors and proposals for preconference activities and parallel sessions. You are all welcome in Amsterdam.

Curriculum vitae

Lex Bouter (Rotterdam, 1956) was trained in medical biology (MSc Utrecht, 1982) and epidemiology (PhD Maastricht, 1988). In 1992 he was appointed Professor of Epidemiology at the Vrije Universiteit Amsterdam. He was president of the Netherlands Epidemiological Society (1996-1997), member of the Health Council of the Netherlands (2001-2013), vice-chair and methodologist of the CCMO (2001-2013). From 2006 until 2013 he was Rector Magnificus and member of the Executive Board of Vrije Universiteit Amsterdam. After a sabbatical leave in 2014 his professorship was broadened to Methodology and Integrity.

Bouter was Editor of Tijdschrift voor Sociale Gezondheidszorg (Journal of Social Health Care) (1991-1999), Editor (1996-2002) and Editor-in-Chief (2002-2006) of the Back Review Group (a Collaborative Review Group of the Cochrane Collaboration) and member of the Editorial Boards of BioMed Central Musculoskeletal Disorders and BioMed Central Neurology (2005-2006).

Bouter chairs the 5th WCRI (Amsterdam, 28-31 May 2017; www.wcri2017.org).