'PUBLISH, AND BE DAMNED . . . ' THE ROAD TO RESEARCH MISCONDUCT

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The main title is not my own! I took it from an article that appeared in the science journal Nature in October 2002; taking it as my own without attribution would have amounted to plagiarism - only four words, a comma and three full stops, but still plagiarism. This may sound pedantic and it probably happens all the time, but taking the words or ideas of another without clearly disclosing their origin is unethical and unacceptable. The Nature article described the Jan Hendrik Schon saga and the allegation that two leading journals Nature and Science had failed in their duty to prevent publication of fraudulent research. Schon, working in the field of nanoelectronics, was found to have fabricated data resulting in the retraction of several papers that had been published in Nature and Science. It was suggested, however, that the review process for these papers may not have been optimal because of the competitive nature of the field and the journal's desire to be at the forefront of breaking news.

A UK PROBLEM?

How often does this happen in the UK? Is it a real problem or is it all a fuss about nothing? The truthful answer is that we do not know. There have been attempts to estimate its frequency but there is no reliable UK database of cases with the exception of those investigated by the General Medical Council (GMC) and of course these only relate to allegations made against registered medical practitioners. The Committee on Publication Ethics (COPE) founded in 1997 publishes an annual report each year that includes anonymised summaries of cases that it has considered that year (www.publicationethics.org.uk).

During the last 20-30 years, the UK has had to live through a number of high profile cases of research misconduct.^{2,3} These predominantly involve employees of Universities and the National Health Service (NHS). Stephen Lock has summarised these cases, many of which were referred to the GMC and some individuals were eventually erased from the Medical Register. Since 1995, the GMC has continued to consider the cases of medical practitioners who have been alleged to have breached accepted standards of research integrity. These inquiries have resulted in the erasure of the gynaecologist Malcolm Pearce, the Edinburgh physician John Anderton, a professor of respiratory medicine, Robert Davies and an NHS consultant surgeon, Anjan Banerjee.3-8 In 2003, Dr Goran Jamal was found guilty of serious professional misconduct and reprimanded by the GMC for falsifying results in a multicentre drug trial. It was alleged during the hearing that Dr Jamal had been promised a percentage of the drug's profit should it come to market.

These cases are just some examples of high profile cases that reached the GMC and the national press. The true extent of research misconduct in the UK remains unknown. In 1988, Stephen Lock, then editor of the *BMJ*, published the results of his survey of clinical academics that probed their knowledge of cases of research misconduct. He concluded that research misconduct was occurring in the UK but was under-investigated and largely concealed. In the same period there have been a substantial number of high-profile cases in Scandinavia, France, Germany and in the USA.^{2,3} There is a wide appreciation that research misconduct is more extensive than the published data would suggest because of the difficulties in detection.

Research misconduct is not limited to biomedicine. During the past five years there have been a number of high-profile cases in a variety of disciplines including physics, nano-electronics (see also Ritu Dhand, COPE report 2002; www.publicationethics.org.uk) and ecology.

EXPERIENCES AT GUT

I had a very limited understanding of research and publication misconduct until I took on the editorship of the journal *Gut* in 1996. Within a few months I had seen examples of redundant (duplicate) publication, plagiarism, and suspected falsification. ¹⁴ The first case of serious plagiarism that came across my desk involved the fraudulent construction of the introduction and discussion of a paper culled from three published papers. It was picked up by a sharp-eyed reviewer who just happened to be the author of all three plagiarised papers!

Some authors still attempt to publish their work on two or sometimes more occasions. Some will say that this is not a major crime and that it does no harm. However, it can lead to publication bias and seriously alter the interpretation of clinical trial data when subjected to meta-analysis. It is also deeply irritating to editors to put a paper through a rigorous peer-review process only to discover that the paper is not original. The last example that I saw was picked up, not by a referee but by an individual who had read the paper online before the

MEDICAL ETHICS

paper journal had been dispatched. Our attention was drawn to not one but two very similar publications that had appeared in other journals within the preceding three to four months. There are occasions when it is totally acceptable to publish a paper or part of a paper that has been been published previously in another journal. The crucial issue is disclosure. As long as the editor and reviewers are aware of the paper's history then a full and fair assessment of its value can be made.

It is also vital to disclose any competing or conflicting interests. This aspect of publication and research ethics has been brought sharply into focus following a declaration by the Lancet with respect to a paper published in 1998 by Wakefield and colleagues on the relationship between MMR vaccine, autism and an associated inflammatory state in the bowel.¹⁵ Several of the co-authors decided to distance themselves from the paper and published a partial retraction.¹⁶ The editor, Richard Horton insisted that had he known that Wakefield was receiving financial support from lawyers who were representing patients and their relatives with autism his attitude to publication could have been different.¹⁷ This seems a rather harsh line to take since it is disclosure of competing interests that is important, not that these interests exist. It might also be relevant that our attitudes towards conflicting or competing interests have refined substantially over the last five to ten years and it may be unfair to judge these authors by today's standards, although it is clear that the Lancet required disclosure of competing interests in 1998.

HOW WE DEAL WITH RESEARCH MISCONDUCT IN THE UK

In 1991, the Royal College of Physicians of London put together a working party to consider research misconduct and how it should be dealt within the UK.¹⁸ The important contribution of this report was the preparation of guidelines as to how cases of research misconduct should be handled. However, there has been no attempt to determine whether these guidelines have been implemented and no national audit of cases that had been investigated in Medical Schools, Universities and the NHS.

Most UK universities have policies for handling research misconduct but, because they are used relatively infrequently by individual institutions, experience is limited. Examples of institutional guidelines can be accessed through most university websites. Cases may fail because the plaintiff's lawyer is able to find flaws in the process. The Department of Health has published excellent guidance on research governance which has implications for both NHS and University employees because of the recommendations of the Follett Report regarding joint working across the two organisations (see Appendix I).

There is no central reporting of research misconduct in the UK and thus, we still have no idea of the size of the problem. Cases that reach the GMC's Professional Conduct Committee are placed in the public domain, as are the cases reviewed by COPE but there are no central databases for cases dealt with by Universities or NHS Trusts. I would suggest that it is unsafe not to have a national picture as we will never be able to answer the simple questions: How common is research misconduct in the UK? Is it increasing?

HOW OTHERS DEAL WITH THE PROBLEM

Research misconduct has been reported from all major European countries, North America, Australia and Southeast Asia; it is a worldwide problem. Many would feel that the UK, one of the world research leaders, has been slow to respond. Other countries have set up national bodies to deal with research misconduct, some of which have been functioning for almost 15 years. In general, all of these bodies were set up following a politically embarrassing, serious research misconduct case in the respective country.

USA

In 1989, the office of Scientific Integrity was established.¹⁹ This was almost certainly prompted by a series of more than 20 high-profile cases over the preceding decade. In 1992, this became the Office of Research Integrity (ORI) which now deals with all cases of research misconduct that arise from publicly funded research. The ORI deals with about 100 new cases each year. The ORI does not normally undertake the investigation of cases (this is left to the employee's institution) but oversees the process, provides external advisors and holds a central database of referrals and outcomes. The ORI has a comprehensive website (see Appendix 1) that includes all of its policy documents and annual reports including a detailed account of cases that have been reported to the ORI in each year.

Finland

In 1991, the Research Ethics Council was founded in Finland.²⁰ The Council is subordinate to the Department of Education. In 1998, the board issued guidelines for the prevention, handling and investigation of misconduct and fraud in scientific research, which are applicable to both private and public research institutions. The Council does not conduct investigations but is informed of all inquiries and investigations and receives a final report from the investigating institution. The Council considers appeals on the outcome of inquiries. The number of cases considered by the Council increased steadily during the 1990s with a total of 47 cases reported by 2000.

Denmark

In 1992, the Danish Committee on Scientific Dishonesty was established.²⁰ In 1997, this developed further into

MEDICAL ETHICS

three separate committees to deal with research in (i) natural science, agricultural and veterinary science; (ii) health and medical science; and (iii) social science and the humanities. The committees have a joint chairperson to ensure uniformity across the fields of research. The Chair is a high court judge and the committees are directly responsible for investigating allegations of research misconduct. The committees publish an annual report that includes anonymised accounts of the cases considered and their outcomes. From 1992–98, the committee received 45 allegations of research misconduct of which 25 were investigated (see Appendix 1).

Norway

The National Committee for the Evaluation of Dishonesty in Health Research was first established in 1994.20 The foundation of this committee was based heavily on the Danish experience. Although initially researchers resisted the establishment of this committee, a national survey confirmed that 40% of principal investigators in Norway considered that fraud in healthcare was a problem. Like the Danish committee, this committee investigates allegations of research misconduct on behalf of employers. Between 1994 and 2000, II cases were investigated. The committee also has a role in promoting good practice. The Norwegian Minister for Education and Research is currently considering setting up a committee that covers all specialist areas along the same line as the Danish committees.

Sweden

Sweden established its national committee for research ethics in 1997. In 1999, a parliamentary commission in Sweden made wide-ranging recommendations in a report Good Practice in Research designed to increase public oversight of research systems including setting up a National Commission to deal with allegations of research misconduct. The Swedish Committee conducts investigations along the lines of the Danish model.

Germany

Following the Hermann and Brach scandal in Germany in 1999, in which suspicions were raised about 47 published papers (sometimes called 'the fall of German science'), the German Research Foundation formulated its 'rules of good scientific practice' and set up a Council of scientists to consult on scientific 'failure'. The Council acts as an advisory and mediating body on behalf of any person who is affected by scientific 'failure'. Investigations are carried out at institutional level.

France

INSERM created the Délégation à la l'Intégrité Scientifique (Office of Scientific Integrity) in 1999, which oversees the investigation of allegations of scientific misconduct involving INSERM personnel. In 1999 and

2000, 43 cases of alleged research misconduct were considered.

A pan-European perspective

The European Science Foundation (ESF) published a policy paper on 'Good Scientific Practice in Research and Scholarship' in which it draws on the best experience in Europe. It supports the concept of independent national bodies but feels we should work towards a pan-European approach to handling research misconduct.

HOW SHOULD THE UK DEAL WITH THE PROBLEM?

In October 1999, a Joint Consensus Conference in Misconduct in Biomedical Research, chaired by Lord Robert Kilpatrick, took place at the Royal College of Physicians of Edinburgh.²¹ There was representation by all major stakeholders and other interested parties. The panel's major conclusion was that 'a national panel should be established – with public representation – to provide advice and assistance on request'. The report went on to suggest that the national panel might:

- develop and promote models of good practice for local implementation;
- provide assistance with the investigation of alleged research misconduct; and
- collect, collate and publish information on incidents of research misconduct.

Since the Consensus Conference there has been wide discussion as to how a National Panel might be established. One of the major issues has been to identify which of the major stakeholders should take the lead. During the past six months the situation has become clearer with the two major employers, namely the universities and the NHS, emerging as the front runners. Discussions are currently underway between Universities UK (led by members of the Health Committee and the Research Committee) and the Department of Health/NHS. It is anticipated that a draft proposal for a National Body will soon be available for wider consultation. It is likely that the proposal will follow the main conclusions of the 1999 Joint Consensus Conference but make additional recommendations regarding standard operating procedures, governance arrangements and the start up resources required to establish the body. The majority of known cases of serious research misconduct in the UK are in the field of biomedicine and it is likely that this should be the initial focus of activity. However, there is a view in UK Universities that the brief should extend to incorporate all spheres of research endeavour, possibly using the Danish model with specialist panels or sub-committees.

CONCLUSION

The UK is a latecomer in the field of research fraud prevention and detection, but steps are now being taken

MEDICAL ETHICS

to establish a body to overview this critical area. It is to be hoped that a national body will be established soon as the UK's position as a leading country in biomedical research cannot be left at the mercy of dishonest research workers.

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APPENDIX 1

Guidelines

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- 5 Committee for Publication Ethics (COPE). Guidelines on Good Publication Practice. (www.publicationethics.org.uk)
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Websites

Office of Research Integrity (USA) - http://ori.dhhs.gov/

European Science Foundation - http://www.esf.org/

The Danish Research Agency - http://www.forsk.dk/

 $Department\ of\ Health\ (UK)-http://www.dh.gov.uk/Home/fs/en$

Medical Research Council (UK) - http://www.gmc-uk.org/

Committee on Publication Ethics (COPE) – http://www.publicationethics.org.uk/

National Advisory Board on Research Ethics (Finland) – http://pro.tsv.fi/