THE LANCET

Coping with fraud

It is 10 years, to the month, since Stephen Lock, then editor of the *BMJ,* published the results of a personal survey, "Misconduct in medical research: does it exist in Britain?" Of 80 senior academics "over half of the correspondents knew of some instance of medical misconduct—most encountered first hand, although a sizeable minority were well authenticated secondhand instances—and there were a few rumours as well". Lock concluded that research fraud was flourishing in Britain and that action should be taken to tackle the problem by establishing an agency like the Office of Scientific Integrity in the USA "to allay professional and public alarm".

Although the UK General Medical Council has been busy with fraudsters since Lock threw down the gauntlet, editors of biomedical journals know that the GMC sees only the tip of an iceberg, the magnitude of which is quite unknown. However, 1998 witnessed a notable gearing up of activity in relation to publication ethics and research fraud, much of which was driven by journal editors. Early in the year the *BMJ* ran a series of articles on "informed consent in medical research". The Committee on Publication Ethics (COPE) published its first report, which included the proceedings of its first meeting "Research misconduct: how should editors respond?" and synopses of 22 cases that were being considered by the committee. To date the committee has considered 41 cases of suspected research misconduct. The report attracted attention in the daily press on both sides of the Atlantic, including a substantial piece in the *New York Times.* To coincide with the publication of the COPE report, the *BMJ* published a further series of articles on "Dealing with research misconduct in the UK". This included views from experts in the USA, Denmark, the UK, and a view from the Medical Research Council. Some authors favoured a move to set up an independent agency to investigate cases of suspected fraud whereas others were more cautious. As always, sensitivities about intrusion crept into the debate, together with concerns about the loss of professional self-regulation. There is a sense among editors that the available approaches to self-regulation are not working and that alternatives must be sought. The GMC, for example, has no jurisdiction over non-clinical scientists.

As the summer progressed, the temperature continued to rise with a volume of *JAMA* being devoted to the proceedings of the Prague Congress on biomedical peer review. The ethics of authorship, conflict of interest, bias, and quality of peer review were all debated. Retraction of papers was also considered. A search of Medline from 1966 to August 1997 revealed that 235 articles had been retracted, 86 of which were deemed to be due to misconduct. It was alarming to learn, however, that these 235 articles had been cited 2034 times after the retraction notice had appeared—old dogs never die! The *BMJ* retracted a paper in June 1998, five years after it had been published. This paper "Evidence of unmet need in the care of physically disabled adults", had influenced the development of services for the disabled and had been used in the part I examination of the Faculty of Public Health Medicine. One of the authors became concerned when he learned that his co-author had been struck off by the GMC. Having failed to confirm that a series of interviews, integral to the study, had taken place, he felt compelled, unilaterally, to request retraction; the action has not been contested by his co-author.

What hopes is there for the future? Last year, the UK Medical Research Council published its procedure for enquiring into allegations of scientific misconduct. This year, the GMC convened a meeting with representatives of the medical royal colleges and heads of medical schools to discuss how to proceed. COPE continues to meet on a regular basis and will publish its second report in 1999. COPE will also publish guidelines on publication ethics which it hopes will set a framework for researchers, authors, and editors which should improve the quality of research published in Britain. COPE has decided to be more responsive when the scientific integrity of submitted papers is in question, following Sir Cyril Chantler's comment on perceived pacificity of editors: "The editors of medical and scientific journals, who have done much to draw attention to the problem, could perhaps do more to help eliminate it. Rather than simply rejecting articles they find suspicious, they should be encouraged to express concerns to the author or contact the named designated person in the organisation that employs the lead author, or both.' COPE has

every intention of following through on his suggestion.

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The Lancet 1998: **352**: (suppl IV): 11
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Review

Handling of scientific dishonesty in the Nordic countries

Magne Nylenna, Daniel Andersen, Gisela Dahiquist, Matti Sarvas, Asbjørn Aakvaag, on behalf of the National Committees on Scientific Dishonesty in the Nordic Countries

Despite a widely recognised need, most countries still have no coherent system to deal with scientific misconduct. Committees have been established by the national medical research councils in Denmark (1992), Norway (1994), and Sweden (1997), and by the Ministry of Education in Finland (1994), to deal with scientific misconduct—ie, to initiate preventive measures, to investigate alleged cases, or both. Each committee includes both scientifically and legally qualified members. The employing institutions are responsible for possible sanctions or punishments. So far, 47 cases have been accepted for investigation, the majority (25) belng Danish. Disputed authorship was the most frequent reason for investigation. Junior researchers made complaints in only three of the investigated cases. Investigations have been completed in 37 cases; in nine cases, dishonesty was revealed—two of them were related to the same researchers. Cooperation between the four Nordic committees has shown close agreement on specific issues and cases, despite minor differences in definitlons, organisation, and procedures.

Scientific dishonesty in medical research has received increased attention over recent years. A survey among 274 medical scientists in Norway showed that 22% knew about cases of serious misconduct, and 3% were aware of falsification or fabrication of data. 9% of the respondents had themselves contributed to one or more incidents of misconduct.[1]

The first reaction of denial within the scientific community has gradually been replaced by a recognition of the need for systems to handle this problem. These systems may include guidelines for good scientific practice and promotion of scientific integrity, definitions of dishonesty, procedures and bodies to prevent, detect, investigate, and punish misconduct when it occurs, and even research into this field.

The international scene has been reviewed by Lock and Wells.[2] The first systems to deal with scientific misconduct were established in the USA in the 1980s.[3] Later on, recommendations were also made elsewhere, but most countries still have no coherent system even though the need for one is widely recognised.[4,5] National funding agencies and research bodies have a special responsibility for setting standards and establishing systems to deal with scientific misconduct.[6]

In the UK, editors of medical journals set up the Committee on Publication Ethics (COPE) in 1997 as a forum for discussion on how to deal with breaches of research and publication ethics.[7] In its first yearly report, COPE strongly recommended the establishment of a national body in the UK.[8]

Denmark, Finland, Norway, and Sweden established national committees on scientific dishonesty during the 1990s, whereas Iceland, the fifth Nordic country, still has no such body. The Nordic experiences and results so far are presented in this paper.

Setting

The four Nordic countries (Denmark, Finland, Norway, and Sweden) have a total population of about 23·5 million inhabitants. During 1996, the Nordic countries spent 2·22% of their gross national product on research. The mean value for countries belonging to the Organisation for

	Denmark	Finland	Norway	Sweden
Committee established	1992	1994*	1994	1997
Committee members	Eight members: a High Court judge (chair), seven senior medical researchers. From 1999, only tour medical researchers in the subcommittee for the health sciences.	Twelve members: one university chancellor (chair), six professors (two MDs, two jurists, two philosophers), one theologian, and four civil servants representing agencies of higher education, research funding, or animal protection.	Eight members: five professors (three MDs, one dentist, one psychologist), one medical director of a drug company (MD), one judge, and one medical journal editor.	Eleven members: one judge (chair), six medical experts, two lay individuals, one representative of the Swedish Drug Agency, one Representative of the National Board of Health and Welfare.
Definition of dishonesty	Intention or gross negligence leading to falsification or distortion of the scientific message or a false credit or emphasis given to a scientist (1992)	Presentation to the scientific community of fabricated, falsified, or misappropriated observations or results and violation against good scientific practice (1998)	All serious deviation from accepted ethical research practice in proposing, performing, and reporting research (1994)	Intention distortion of the research process by fabrication of data; theft or plagiarism of data, text, hypothesis, or methods from another researcher's manuscript or application form or publication; or distortion of the research process in other ways (1997)
Procedures	Centralised. Cases are submitted directly to the committee. The principle of contradiction is firmly adhered to. The decision will be presented to the accused scientist's institution in case of proven dishonesty. No appeal mechanism.	Decentralised. Suspicion or accusation of dishonesty is filed to the rector or director of the research institute involved. This person is responsible for the initial inquiries and investigations. A second opinion can be requested from the National Research Ethics Council which may propose additional investigations.	Centralised. Committee investigates the case upon agreement with the employer of the accused person, and reports finding to the employer and to the two parties. No appeal mechanism.	Dencetralised/centralised. After an initial inquiry within the faculty, a centralised investigation should be requested by the local rector. A centralised investigation is made by an expert group chaired by a judge. The decision by the expert group is forwarded back to the local rector who decides on sanctions. No appeal mechanism.
Number of cases received	45	7	9	7
Number of cases investigated	25	7	8	7
Investigations completed	24	5	4	4
Dishonesty disclosed	4	2	0	3†

*The Finnish Committee was established in 1991 but did not deal with specific cases of dishonesty until 1994. †Two of the Swedish cases were related to the same researchers. Dishonesty was disclosed in both cases but for different reasons.

Table 1: **National committees on scientific dishonesty in the Nordic countries**

Economic Cooperation and Development (OECD) is 2·16%. There were, however, substantial differences between the four countries: Sweden spent the most (3·02%), and Norway the least (1·72%). Clinical medical research has a strong position in the Nordic countries: 406 clinical research papers were produced per million inhabitants in 1996, compared with the OECD average of 197. The average number of citations per paper was also higher than the OECD average: 4·20 versus 3·76.[9]

The Danish Medical Research Council initiated a report on scientific dishonesty and good scientific practice in 1991.[10] On the basis of recommendations in this report, the Danish Committee on Scientific Dishonesty was established in November, 1992. From 1996, this committee reported directly to the Ministry of Research. In January, 1999, three subcommittees were formed, and the committee's area of function was extended to all fields of research.

In September, 1994, the Norwegian Medical Research Council established a similar national committee mainly based on Danish experiences.

The National Research Ethics Council of Finland, which was established in 1991, and which covers all branches of science, also deals with scientific dishonesty and, since 1994, has reviewed specific cases of fraud and misconduct.

In Sweden during 1996, the Committee for Research Ethics within the Medical Research Council suggested the formation of a national expert group to deal with dishonesty in medical research. In January, 1997, the Expert Committee was instituted.

All the committees have both scientifically and

legally qualified members. Characteristics of the Nordic national committees are given in table 1

Definitions

In the USA (the country with the longest and most extensive experience of handling scientific dishonesty in a systematic way), the definition of dishonesty became a major issue at an early stage. The main question was whether to use a narrow or a wide definition. The former defined scientific misconduct as fabrication, falsification, and plagiarism in proposing, performing, and reporting research, as suggested by the National Academy of Sciences, the National Academy of Engineering, and the Institute of Medicine.'[11] The wide definition, as suggested by the National Science Foundation and by the Public Health Service, includes a statement saying that scientific dishonesty also includes other serious deviations from accepted research practices.[12] Schachman has argued that such an open-ended definition "breaches an important principle of due process, the right to know in advance those activities that are proscribed".[13]

In the Nordic countries, formal definitions have never been considered critical or even feasible, since dishonesty is regarded as ranging from minor deviations from good scientific practice to obvious misconduct. Scientific dishonesty has therefore been broadly characterised, and the establishment of a verdict relies on sound judgment rather than rigorous definitions.

The definitions of dishonesty used by the Nordic committees are given in table 1. Important for the judgment of dishonesty is whether the deviation from good scientific practice is serious or intentional. The Finnish guidelines initially defined scientific dishonesty narrowly, but the amended guidelines now have a wider scope.

Procedures

The mandates of the Danish, Norwegian, and Swedish committees are fairly similar and, in principle, two-sided: to investigate alleged cases of misconduct, and to initiate preventive measures. In Sweden, cases cannot be referred directly to the national expert committee; instead, this body offers the medical faculties a centralised inquiry in response to a request from the dean or rector. The inquiry is a two-step procedure. Within a month, an initial inquiry decides whether there is reason to undertake a complete inquiry. A complete inquiry then takes 3–6 months, and determines whether dishonesty, according to the definition, can be verified or not. The inquiry group collaborates actively with the Medical Research Council's coordinating Committee for Research Ethics in developing guidelines for good medical research practice and other preventive strategies.

Alleged misconduct	Number of cases*
Disputed authorship	16
Manipulation of data	8
Wrongful use of data	8
Plagiarism	5
False description of methods	3
Twisted statistics	4
Theft of data	6
Fabrication of data	5
Other†	8

*Each case may include more than one kind of alleged misconduct.
†Conflicts of interest (economical *vs* scientific), manipulation of experimental set-up, suppression of unwanted data, presentation of research to the general public without scientific publication.

Table 2: **Specification of cases according to accusation (n=47)**

In Denmark, cases can be referred directly to the committee without initial institutional inquiry. Anonymous complaints are discouraged, but can be accepted under special circumstances. The Norwegian committee can investigate cases only after agreement with the relevant institution, and anonymous complaints are, in principle, rejected.

The Finnish Research Ethics Council has adopted an approach different from those of the other Nordic countries. The National Council in Finland does not itself investigate cases of suspected misconduct, but, in 1994, produced guidelines for prevention, handling, and investigation of misconduct and fraud in scientific research. According to these guidelines, universities and research institutes are responsible for preventing all forms of scientific misconduct, and for investigating suspected or alleged cases of dishonesty. A suspicion of misconduct is reported to the rector of the university or the director of the research institute; consideration of cases without a filed suspidon may also be given. The investigative procedure includes an initial inquiry followed, if necessary, by a full investigation by a specially appointed committee. The Council is informed of all inquiries and investigations, and receives the final report on each case. If not satisfied with the investigation, the researcher involved, or the informant, can request an opinion on the procedure or the final report from the Research Ethics Council, which can recommend additional investigations by the university or the research institute.

The national committees of all the Nordic countries may use external experts when investigating individual cases. Full reports of the cases, together with the decision of the committee, are sent to the person who made the complaint, the accused, and the employing institution, which is

responsible for possible sanctions. The Nordic committees take on any case, irrespective of funding.

Experience

In Denmark, the establishment of a national committee on scientific dishonesty was met with approval by scientists, institutions, and professional and lay press. In Norway, there was some resistance, primarily from the unions of physicians and researchers, but also from some prominent scientists. In Sweden, planning for the establishment of a national committee started in 1993, but responses from the medical faculties during this period were extremely slow (which may be interpreted as a kind of passive resistance), and the process was delayed. A media debate about the honesty of several members of the Medical Research Council itself (which led to a complete renewal of the Council in 1995) accelerated the process of establishing a national committee. In Finland, there was much concern about fair and due process, and ill-founded stigmatisation, and this was one reason for the narrow definition of misconduct established in the first place. In some faculties, there was initially doubt as to whether fraud is a significant problem.

As of February, 1999, 68 complaints had been received by the Nordic committees (including seven cases from clinical or biomedical research of a total of 14 cases reported to the Research Ethics Council in Finland). Most cases (45) were reported in Denmark (table 1). 21 cases were not investigated, mainly owing to lack of substance, obsolescence, or because they were referred to other countries or authorities.

47 cases were accepted for investigation. Disputed authorship was the most frequent reason for investigation (table 2). The most common complaints were made by one senior researcher about another. Junior researchers complained about senior researchers in only three of the investigated cases. Ten of the 47 cases are still pending. In nine cases, dishonesty has been revealed, of which two were related to the same researchers.

Case 1—The author of a paper published in a Nordic journal discovered an abstract in MEDLINE with an identical title and data. The abstracted paper originated from a foreign journal. Plagiarism was established, and the paper was retracted. Later on, more than 20 papers were found to have been plagiarised by the same person, who was dismissed from his professorship.

Case 2—A senior registrar published research results from his work at a clinical department without the permission and knowledge of his superiors, and he included them as authors without their knowledge. The registrar was dismissed.

Case 3—An American information company offered a Nordic expert the authorship of a completed review paper recommending a certain drug. The company was wilfully dishonest since it attempted to give the impression that the review was impartial, and because it broke the rules for authorship (ghost authorship). The name of the company was disclosed in the committee's yearly report.

Case 4—A registrar had stated, in a published paper, that he had done a masked evaluation of a new diagnostic method. Perusal of the clinical records proved, however, that an open evaluation had been done. A correction was published in the journal. No further action was taken.

Case 5—Two clinical scientists (a professor and a senior lecturer) had distorted their research results. The number of reported patients was larger, and the reported follow-up period was longer than what could be reconstructed after work-up in several independent registers of patients. The case was reported to the relevant journals, and the researchers were withdrawn from their honorary positions at the university.

Case 6—A senior researcher had selectively excluded several patients in a long-term multicentre clinical study of a new therapeutic method. The distortion resulted in unreliable scientific publications. In addition, several counts of violation of good scientific practice were found, including grossly inadequate research plan, lack of ethical evaluation, and insufficient supervision of the project by the administration of the clinical institutions involved. There was no information on sanctions.

Case 7—A researcher in a biomedical research laboratory published a paper on a study in which material received from another laboratory was used. The material was used in breach of a mutual agreement between the researchers. The report of the case pointed out that there were no internal guidelines for good scientific practice in the institute. The researcher left the institute before sanctions were taken.

Case 8—A senior researcher had distorted data to make better the results of a new modification of a surgical procedure developed in collaboration with a research student. The senior researcher had also published the results as a single author. The

senior researcher was prevented from tutoring research students, and from receiving grants as a main investigator.

In most cases, no dishonesty has been confirmed, and in several of these cases, the committee's most important task has been to acquit the accused. In a widely published case, the vice-chancellor of a Nordic university was accused of scientific fraud, which, it was claimed, had been committed 20 years earlier at an American university. After a thorough examination involving several international authorities and site visits, the vice-chancellor was cleared.

The national committees publish yearly reports on their activity. The Danish committee has published five sets of guidelines covering presentation of research protocols, data documentation, rights and duties in using and storing scientific data, authorship, and agreements between researchers at the beginning of cooperative projects."[4] Further guidelines are under production by the Norwegian committee on scientific dishonesty. In Sweden, this work has been done by the coordinating Research Ethics Committee. Education of researchers is an important part of prevention, and the national committees are involved in courses and seminars, including three Nordic conferences.

Discussion

The fact that the notion of scientific dishonesty is inexact makes the question of definition elusive. The delineation of the concept therefore requires an element of judgment, and several cases to serve as illustrative examples. In the Nordic countries, scientific dishonesty is described in slightly different terms—"serious deviations from good scientific practice" (Norway), "intentional distortion of the research process" (Sweden), "violation of good scientific practice" (Finland), and "acts which falsify or distort the scientific message" (Denmark). The definitions include a wide range of acts (eg, fabrication of data; plagiarisms of data, text, hypotheses or methods; and dishonest selection of data). Intention to deceive is considered of major importance in all four countries, but Denmark also includes gross negligence. Whether or not an act is defined as dishonest will depend more on the culture in the research communities than on the precise wording of concepts. Experience from a Nordic conference dealing with this subject, and from discussions of mock cases, has revealed almost complete agreement despite differences in definitions between the four countries.

The reason for the high number of cases referred to the Danish committee, compared with the other national committees, is unclear. The general approval of the committee, and lack of resistance to its establishment from the scientific community in Denmark may be important, as well as the fact that the Danish committee was established earlier than those in the other three countries. The Danish Committee on Scientific Dishonesty has published a series of national reports,[15] and has probably been more visible and active than any of the other Nordic committees. In contrast to the procedures in Sweden and Finland, cases can be referred directly to the Danish committee without initial institutional inquiry, and no agreement with the involved institution is needed to initiate investigation, whereas it is in Norway. Even anonymous complaints can, under special circumstances, be accepted in Denmark. Thus, it may be easier to make complaints in Denmark than in the other Nordic countries.

In three-quarters of cases investigated, dishonesty in the strictest sense was not disclosed by the investigative bodies. In some of these cases, however, deviation from good research practice was revealed. Many researchers might feel that the committees should confine themselves to giving their judgment on whether dishonesty had taken place or not. However, experience has shown that such constraint does not work. If the responses from the committees are dichotomised into "black or white", no indication will be given of whether the committees find the practice completely free of reproach or whether they find it deviating from good scientific practice to a greater or lesser extent. The decision "no dishonesty" may be interpreted as an approval from the committees. For this reason, and to increase the educational and preventive value of the decisions, a practice has developed within the committees not only to conclude on a dishonesty/non-dishonesty judgment, but also to describe explicitly in what way a non-dishonest practice is found to deviate from good scientific practice. Experience also suggests that dishonest acts at all levels of severity should be dealt with by a unified set of guidelines and procedures. Disputed authorship is increasingly frequent among medical scientists.[16] It is an alleged misconduct in a third of investigated cases; this high proportion reflects the importance and extent of authorship as a problem in research ethics. The addition of specifications of each author's contribution to a paper[17] to the Vancouver Group's definition of authorship[18] might prove useful, but as long as bringing credits to authors

has become one of the main tasks of scientific publishing, unethical practice in this field must be expected. The concept of authorship should be further discussed among researchers, editors, medical schools, and funding agencies. International guidelines should be developed and, most importantly, followed.

The lack of complaints from younger researchers is probably due to fear of sanctions.[1,19,20] 47 of 68 "whistle-blowers" reported negative action as a result of their revelations in an American study.[21] Lower-ranking faculty members, and students and fellows in basic science departments were most likely to have experienced such negative action. An American Commission on Research Integrity in 1995 suggested a whistleblowers bill of rights and responsibilities "intended to encourage institutions to treat good-faith whistle-blowers fairly, shield them from retaliation, and to articulate the responsibilities of any individual who accuses another of research misconduct".[22]

Anecdotal evidence, also from the Nordic countries, shows that younger researchers are particularly reluctant to bring cases of suspected dishonesty before a national committee because of fear of retaliation. Michael Farthing, chairman of the Committee on Publication Ethics (COPE) has written: "I have been approached by a number of whistle-blowers from various institutions, each asking for my advice. My experience is that these people are not treated appropriately by their own institution".[23]

Experience from the Nordic countries shows that national research councils can set up appropriate bodies for handling of misconduct in medical research. These bodies can be an integrated part of a broader ethics system including all branches of science and scholarly activity (Denmark, Finland), or separate committees for medicine and health sciences (Norway, Sweden). Inquiries in the first instance can be made within the faculty or institution (Finland, Sweden), or cases can be referred directly to the committee (Denmark, Norway). Even though the Nordic countries define scientific dishonesty in slightly different ways, the national committees' judgment of individual cases is similar. The main difference between the four countries seems to be the conditions under which a committee can start an investigation.

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Commentary

Scientific misconduct: exaggerated fear but still real and requiring a proportionate response

The overlords of research probity have secured a firm place among science policy-makers, but not without blood being spilt. The process began in the USA in the 1980s, when over-enthusiastic investigators from the Office of Scientific Integrity blundered into laboratories to investigate several celebrated cases of alleged misconduct. After the agency was reborn as the Office of Research

Integrity (ORI), these armies of auditors adopted a more careful strategy, one that has seen their efficiency rise as their caseload has fallen.[1] The ORI is now more respected than reviled.

A Danish Committee on Scientific Dishonesty followed in 1992, and it succeeded from the start in being not only visible but also credible. Its guidelines on good scientific practice[2] make recommendations about protocol development, data documentation and storage, and authorship. France established a committee on scientific integrity in 1998 and Germany is linking eligibility for research funding to provision of institutional procedures promoting good scientific practice. In the UK, although there is a case for establishing a central agency to review alleged instances of misconduct,[3] the creation of an informal advisory body, the Committee on Publication Ethics (COPE), to which possible breaches of good publication practice can be referred, has been left to editors.[4]

The review in today's *Lancet*, by Magne Nylenna and colleagues, shows that national committees for handling scientific dishonesty are not only feasible but also highly efficient and effective. Norway (1994), Finland (1994), and Sweden (1997) have followed Denmark in establishing their own committees, and together they have received 68 complaints, the commonest being disputed authorship (34% of referrals). Fabrication of data accounted for far fewer cases (11 %). These agencies were able to set standards, offer training and education, provide guidance during investigations, and act as an institutional memory for this case-experience.

Nylenna and colleagues draw the following conclusions. First, despite differences between the four Nordic countries in the definition of misconduct, "the national committees' judgment of individual cases is similar". Protracted wranglings over definitions seem unnecessary; even if misconduct is hard to define precisely, scientists recognise it when they see it. Second, although most cases of alleged dishonesty were not proven, "deviation from good research practice was revealed". And third, "dishonest acts at all levels of severity should be dealt with by a unified set of guidelines and procedures".

Given the great publicity research misconduct has received, there were surprisingly few cases of serious scientific dishonesty. Is the prevalence of scientific misconduct exaggerated? On current evidence, yes, although this conclusion may be premature. Nylenna has considered why so few cases have been submitted to the Norwegian national committee.[5] Potential complainants may hesitate to report cases, the committee may not enjoy the confidence of scientists, the existence of the committee may not be well known, or there may indeed be no more misconduct to be found.Which of these explanations is true is not known.

Yet the pressure for even greater oversight of research is increasing. A Swedish parliamentary committee has recently recommended that each of the country's universities should create an ethics team composed of equal numbers of scientists and lay people to scrutinise all human research, private and public.[6] In the USA, the Office of Protection from Research Risks (OPRR) raised its profile by closing down 2000 research projects at Duke University for 4 days in May this year.[7] OPRR's budget and staffing are likely to be increased soon to enable it to extend its work.[8]

A backlash is developing. Researchers are concerned that excessive regulation and the threat of public witch hunts[9] will deter investigators from doing important research. According to Richard Peto and colleagues, for example, new regulatory constraints, "however well-intentioned, may well do more harm than good to patients". Peto has criticised the editors of the *New England Journal of Medicine* and *JAMA* for their "inappropriately harsh editorials" that seemed to jump on the misconduct bandwagon after allegations were made against the cancer trialist, Bernard Fisher. The issues at stake are serious:[9]

> ". . . intrusive, time-wasting audits that treat those who organise trials and those who collaborate in them as potential delinquents might well divert or discourage clinical research workers from organising as many trials as they could otherwise have done, and could deter many of the thousands of practicing doctors who might otherwise have offered their collaboration. This would mean that life-or-death questions will not be answered as quickly or reliably as they should be".

Failures of due process lie at the heart of this concern. Barbara Mishkin, a US lawyer specialising in scientific integrity, has written that, "the greater the potential effect on an individual's reputation, freedom, or livelihood, the greater must be the due process afforded". Procedural justice demands, as a minimum, that there be published rules and procedures, that the charge be precisely framed, that innocence be presumed, that the institution be distanced from the investigation, that the accused has full access to the evidence, and that the opportunity exists for full cross-examination of that evidence. Those are the lessons learned by ORI, most painfully after the

spurious allegations made against Thereza Imanishi-Kari and David Baltimore,[10] lessons that have yet to be learned by some fledgling national committees.

Given the wide US and European experience with research misconduct, what next? First, editors could do more to raise awareness about good research and publication practice. As Debra Parrish has argued, the "Fisher case brought attention to how disconnected journal editors have been from the scientific misconduct process".[11] Editors must be more explicit in their approach to research error, intentional or otherwise.[12] The Nordic experience, and that of COPE,[4] should help to prevent the grotesque abuses perpetrated against scientists when misconduct investigations go wrong.

Second, researchers should distance themselves from instances of misconduct. John Budd and colleagues reported that 235 research papers retracted between 1996 and 1997 were cited 2034 times after the retraction.[13] Should retracted research be better sequestered from the searchable scientific literature? Third, policy-makers must design a proper research agenda to discover, for example, whether "low-level" misconduct (minor authorship disputes) leads to major misconduct (outright fabrication of data).The ORI has made a welcome start in this direction.[14] And finally, editors must pool their international experience and agree on procedures, norms of due process, protection for whistleblowers, and sanctions. They must also rethink their approach to publication. Many instances of error either go unnoticed or become the subject of unnecessary dispute because of failures by authors to disclose in sufficient detail what they did. Stephen Lock has proposed "a new philosophy of encouraging the longer and better article at the expense of the shorter and meretricious one".[15]

Is there a danger that editors are over-reacting to the threat of scientific fraud? If editors write rigid regulations for researchers to follow, overtrain the institutional muscle of agencies responsible for scientific oversight, or impose wider-ranging sanctions against scientists found to commit minor misdemeanours, they should not be surprised if Peto's predictions come true.

But to ease back now and let recent injustices stop efforts to raise the standards of research and publication practice would be a mistake. "Doctoring the evidence", "Not worth the papers they are written in", "Fraudulent research a threat to patients" are recent headlines that may eventually persuade the public to withdraw its trust from doctors still further. The chain of trust that links patient to doctor and doctor to researcher is fragile. Research evidence strengthens this chain, whereas fraud weakens it. The review by Nylenna and colleagues should help to reinforce that trust in Nordic countries, an outcome that researchers and editors everywhere are likely to applaud and draw important lessons from.

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