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Section 3: Behind the data

Charlatans and copy-cats.
Research fraud in the
medical sector

Steven Scheerooren

Although fraudulent practices may occur in many areas of research, it is arguably most problematic in the field of medicine, where the outcomes of studies often directly influence health-care policies, and by extension, the wellbeing of many. For the purpose of this article, fraud is defined as the intentional deception of others for personal gain. Some authors have pointed out that when it comes to research it can be difficult to distinguish fraud from simple errors, misunderstandings or incompetence (1, 2). After all, errors can sneak in due to a faulty design of the study, improper conduct of research or a biased interpretation of the outcome (3, 2). Subsequent publications of such studies might be heavily flawed, but it would be rash to accuse researchers of fraud because of this. An equally appropriate term for unacceptable behavior is 'research misconduct'. This is defined by the US Federal Research Misconduct Policy as "fabrication, falsification, or plagiarism in proposing, performing, or reviewing research, or in reporting research results" (4). This article will first provide a brief overview of various types of research misconduct and why such misconduct takes place. The second half of the article focuses on the consequences of misconduct and what can be done against it.

Misconduct's many faces

There are many forms of what one might consider to be unethical conduct, ranging from seemingly harmless 'honorary authorship' to faking entire studies. One way to categorize misconduct is to make the distinction between 'publishing misconduct' and 'research misconduct' (see quote), whereby the latter can then be split into fabrication, falsification and plagiarism. However, I here suggest dividing it into three different categories. Firstly, there is **data** related misconduct. In its minor form, this is the misuse of data by inappropriate statistical analyses or the manipulation thereof. One could deliberately present one's findings in a way that is misleading, or draw conclusions that are not supported by test results. Researchers might also choose to present only a selection of their data to make it support their hypothesis. This falls into the category of falsification, which besides omission of data also includes the 'adjusting' of data and manipulating research equipment or processes (3). Some researchers may even go so far as to repeat an experiment until the desired outcome is reached (1). It should be noted however, that falsification can be a grey area. Baerlocher et al. mention that some alterations to data - e.g. deletion or minimization of outliers - may not be considered appropriate by a statistician, but would not be deemed 'fraudulent' (5). One severe form of unethical creativity with data is fabrication: producing a study without conducting any actual research, e.g. inventing patients and test subjects that never existed, and describing tests that did not take place.

"In essence there are two ways of misconduct. One has to do with misconduct in the publishing process, the other has to do with misconduct in the research process. The difference between the two is, broadly speaking, that when we talk about publishing misconduct, then the data as such can be ok, but the way they are published is unethical. When it comes to research misconduct then there is great doubt about the validity of the data as such, and that can be very misleading. [I]n general therefore research misconduct is much more serious than publishing misconduct."

Dr. Jaap van Harten,
Executive Publisher, Elsevier (17)

Secondly, we have misconduct related to **authorship**. From a few lines or a paragraph, to stealing entire articles and publishing them under one's own name, plagiarism – i.e. copying ideas or data without giving due credit – comes in all sizes. This includes self-plagiarism; reusing parts of previous research in subsequent publications. Plagiarism is possibly the most common form of research misconduct, but it is certainly not the only misconduct when it comes to authorship. What also occurs in academic writing is false (a.k.a. 'gift' or 'honorary') authorship: listing someone who did not in fact contribute to the research as a co-author. Although not as grave as plagiarism, a recent survey showed that false authorship was considered unacceptable behavior by most respondents (6). On the other side we have what is known as 'ghost authorship' (also, 'ignored' or 'neglected' authorship); not listing someone who did contribute to the research.

Finally, there is misconduct related to **publications**. Fairly common is the practice of 'shot-gunning', a.k.a. having so-called dual, multiple, replicate, repetitive, or secondary publications. Some researchers choose to submit manuscripts to more than one journal (often within the same period to avoid detection), or to publish the same article in more than one language (7). It should be clear that the latter is as inexcusable as the former, when done with the intent of merely increasing one's publication output. Translating an article into English to reach a wider audience can be perfectly acceptable, if the author clearly indicates this in both papers by means of a reference (8). However, in a study by Schein and Paladugu, none of the examined duplicate publications contained such a reference (7). The argument of 'trying to reach a different audience' can also be heard in cases where both articles are written in the same language. For example, an author might publish his or her article in both a surgical and a non-surgical specialty journal. Here Schein and Paladugu raise the valid question of whether this still makes sense at all in an age where publications can readily be found in online databases such as [Scopus](#). Another form of publication-related misconduct is 'templating' or 'salami-slicing'; publishing a study in several parts, sometimes containing a substantial part of a previous publication (1, 7).

Pressure all around

So why do people commit research fraud? Something that is often mentioned in regard to scientific misconduct is the 'publish or perish' atmosphere that appears to have become the norm at research institutes the world over (9, 7, 10). Institutes as well as individual researchers may feel they are judged by the quantity rather than quality of their publications. Although one could argue this is no reason for dishonest behavior, this sort of pressure could add to the likelihood of researchers taking unethical steps to increase their output and reputation (1, 9). In addition, the desire to be published in a well-known journal may be so strong that a researcher is prepared to manipulate research data (10, 9).

"Promotion, appointments and academic careers are really relying on publication and while that is in some ways good for the publishers and opens up some opportunities, I think there is always concern that if the pressure is too high it will create an atmosphere in which the temptation to commit research or publication misconduct is increased."

Dr. Elizabeth Wagner,
Council member of the Committee
on Publication Ethics (COPE) (18)

Another common factor underlying fraudulent behavior that is mentioned is a conflict of interests, usually of a financial nature. This is especially true for clinical trials sponsored by pharmaceutical companies (3, 9). The former editor of the BMJ, Richard Smith, even went so far as to say that "medical journals are an extension of the marketing arm of the pharmaceutical industry" (10). In this light, the temptation to falsify or fabricate data in order to make a sponsor look good is always present. A similar cause for misconduct is the publishing bias of journals or editors (3, 10, 8). It has been suggested that studies with neutral or negative outcomes may be bypassed in favor of articles that 'advance' science rather than confirm the status quo (3). Plagiarism, on the other hand, is blamed on a variety of other factors.

Other than a desire for fame, some of the suggested reasons are "cultural differences, lack of good command of the English language, or (...) unawareness, misconception or misunderstanding of plagiarism" (11).

Finally, the fairly low chance of getting caught may also play a role. The quality of science lies in the reproducibility of its results. Unfortunately, when faced with difficult or costly studies, institutes and researchers alike might see no reason to replicate tests if they already have one publication with a favorable outcome. In this way, fraudsters can get away with all kinds of misconduct. "Once successful fraud has been performed the temptation to repeat it may well be very strong" (9).

Ripple effects

When fraudulent data is published its effects can last up to several years after the fraud has been discovered. The slow progress of replicating test or validating data means that an article might not be retracted before other researchers have started citing it in their own publications, thus compounding the errors (10, 12). This could lead to situations where people will have to spend more time on "trying to confirm the work of others rather than building on it" (10). For the original author, the consequences can be quite severe. Once a single publication has been discredited, this will cast doubt on the scientific and ethical validity of all of a researcher's previous and subsequent publications (13, 8, 12). Of course, this is also damaging to the institution that had employed the researcher. One serious concern here is that institutions will wish to avoid publicity when misconduct occurs (9), or may even refuse to investigate alleged misconduct (12). Thus, scandals will not tarnish their name, but it comes at a price: good research may be tainted by fraudulent data. The problem extends well beyond the offending author and the affiliated institution. Co-authors may also find their publications questioned, thus suffering irreparable damage to their reputation (10). The same can be said for the review panel or editors of a journal, whose credibility will be doubted. Patients may have already been treated based on falsified or fabricated test results, their health put at risk by unethical research. Last but certainly not least, is the loss of public trust in science. When a case of misconduct becomes known to the public, it can lead to distrust not only of a particular researcher, but of science in general (3, 10).

The antidote

What can we do against scientific misconduct? Generally speaking, the choice is between punishment and prevention, though a third possibility is also given below.

a) **Punishment.** If the misconduct is considered to be only a minor transgression, a warning may suffice. For example, earlier this year a PhD candidate from Leiden University was given a second chance after it was discovered that his thesis contained plagiarized material. This same candidate was later expelled however, when plagiarism was again found in the revised version (14). For a researcher, similar measures may include suspension from his or her current position, revoking licenses (in case of medical researchers), or publishing bans (7, 10). Other options are giving fines or, when a case of fraud is deemed so severe as to warrant intervention by the law, even prosecution or imprisonment (10). Of course, one measure that should always be taken is the retraction of suspicious publications (12).

Regulatory organizations such as the Committee on Publication Ethics (COPE) or the Office of Research Integrity (ORI) have been set up to monitor, investigate and remedy scientific misconduct (3, 10).

b) **Prevention.** Since a fair portion of misconduct is blamed on a lack of awareness of ethics in science, better education or guidance may be the most likely prevention tool (11). To this end many institutions have set up guidelines such as the now internationally recognized Good Laboratory Practice (GLP); a set of principles that provides a framework within which laboratory studies are planned, performed, monitored, recorded, reported and archived (15). Similar controls are the Good Clinical Practice and Good Scientific Practice. Whereas these all focus on the prevention of research misconduct, there are of course also guidelines to prevent misconduct related to authorship and the publishing process, such as the Vancouver guidelines, or the Publishing Ethics Research Kit (PERK) designed by Elsevier (16).

“Usually, whistleblowers in any arena have a bad time, often being disregarded, suspended, shamed or threatened by peers or managers. Furthermore, whistleblowers face economic and emotional deprivation, victimization, and personal abuse and they receive little help from statutory authorities.” (10)

c) **Correction.** There may also be a third option; a middle-way between prevention and punishment. Besides responding after misconduct has already occurred, or attempting to make sure it does not occur, there is the possibility of intervening the moment potential misconduct is suspected or found. Since it can be very difficult for reviewers or editors to detect fraud in manuscripts, most research misconduct is brought to light by whistleblowers (10). It ought to be so that when a collaborating researcher or research assistant disagrees with a colleague’s conduct – in whichever phase of the research or publication – they should be able to openly voice their concerns. Unfortunately, this is not yet a reality. Many collaborators will keep silent or simply withdraw from a study, instead of reporting (suspected) misconduct to the proper authorities (5). The problem is that whistleblowers simply do not feel safe. If scientific literature wishes to remain “a record of the search for truth” (12) this will have to change.

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