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Integrity in Research

Integrity in research refers to the behaviours and values that result in "high quality, ethical and valuable research".[1] This POSTnote considers current approaches to fostering an environment conducive to good research in the UK, and detecting and preventing practice that falls short of expected standards. It also examines the mechanisms for supporting integrity and how this might be improved.

Overview

- There are concerns about how to maintain integrity in research, because of fears that the 'publish or perish' culture leads to poor or questionable research practices.
- Compromised research integrity can put public health at risk and waste resources, undermine public trust in science and damage reputations. High profile cases of deliberate misconduct are rare.
- Various mechanisms exist to promote good practice in research, including: institutional guidelines; a sector-wide concordat; regulatory bodies for some disciplines; peer review; and a variety of legal actions.
- There are differing views over whether these mechanisms are sufficient, or if another form of oversight, such as regulation, might be preferable.

Assessing Integrity in Research

Several practices in research fall short of the standards required to ensure that it is "rigorous, accurate, original, honest and transparent".[1,2]

- **Deliberate misconduct** such as falsification, fabrication, cherry-picking of results, or failing in the duty of care to research participants or patients. Publication misconduct, such as plagiarism or a researcher duplicating findings in different publications, is also considered important.
- **Inadvertent errors** or **questionable research practices** such as data mismanagement, and poor experimental design.

There is a continuum of poor practice from minor errors to serious misconduct (Box 1). Questionable research practices are a widespread concern, as they are thought to be more prevalent and have a greater impact on the research record than deliberate misconduct.[3] While fraud may occur, it is thought to be extremely rare.

In 1998 a paper published in the Lancet claimed a potential link between the measles, mumps and rubella vaccine and autism.[4] The Lancet fully retracted the paper in 2010 on the grounds that "several elements of the paper by Wakefield et al. were 'incorrect".[5] A 2011 British Medical Journal article argued lead author Andrew Wakefield perpetrated fraud.[6,7]

Although data are limited, a 2014 review by the Nuffield Council on Bioethics found that 26% of survey respondents (primarily researchers from higher education institutions) had felt tempted or under pressure to compromise on integrity and standards.[1] A 2009 study analysing international data from 1987–2005 reported that:

- 2% said they had falsified, fabricated or altered data.
- 34% admitted other questionable research practices.
- 14% said they knew that a colleague had fabricated, falsified or modified data.[8]

The consequences of a lack of integrity in research include:

- **Undermining public trust** in research, through conflicting claims and misleading information. **Misdirecting funding** and unfairly crediting researchers or laboratories on the basis of substandard research, leading to resources being wasted.
- **Damaging reputations**, both of institutions which have been implicated in high profile cases and that of the UK within the international community.
- **Risking public health**, for example by asserting evidence that may cause people to decide to either undergo or refuse trials or treatment or to use products

Box 1. Measuring Integrity in Research

Information about the extent to which bad practice takes place is limited, with most data giving estimates. The few studies available focus on international biomedical sciences and suggest misconduct has grown, although this is partly attributable to improved detection. From 2001–2010, the number of papers retracted each year, even when adjusted for the growth of literature, increased 11-fold (representing 591 articles in 2010). Though retractions (withdrawals after publication) are not necessarily indicative of bad practice, the reasons for retraction included publishing misconduct (47%), research misconduct (20%) and questionable data/interpretation (42%).[9] A 2012 study found that two-thirds of the 2,047 retractions on a biomedical database were attributable to misconduct, including fraud or suspected fraud (43%), duplication (14%) and plagiarism (10%).[10]

that have not been shown to be safe or effective. For example, despite Wakefield being struck off the medical register, and the retraction of his paper in 2010, the take up of the MMR vaccine has only recovered to the pre-1998 level in the last two years.

Current Approaches to Research Integrity

Policies, Guidelines and Codes of Conduct

Several initiatives are in place to promote research integrity and the Nuffield Council on Bioethics found that 60% of those surveyed thought these were having a 'positive or very positive effect' in encouraging high quality science.'[11] Government policy on research integrity is the responsibility of the Department for Business, Energy and Industrial Strategy;[12] and other bodies with a stake in this area are:

- Higher education institutions (and their representative body, Universities UK), and research institutes.
- Academies, learned societies or professional organisations (such as the Royal Society).
- Funders including government bodies (Research Councils and Higher Education Funding Councils {HEFC}), research charities such as the Wellcome Trust, industry and overseas funders.
- Statutory regulatory bodies.
- Research publishers, notably journals. Most are members of the Committee on Publication Ethics (COPE) that promotes publication integrity through advising editors on how to handle misconduct cases. It can oversee investigations to see if journals comply with procedure, and recommend improvements.
- Other charities, such as the UK Research Integrity Office (UKRIO) to which many universities subscribe. It provides independent, confidential advice to researchers, institutions and the public, and training, publications, and procedures for organisations to adopt.

Many bodies have policies on integrity and although these may vary between organisations and across disciplines, they usually set out expected standards and specify procedures for handling allegations. One concern raised is that this has resulted in the system being disjointed. There can be discrepancies and overlap between the provisions of these numerous bodies. There is also no comprehensive framework for reporting concerns, so they may be reported to either employers, journals or funders.

Box 2. The Concordat to Support Research Integrity[14]

The Concordat is seen as having value because:

- It requires compliance for funding
- it promotes audits of institutions' policies on integrity
- it is a symbolic document, codifying and formalising a commitment to placing more emphasis on integrity.

A review of the Concordat by UUK found that it provides a mechanism through which managers can engage with the research community to promote integrity. The review recommends that funders should be clear that they expect universities to publish an annual public statement on compliance with the Concordat.[13] This suggestion is broadly supported as it ensures that universities audit their own practices and keeps integrity on the agenda of senior university staff.

The Concordat on Research Integrity

Universities UK (UUK) published *The Concordat to Support Research Integrity* in 2012.[14] This sector-wide guidance sets out high level commitments to foster a culture that promotes the highest standard of research practices and the responsibilities of each individual or body in upholding them.

All universities that are members of UUK are signatories, as well as many research funders. Several funders make compliance with the concordat a condition of funding, including RCUK, HEFCs and the Wellcome Trust. Some funders assess compliance by asking institutions to complete assurance questions or statements. If dissatisfied, they can audit university practices. Investigations into questionable research practices are handled by the researcher's employer. Given the potential reputational cost to universities from not investigating allegations properly, some suggest that these investigations should be more robust and universities be more transparent about outcomes.[15] It is suggested that funders ought to make disclosure of the outcomes a condition of funding.

The Role of Peer Review

Peer review is the process by which the quality, validity and originality of research is evaluated prior to publication. The House of Commons Science and Technology Committee found that although peer review was an important tool to promote the publication of high quality research it was incapable of detecting all forms of misconduct, because:

- it assesses methods, not underlying data. While it may detect plagiarism and duplication (for which text-matching software can be used), data mismanagement or falsification are less likely to be picked up.
- it is usually an extra, unpaid task performed by academics. Reviewers may not have time to scrutinise work closely in order to detect poor practice. There is also a lack of systematic training for early career researchers on how to conduct reviews.
- detecting problems in multi-disciplinary research is harder as reviewers may lack expertise in all areas.16

More informal but valued forms of peer review also operate at other stages, such as researchers sharing pre-publication findings at conferences. Some question presenting findings at this stage without some form of prior review.

Sanctions

A range of bodies impose sanctions for poor practice to reflect the severity of potential or actual consequences. For

example a journal may require a paper be amended or withdrawn after publication, called 'correction' or 'retraction', research institutions may impose disciplinary proceedings or funders may withdraw funding and refuse any future funding. Some professional bodies impose other sanctions, for example the General Medical Council can remove doctors from the medical register. In extreme cases, poor practice can lead to legal action, including claims of negligence,[17] under consumer and sale of goods legislation, or legislation to protect public health.[18,19] One UK scientist was imprisoned in 2013 for fabricating cancer drug trial data.[20] Some suggest sanctions against individuals should go further (Box 3) but a majority of stakeholders disagree.

Box 3. Criminalising Misconduct?

Some suggest criminalising misconduct so that the police and Crown Prosecution Service have responsibility to investigate and prosecute cases has been considered, through fines or imprisonment.[21]

Opponents argue that:

- it targets only a small subset of serious integrity offences
- criminal sanctions may not be an effective deterrent
- the police may lack the expertise to investigate and there may be a reluctance to report suspicions
- it could deter those seeking advice over mistakes
- this places the emphasis on individual researchers, and fails to have sufficient regard for wider systemic problems in research which contribute to misconduct.

Challenges of Research Culture

Demonstrating Research Impact

Securing employment and research funding rely heavily on publication history, particularly in high impact, prestigious journals from which articles are most widely cited (such as Nature and Science). The Research Excellence Framework (REF) is the means by which research quality in universities is assessed and £2bn in research funding allocated. The Nuffield Council nonetheless found that the REF is perceived as a "key driver of the pressure to publish in high impact journals".[1] However many people feel that this survey overstates the role of the REF, pointing out that it distributes only one quarter of HEIs' funding, operates only in the UK, and does not assess on the basis of the specific journal it was published in, but considers the quality of all research outputs. Of those surveyed, 38% thought this 'pressure to publish' encouraged the fabrication, alteration, omission or manipulation of data,[1] because:

- to publish regularly, researchers feel pressured to reduce the timescales in which they conduct research and so adopt less rigorous methods. One study found inadequate statistical analyses in social and behavioural sciences was rewarded as researchers generated more publications.[22]
- there is a perception that publication in 'high impact' journals requires demonstration of 'positive' results (that the particular outcome that was being tested for was found) rather than 'negative' results (it was not found). According to the Nuffield Council, 31% of respondents felt pressure to focus on and report positive results.[1] This could lead to falsification or fabrication of data in order to get 'publication-worthy' results, as well as a failure to write-up and publish negative or null results.

The Changing Nature of Research and its Practice

Laboratories and research groups are often much larger than in the past, making effective oversight by the principal investigator (PI, a senior researcher in charge of a research project), more challenging. This is compounded because studies often involve multiple researchers from different academic disciplines and locations. As some journals and funders are thought to prefer research with a practical application, the Nuffield Council raised concerns that researchers may also exaggerate the application of research,[1] and underplay the timescales necessary for its completion, prompting corner-cutting later.

Funding Sources

Research is funded from a variety of sources. Of the £7.9bn income received by UK universities for research in 2014-15, 66% was from publicly funded government sources, 13% from charities, 11% from EU sources, 6% from other sources and 4% from UK businesses.[23] Various mechanisms seek to address any potential conflicts of interest that might arise as a consequence of the source of research funding (Box 4). These include disclosure of funding sources in publications or grant applications, and consideration of the funding source as part of ethical review processes (required for research involving people or animals). However, concerns are still raised that integrity and impartiality can be influenced by the funder, for example in the case of funding from industry or government.[24] It is suggested that this influence might occur in various ways:

- Results may go unpublished if results are unfavourable to the funder, which then limits progress.[25] If academics do publish the results, they may then find it harder to secure future funding from that source.
- Researchers may feel pressure to find a particular outcome. This could influence the research question, study design, or the way data is interpreted.
- Industry might not publish research citing commercial sensitivity, or because there is no publication incentive. This can undermine the integrity of the scientific record.

Improving Research Integrity

Given concerns about research culture, changing the institutional pressure on researchers is seen as important. Although strategies are in place to tackle this,[26] it is thought there is room for improvement.

Improving Openness and Transparency

Greater openness and transparency enables more scrutiny of research, as well as greater exploitation of data.

- **Open Access (OA):** if papers are freely available online, it permits greater scrutiny of the findings. Many funders, for example the Wellcome Trust and RCUK make OA a condition of funding or fund the additional cost that it incurs. While this may encourage more rigorous research, some traditional journals have concerns that papers in OA journals are not as robustly peer reviewed, but there is no clear evidence for this.[27]
- **Publishing data-sets:** the *Concordat on Open Research Data* encourages data sharing. To support this, funders could make it a condition of funding, or offer 'bridging' funding to give researchers more time to

make data available. Some journals, for example Science, make it a condition of publication that data are publicly available. There are concerns that data sharing places an extra burden on researchers, and there are not enough repositories to store data.

- **Checklists:** some journals, such as Nature, require researchers to complete a 'checklist' with details of the statistical analysis, samples and computer codes used, and how to access data sets. This makes it easier to reproduce results and thus promotes research integrity.
- **Reporting on clinical trials:** half of the clinical trials on licensed medicines go unpublished.[29] The UN has called on governments to legislate for registration of clinical trials, with full reporting of methods and results.[30] Pre-registration of trials and pre-publication of protocols enables methodologies to be scrutinised in advance, encouraging good practice.[31]

Box 4. Managing Conflicts of Interest to Protect Integrity
Several approaches can manage conflicts of interest but ensuring transparency is difficult, given that conflicts can be subtle, and may be indirect or non-financial. Most journals list funding sources and authors must declare relevant affiliations. Publication can be refused on these grounds. Most universities have policies relating to conflicts of interest, though some stakeholders have called for a sector- wide code of practice on relations between universities and industry.[28]

Oversight, Training and Sharing Best Practice

There is an incentive for researchers to scrutinise peers' work as retractions affect all collaborators. Scrutiny of raw data and research by the PI is thought to be key, with electronic lab books allowing data to be monitored easily from any location. There is debate about whether a PI has to provide effective oversight themselves, or whether having appropriate policies and processes is more important. This is balanced against not wanting to suggest that researchers cannot be trusted, or to undermine the idea that everyone, at every level, is responsible for their own research.

Training and continuing professional development varies across institutions with many stakeholders calling for better training on integrity and practice for researchers (such as methods and statistics). Integrity courses are mandatory in some, with many universities committed to expand training. There is consensus that training reflecting changing responsibilities throughout a researcher's career is important, for example, teaching PIs leadership skills and how to embed a culture of integrity within their group. The Russell Group Research Integrity Forum and COPE also consider mentoring of early career researchers by senior academics important. Guidance and advice for whistle-blowers is also provided.[32] Greater collaboration and dialogue between university staff (such as the Russell Group Research Integrity Forum) and also academics, funders, publishers and UKRIO, is welcomed by research integrity managers.

Re-aligning Incentives for Researchers

To ensure researchers are incentivised to conduct rigorous research, various initiatives have been suggested:

- **Amending the REF:** to include a research integrity statement to encourage universities to go beyond the 'minimum' to improve practices, and require individual researchers to reflect upon their practices. The Stern review of the REF suggested that too much emphasis was placed on individuals rather than groups.[33]
- **Revisiting correction of research literature:** as retractions are viewed as 'black marks', with possible negative career impacts, there is a reluctance to retract articles with mistakes. One suggestion is that researchers be encouraged to publish 'corrections', so as to reduce inaccuracies on the scientific record and that the reasons should always be made clear.
- **Extending funding**: the time taken to conduct and publish some research is longer than the duration of junior research positions. The urgency to complete and publish may incentivise corner-cutting. One option would be to extend the time positions are funded for, or to permit 'extensions' of funding (which could be tied to good integrity practices), but this would result in funding cuts elsewhere. Alternatively efforts could be made to adjust the expectations placed on researchers.
- **Reproducing findings:** although initiatives exist to enhance reproducibility,[34] funders could encourage this by being more willing to fund studies to replicate the findings of frequently cited research. Evidence suggests that many key results cannot be reproduced, often due to inadequate documentation and data management. Knowing that successful studies may be replicated may therefore incentivise researchers to make data more accessible. More emphasis by journals on publishing replications has also been suggested.
- **Journals placing less emphasis on positive results:** rather than focusing on positive results some journals such as *PLoS ONE* and *Trials* look only at validity and rigour.[35] However, change may be difficult until negative or null results are viewed as of equal value. A public repository is seen by some as an appropriate place for such results. The Wellcome Trust is running a pilot publishing platform that allows its researchers to publish various datasets and null and negative results.[36]

A Regulatory Body in the UK?

One view is that a regulatory body could oversee publicly funded research.[37] The US and Denmark have this model, adjudicating on falsification, fabrication and plagiarism. Any such approach would need to take account of the diversity in how research is conducted; this could be burdensome and expensive and the relationship between this body and other bodies would need to be clarified, as would any powers to adjudicate and impose sanctions. While some suggest that UKRIO should have regulatory powers, this is deemed inappropriate by many, including UKRIO, on the grounds it would undermine its independence and ability to advise. Another concern is that a regulatory approach would not foster a culture of wider integrity in institutions. The UUK has reported that universities have voiced concerns,[38] citing increased bureaucracy, less autonomy, and creation of a 'compliance culture'. It is also suggested that it would hamper transparency by making researchers less willing to raise concerns and universities less open about allegations and the outcomes of investigations.

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Endnotes

1 Nuffield Council on Bioethics, The Culture of Scientific Research in the UK, December 2014
2 Universities UK, 'The concordat to support integrity in research' (2012) Forward by the Minister for Universities and Science, David Willetts
3 John L, Loewenstein G, and Prelec D, Measuring the Prevalence of Questionable Research Practices With Incentives for Truth Telling (2012) Psychological Science 23(5) 524–532
4 Wakefield, AJ et al.RETRACTED: Ileal-lymphoid-nodular hyperplasia, non-specific colitis, and pervasive developmental disorder in children. *The Lancet* 1998; 351(9103)
5 *"Following the judgment of the UK General Medical Council's Fitness to Practise Panel on Jan 28, 2010, it has become clear that several elements of the 1998 paper by Wakefield et al are incorrect, contrary to the findings of an earlier investigation. In particular, the claims in the original paper that children were "consecutively referred" and that investigations were "approved" by the local ethics committee have been proven to be false. Therefore we fully retract this paper from the published record."* The Lancet 2010; dx.doi.org/10.1016/S0140-6736(10)60175-4
6 F Godlee, Wakefield's article linking MMR vaccine and autism was fraudulent' 2011 *BMJ* 342:c7452
7 Note that the BMJ published a correction to (6) which reads *"The BMJ should have declared competing interests in relation to this editorial by Fiona Godlee and colleagues (BMJ 2011;342:c7452, doi:10.1136/bmj.c7452). The BMJ Group receives advertising and sponsorship revenue from vaccine manufacturers, and specifically from Merck and GSK, which both manufacture MMR vaccines. For further information see the rapid response from F Godlee (www.bmj.com/rapid-response/2011/11/03/response-john-stone)."*
8 Fanelli D. How many scientists fabricate and falsify research? A systematic review and meta-analysis of survey data. *PLoS One* 2009; 4
9 Grieneisen ML, Zhang M. A comprehensive survey of retracted articles from the scholarly literature. *PLoS One* 2012;7
10 Fang FC, Steen RG, Casadevail A. Misconduct accounts for the majority of retracted scientific publications. *Proc Natl Acad Sci US* A2012: 109
11 Nuffield Council on Bioethics, The Culture of Scientific Research in the UK, December 2014, 30.
12 Research and Development, Department for Business, Energy & Industrial Strategy
13 Universities UK, Concordat progress report (November 23, 2016)
14 The Concordat to Support Research Integrity to Support Research Integrity, Universities UK, 2012
15 Investigations and other measures related to Macchiarini case, Response from the Karolinska Institutet, February 2016
16 House of Commons Science and Technology Committee, Peer review in Scientific Publications, Eighth Report of Session 2010-2012 (2011) HC 856
17 Hedley Byrne & Co Ltd v Heller Partners Ltd [1946] AC 465
18 Consumer Protection Act 1987, s 3(1)
19 Sale of Goods Act 1979, s 13(1)
20 BMJ, 'Bioanalyst gets jail sentence for falsifying preclinical trial data', 2013;346.
21 I Freckleton, Criminalising research fraud (2014) Journal of law and medicine 22(2):241-54; Bhutto and Crane, 'Should research fraud be a crime?' BMJ 2014;349:4532.
22 Smaldino P, McElreath R, 'The natural selection of bad science', R. Soc open sci. 2016 3 160384
23 University Funding Explained, Universities UK
24 S. Sedley, Missing Evidence: an inquiry into the delayed publication of government-funded research, Sense about Science, June 2016
25 Kondro W et al, Drug company experts advised staff to withhold data about SSRI use in children (2004) *CAMJ* 170(8), 1211.
26 For example the *Declaration on Research Assessment* (DORA) and the work of the *Forum for responsible metrics*.
27 Open Access to Scientific Information, POSTnote 397, Parliamentary Office of Science & Technology, 2012
28 It's silly to assume all research funded by corporations is bent , The Guardian, 15 May 2016
29 www.alltrials.net How Many Clinical Trials are left Unpublished? August 2015
30 Report of the UN Secretary General's High Level Plan on Access to Medicines, September 2016
31 Clinical Trials, POSTnote 390, Parliamentary Office of Science & Technology, 2011
32 UK Research Integrity Office
33 Building on Success and Learning from Experience, An Independent Review of the Research Excellence Framework, July 2016
34 See for example The Reproducibility Initiative: Cancer Biology
35 www.trialsjournal.com/about. [Accessed 24/10/2016]
36 Wellcome Trust, A new way for researchers to share their outputs, 2016
37 House of Commons Science and Technology Committee, Peer review in Scientific Publications, Eighth Report of Session 2010-2012 (2011) HC 856
38 Universities UK, Concordat progress report (November 23, 2016)