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Research misconduct: learning the lessons

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Michael Skjelderup

Michael is a publication series named after professor *Michael Skjelderup* (1769-1852), one of the fathers of Norwegian medicine. He was born in Hof, Vestfold in Norway as the son of a priest, and was raised in the Norwegian countryside. Because of severe speech disturbances as a boy he did not get proper schooling, but was at last accepted as an apprentice in an apothecary's dispensary in the city of Fredrikstad at the age of 16. During his youth he tried through hard work and by means of an intensive self-discipline to overcome his handicap, and he really succeeded, except for in stressed situations.

Lacking a student examination, an academic training seemed out of question, in spite of his obvious bright mind. However, in 1789 he was admitted to the new Surgical Academy in Copenhagen, where academic qualifications were not required.

From now on, his career flourished. He passed the surgical examination with the highest grade in 1794, entered positions in Copenhagen hospitals and at the University, where he defended his doctoral thesis in 1803 and was appointed professor in 1805.

The first University in Norway was founded in Christiania (now: Oslo) in 1811. Medical teaching was supposed to commence from the very beginning, and from 1814 the new medical faculty could offer medical training. Michael Skjelderup was appointed its first professor 1813, and started his teaching, mainly in anatomy in the fall of 1814, after a dramatic war time sea voyage from Denmark across the waters of Skagerrak where hostile Swedes fired at his swift sailing vessel.

As a University pioneer, he became active in several medical fields. Among other achievements, he published an authoritative textbook in forensic medicine in 1838. When he resigned in 1849, eighty years old, he had seen all Norwegian trained medical doctors in his lecture room.

Skjelderup was instrumental in building a scientific medical community in Christiania. Together with his University colleague Frederik Holst (1791-1871) he founded the first Norwegian medical journal *Eyr*, named after a norse medical goddess, in 1826. A reading club of physicians established in 1826 was formalized into an association in 1833, the still existing Det norske medicinske Selskab (The Norwegian Medical Society), which over the decades to come played an important role in the development of the health services and of a national medicine.

Michael is devoted to the memory of the man who first realized the importance of a regular, national medical publication activity in Norway and implemented his ideas in 1826. *Michael* is published by the same association as was founded by Michael Skjelderup and his colleagues – Det norske medicinske Selskab.

The editors

Magne Nylenna

Research misconduct: lessons to be learned?

Michael 2007;4:7–9

"It can never happen here" has been the traditional saying in Norway when incidents of scientific dishonesty have been disclosed around the world. In a small country with a limited number of medical researchers, traditions for transparency and a strong belief in honesty, there has been a more or less naïve attitude to fraud and research misconduct.

When in January 2006, on Friday 13th (!), the news was broken that a Norwegian scientist at Rikshospitalet-Radiumhospitalet, Jon Sudbø, had admitted to research misconduct in a recently published paper in *The Lancet* (1), it became a national sensation. The case made headline news in all major newspapers and television networks, more than 330 media reports were registered over the first two weeks and the case received huge international attention.

At an early stage it became evident that the actual case, widely known as the Sudbø case, included fabrication of data, and a special Commission was appointed on 18 January to conduct an independent investigation. The Commission chaired by the Swedish epidemiologist, Professor Anders Ekbom, then presented an extensive report on 30 June 2006 (2).

"The bulk of Jon Sudbø's scientific publications are invalid due to the fabrication and manipulation of the underlying data material", read the main conclusion of the Commission. Based on investigations into the entire body of Sudbø's scientific work, 38 published papers, the Commission found several breaches of good scientific practice. Jon Sudbø, a dentist and physician, had been doing research on the early stages of oral cancer. One of his main questions was whether and to what extent different types of leukoplakia could predict the risk for developing oral cancer. Sudbø's results had been published in high-profile international journals (1,3,4) and formed the basis for his PhD thesis. A series of flaws were, however, found

in his data material and the summing up by the Commission was harsh: "The Commission is of the opinion that the errors and defects that have been exposed are too numerous, too great and too obvious to be attributed to random errors, incompetence or the like; and that the raw data therefore appear to have been fabricated, manipulated and adapted to the desired findings"(2).

The Sudbø case has been intensively discussed within the health care sector in Norway over the last year, and has undoubtedly led to an increase in the awareness of research misconduct. Many institutions have reconsidered their research programmes and routines. Supervisory and regulatory systems have been introduced.

The Sudbø case is also of interest from an international perspective. Learning from adverse events is a way to improve quality in all parts of medicine - research as well as patient treatment. What lessons can be learned by this and other revealed cases of scientific fraud for researchers, research institutions, scientific journals, and other parties? Is a more detailed bureaucratic regulation of research the inevitable consequence? Can misconduct be prevented through information campaigns? And who is really responsible for the quality of published research?

These questions were raised at a one day international conference in Oslo, 8 December 2008. The conference was organised by *Helsebiblioteket* (The Norwegian Electronic Health Library)/The Norwegian Knowledge Centre for the Health Services, *The Lancet*, and the *Norwegian Medical Society* and attended by more than 100 researchers, clinicians and health administrators.

The presentations from the conference are published in this issue of *Michael* with financial support from *The Norwegian Research Council* and the *Norwegian Ministry of Education and Research.*

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Anders Ekbom

Investigation of scientific misconduct – some personal reflections

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This paper consists of some personal reflections on how to approach an investigation of scientific misconduct. It will not describe the entire process, but it will confine itself to some specific questions such as the differences between a normal scientific endevour and an investigation of suspected scientific misconduct, the need to have access to expertise outside the medical research community, time, and resources.

Terms of reference

When I was asked to chair the Investigation Commission appointed by Rikshospitalet- Radiumhospitalet MC and the University of Oslo (the appointing institutions) in January 2006, it probably mirrored the desperation of these institutions to identify anyone from the outside who could give legitimacy to the claims that everything should be done in order to clarify the circumstances surrounding the article by Jon Sudbø published in *The Lancet* during the fall of 2005 (1). However, my experience of investigating scientific misconduct were limited although not non-existent, but the omnipotence characterizing most physicians made it possible for me to accept the role as chairman and also the terms of reference formulated jointly by the appointing institutions.

The appointing institutions had chosen, or had been forced to choose (?), an uncommon pathway when an institution faces a case of suspected scientific misconduct. Instead of taking the normal route of hiding and/or downplaying the problem, the appointing institutions made an early commitment that all findings should be made public and the investigation would be carried out by individuals without any ties to any of the appointing institutions. As the chairman to be, I had accepted the terms of reference before the rest of the members of the Commission had been identi-

fied, which in hindsight was a mistake, especially as some terms were vague and the Commission was given less than three months to file a report. Eventually the composition of the Commission was finalized with the following members:

– Professor *Anders Ekbom* (Chair) Karolinska Institute Stockholm
– Special Advisor *Gro Helgesen*, the Research Council of Norway
– Researcher *Tor Lunde*, the Faculty of law, Bergen
– Professor *Aage Tverdal*, The Norwegian Institute of Public Health
– Professor *Stein Emil Vollset*, Bergen, and
– Research fellow *Sigmund Simonsen* (Secretary), Master of Law, Trondheim.

In addition, the National Cancer Institute (NCI), USA, was offered a seat on the Commission but did not accept the invitation.

The chairman eventually realized that he was to be congratulated on the choice of the members of the commission, who turned out to be an extremely hardworking group and dedicated to the task. In all the Commission met 13 times, had 11 telephone meetings, and in addition some members made site visits on different occasions. Another interesting note is that no leakage to the media or any other party occurred during its work. The experience and knowledge of legal procedures of two of the members of the Commission was an additional essential part, although the Commission was not a "public investigation commission". Their input made it possible to define the rules for our work which to a large degree adhered to the rules laid down for a public investigation commission. In addition, the Commission placed a great emphasis on independence in its contact with the appointing institutions, which was possible as no restrictions were placed on the use of resources. For instance all meetings were held outside the appointing institutions and the secretariat was placed in Trondheim.

The Commission´s primary task was to clarify the facts with the aim of discovering whether and to what extent breaches of standards for scientific research and other blameworthy acts had occurred. One of the first tasks for the Commission was therefore to establish the degree of proof that should be required as a basis for criticism. Taking into account the serious legal consequences and sanctions that might be triggered by such an act for an individual, the Commission decided that the degree of proof to be applied in order for it to rely on a particular fact as proven should be proof by a so-called qualified preponderance of probability. In the interaction within the Commission between those with a medical research and those with a legal background both parties eventually managed to conceptualize what the other party meant, although a p-value would had been helpful. In

other words the Commission applied a very high threshold for criticism of persons. Moreover, the individuals who were investigated were notified of this and also informed that they might be subjected to criticism. The individuals who were subjected to criticism were allowed to read memos, documents, and finally a draft of the report and were also given the opportunity to respond and make contributions.

In relation to institutions, the Commission had a somewhat different approach. Two institutions were notified that they might be subjected to criticism and were given the opportunity to read the criticism, but not the full draft report, and had therefore only a limited possibility to contribute. Finally, the Commission chose not to notify the appointing institutions in order to uphold its independence and to prevent the risk of any unfortunate influence from these institutions. Moreover, the opinion of the Commission was that institutions, to a completely different degree than individuals, must be prepared to put up with public criticism.

The role of the co-authors

As mentioned previously the terms of reference formulated appointing institutions were vague and broadly stated, which meant that there were no restrictions imposed on the Commission, but also that the Commission had to prioritize. It became obvious early on that the entire scientific activity and production of Jon Sudbø had to be investigated, in all 38 publications according to the PubMed database. This meant that all co-authors who had contributed, 60 individuals, were approached. All were treated equally and were notified in writing that they were subjected to investigation and formally notified that this could result in criticism. They were also asked to make a written statement about their involvement of the research they had conducted with Jon Sudbø. In addition certain individuals who were named in Acknowledgements were approached in a similar manner as the co-authors. All co-authors and those other individuals approached by the Commission responded, and in quite a few instances there was a follow-up correspondence or a face to face interview.

One of the main interests of the media coverage of the Commission's work was on the role of the co-authors. It therefore became clear that that the Commission had to choose a strategy to adhere to the so called Vancouver rules for authors.

The Vancouver Rules set forth three key conditions for authorship:

1. Substantial contributions to conception and design, OR acquisition of data, OR analysis and interpretation of data,

2. drafting the article, OR revising it critically for important intellectual content, and
3. final approval of the version to be published.

All three criteria must be met.

However, early on it became obvious that some individuals had not adhered to the Vancouver rules. For instance some co-authors were not aware of their status as a co-author, and in some instances they had even objected to being included both before and after publication. On the other side of the spectrum, there were some co-authors who undoubtedly fulfilled the criteria, but the majority of co-authors were in a "grey zone", where further investigation was needed in order to establish to what extent the criteria were fulfilled. Keeping in mind, as mentioned above, the potential serious consequences for an individual, who would be criticized in a final report from the Commission for not fulfilling the Vancouver rules, and the stringent standard which had to be applied for such criticism for 60 different co-authors, the Commission chose not to name any specific individual. This decision was made, to some extent, based on the impression that there are different perceptions of the authority as well as knowledge of the Vancouver rules within the medical research community in Norway. This is not a unique phenomenon from an international perspective, as similar problems have been documented in other countries.

Although the management of the appointing institutions could demonstrate a clear attitude with regards to the Vancouver rules, manifested by internal work instructions and other measures, the Commission was left with the impression that these measures had not been followed up well enough. The Commission therefore in the end chose to raise criticism against the appointing institutions for failure to create guidelines and follow-up systems with regard to authorship.

It also became obvious that at least for some articles a more active involvement of the co-authors in the handling of the manuscripts would have led to an earlier discovery of the use of fraudulent data. The Commission therefore believes that in order to contribute to a better compliance with prevailing rules, medical journals should introduce and practice a system in which all co-authors are made part of the communication with the journals. This includes a confirmation message to all co-authors that the paper has been submitted and also copies of review statements. In this way the individual co-author´s awareness of his/her responsibility would be strengthened and avoid the possibility that researchers are listed as co-authors without any knowledge of this fact.

The scientific production of Jon Sudbø

There was a need to evaluate the whole scientific production of Jon Sudbø. This evaluation was greatly helped by the Norwegian Cancer Registry, which ran a parallel investigation. Early on in this process it became obvious both for the Commission and the Norwegian Cancer Registry that the data which was the core in most of the articles published by Jon Sudbø did not add up. However, to establish beyond any doubt that the data were fraudulent was deemed by the Commission to be impossible within the time frame which was originally in the terms of reference. In order to keep to the time schedule we therefore initially tried another strategy.

The core of Jon Sudbø´s subsequent scientific production appeared already in three papers in his PhD – thesis. In these studies 150 individuals with premalignant changes in the oral cavity had been identified through different centers in Norway and then followed up through linkage with the Norwegian Cancer Registry for a subsequent cancer occurrence. In two separate papers, which both were included in the thesis work, the histopathological evaluation process of those premalignant changes was of particular interest. In the article published in *The New England Journal of Medicine* in 2001 (2) it was stated: "All histological sections were reviewed by four separate pathologists working at three different institutions (Department of Pathology, Haukeland Hospital, University of Bergen; The Norwegian Radium Hospital; and Department of Oral Pathology, University of Oslo)." In the article published in *Journal of Pathology* 2001 (3) it was stated: "All histological sections were subsequently reevaluated by four pathologists according to the guidelines of the *World Health Organization*. Consensus on the classification of dysplasia was reached in the case of 196 of the 242 patents (81 %)." No information was given about the identity of those four pathologists and there were seven potential candidates among the authors or those listed in the acknowledgements.

After interviewing all seven potential candidates it was clear that none of them had seen all specimens and subsequently all of them believed that they did not belong to the group of four pathologists. The members of the Commission then confronted Jon Sudbø and his lawyer during a face to face interview with these facts thinking that we had a good case to prove that these articles were a result of scientific misconduct. Their response was to point out (and rightly so) that we had misinterpreted the texts. An alternative interpretation was that four pathologists were involved and that nowhere in the text was it stated that any of four pathologists had had access to all specimens. Although the chairman of the Commission persisted in his opinion that the two texts were misleading, the Commission decided

that this was not good enough in order to make the case that any of these articles could be classified as fraudulent.

It was then obvious that the Commission could not file a report at the end of March, 2006 and we therefore approached the appointing institutions with two alternatives. They could find themselves a new Commission or extend the time limit. If the institutions decided to choose the latter alternative, the Commission would not be able to provide a final date. We were not particularly surprised when the appointing institutions decided to keep the Commission intact, but then we faced the dilemma how to chart our subsequent work. The Commission decided that there was no more room for shortcuts and in essence went back to all original files from the different institutions, in order to explore to what extent the different studies could be replicated. This was done in close collaboration with the Norwegian Cancer Registry, which provided invaluable help, but we also received good support from the Rikshospitalet- Radiumhospitalet MC and the University of Bergen.

After a time-consuming process the Commission became convinced that the original patient material published in *The New England Journal of Medicine* in 2001 (2) contained data which did not correspond to the data which we and the Norwegian Cancer Registry were able to retrieve. The Commission was of the opinion that "these errors and defects which were exposed was to numerous, too great, and to obvious to be attributed to random errors, incompetence or the like; and that the raw data therefore appear to have been fabricated, manipulated and adapted to the desired finding". The Commission therefore recommended retraction of the majority of Jon Sudbø´s scientific production as it suffered from errors and flaws caused by scientific dishonesty.

Conclusions and future perspectives

What did I learn? There were at least three things I realized after my involvement with this case and taking into account other instances of scientific misconduct:

1. It will happen again!
2. It will happen again!
3. It will happen again!

In other words the scientific community has to be prepared to deal with situations when there are suspicions of scientific misconduct. Ideally one should have an organization in place, but if this is not the case at least use the experiences from this commission and similar ones. Other investigators

should not be forced to re-invent the wheel! My take-home message to them can be summarized in four sentences:

1. You need lawyers, or access to good legal advice.
2. It is a costly and time consuming process.
3. You have to be an outsider.
4. Investigating is different from research.

Finally, a personal note. Doping among athletes has been used as a metaphor for fraudulent research, but in my opinion that is a dangerous and misleading comparison, especially if it is used in order to give legitimacy for the introduction of more rules and regulations as preventive measures. What one should not forget is the two entirely different goals characterizing these two activities. Among athletes the underlying aim is at a given moment to produce results which will surpass those of the opponent(s). In order to make that happen, the athletes or their coaches will use their creativity, and sometimes they will stray from that which is allowed. The rules and regulations are there to provide fair competition. In research, on the other hand, the underlying aim is to increase knowledge, sometimes in a competitive way. But creativity is unfortunately a scarce commodity and anything which dampens that creativity will potentially become an obstacle in the research process. Therefore the research community does not need more rules and/or regulations. We must learn to adhere to those which have emerged over time such as the Helsinki declaration and the Vancouver rules.

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From Darsee to Sudbø: NLM's role in the retraction process

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Today, virtually all biomedical scientists, many health practitioners, and an increasing number of patients search the MEDLINE database using PubMed to learn about published research findings. MEDLINE has evolved over the decades to become a service that is not only indispensable to medical research and practice, but one that is consulted millions of times each day. Anyone with access to the Web can search an immense database of references and abstracts to more than 16 million journal articles.

Since 1984, the *National Library of Medicine (NLM)* has played a major role in informing the users of MEDLINE of indexed journal articles that have been subsequently revealed as fraudulent (1). Far fewer than 1 % of more than 600 000 articles indexed annually are retracted. However, the potential impact can be great if inaccurate information forms the basis for subsequent research or is used in the treatment of patients. By NLM's definition, a retraction states that an article previously published, was based on deliberately falsified or unsubstantiated data (2).

There have been examples of scientific fraud throughout history (3). But it was not until the early 1980s when John Darsee, a researcher at Harvard University, admitted to systematically falsifying data in several experiments, that fraud began to attract the concern of many scientists and of NLM. As the compiler of the world's largest biomedical database, NLM staff realized that if we did not help to bring this behavior to the attention of users, we could be guilty of contributing to the dissemination of incorrect information. Prior to this, printed retraction notices existed in journals but there was no way to link users from these notices back to the original article and visa versa.

Retractions

For NLM to label something a retraction, the notice must be cited on a numbered page in a journal indexed in MEDLINE and generally, the retraction notice must appear in the same journal title that published the retracted article (2). Only statements that are specifically labeled retraction or withdrawal are considered to be retractions. If the statement is headed "Questionable Science" or something similar, it is labeled as a 'comment' by NLM. Comments are substantive articles, letters, or editorials that challenge, refute, support, or expand upon a previously published article.

Before I continue with more information about NLM's role in retractions, let me mention some ways we alert users to other types of publication practices. Corrections or error notices, whether originating in the publication process or due to errors in scientific logic or methodology, are labeled as 'Errata'. If the correction is part of the NLM citation or abstract, we will update the citation to its corrected form and will indicate in brackets that the citation has been corrected.

Other notifications include 'Corrected and Republished Articles' where an entire article is reprinted, usually rectifying an editorial or printing error in the original article. In MEDLINE the original article citation remains with a reciprocal link to the republished article citation. 'Duplicate Publication' is used to identify an article that substantially duplicates another article without acknowledgement. Usually the duplicate article will appear in a lesser known publication or in a more esoteric language. It is important to note that NLM does not use this label for acknowledged simultaneous publications such as joint editorials of the *International Committee of Medical Journal Editors* or the simultaneous publication of a practice guideline by two societies. Plagiarism, in which one author reproduces another author's work without acknowledgement, is a form of scientific misconduct and is covered by NLM as a 'Retraction'.

How many reports of fraud in science are there each year? Retractions remain an incredibly small portion of the 623 000 articles we index but the numbers are increasing as the amount of indexed articles rises each year. A huge jump occurred in 2006 when we increased from 67 retractions to 97. Since the policy began more than 20 years ago, through the end of the government fiscal year in September 30, 2006, we have entered 691 retractions of publication that retracted 738 articles. A few general observations are in order. The top tier journals issue more retractions than other journals. This may be a result of higher ethical standards or because their editors are more willing to risk law suits, or that more of their authors crave success even at any cost of falsifying research. It takes a long time to publish a retraction –

often 24 months – so that users may innocently retrieve citations to articles that we already know to be fabricated or at least questionable, but still lack any statement from the journal.

Misconduct

Why do we continue to see misconduct in science? The simple answer is that it is difficult to protect against it. It is difficult to challenge the integrity of an author, more difficult when several authors, whom you assume have shared their data, collaborate. When an author is well-known researcher in the field, it is even more difficult.

It is ironic, as Arnold Relman the former editor of *The New England Journal of Medicine* pointed out years ago, that scientific research, in many ways one of the most questioning and skeptical of human activities, should be so dependent on personal trust (4). We trust the scientist that her research is pure and unadulterated; we trust the young researcher that he has not plagiarized another's intellectual output and claimed it as his own. We trust editors and others who can act to control these actions to act swiftly.

Violations of trust, as Relman pointed out, are probably not as common as the publicity that they receive suggests, but whatever their frequency, they are always a reason for serious concern and soul-searching. As the Report of the Investigation Commission chaired by Prof. Ekbom pointed out, they can threaten the very foundations of scientific research.

Let me illustrate this by briefly examining four egregious examples of misconduct to see what we can learn from John Darsee, Robert Slutsky, Eric Poehlman, and Jon Sudbø. They seem to have elements in common that are found in all well-known cases: high profile researchers; popular scientists; powerful supporters; and claims of misjudgment or stress. Each of the well-publicized incidents of scientific fraud brought unprecedented attention to these men for a short period of time. Unfortunately, this attention rarely results in lasting change.

John Darsee committed scientific fraud for years at Harvard and Emory universities. At Harvard he was in the lab of the esteemed physician Eugene Braunwald whose work as well as Darsee's was funded by large NIH grants. Darsee's first known act of fraud in 1981 involved labeling data that had been obtained over a period of a few hours to make it look as if the data had been recorded over two weeks. Darsee said it was a single, isolated, foolish act of misconduct. As writer Barbara Culliton reports in her summary of the Darsee case in *Science* (5), Eugene Braunwald unfortunately believed Darsee. Braunwald said he didn't want to damage Darsee's career and he probably did not wish to damage the reputation of his institution. In the

end, 8 papers and 21 abstracts given at scientific meetings, had to be retracted. In hindsight, Braunwald and Harvard admitted they should have acted more promptly to conduct an audit and should not have believed Darsee's claim that his 1981 fraud was an insolated case.

In 1983, Robert Slutsky published 34 articles in journals indexed in MEDLINE and in 1984, he published another 31. He slowed down in 1985 publishing only 15 articles when his output ceased in August of that year. Many of these articles were eventually retracted. In hindsight one can ask why the editors to which he submitted papers didn't question how often he sent them manuscripts. Thirteen of his articles were published in the *American Heart Journal*; ten each in *Radiology and Investigative Radiology*; and nine in the *American Journal of Cardiology* – all top tier journals in their field. Why didn't one of these editors question Slutsky's ability to be so prolific in a relatively short period of time?

Eric Poehlman is considered by some to be the American version of Jon Sudbø. Poehlman agreed to retract or correct ten scientific articles which he authored between 1992-2002, because of falsified or fabricated data. Nine of these are indexed in MEDLINE; one is from an Indian publication not indexed. Poehlman came under suspicion in 2000 when a young research assistant found inconsistencies in spreadsheets used in a longitudinal study on aging. In an effort to portray worsening health in his subjects, Poehlman would switch the data points. In his 1995 paper published in the *Annals of Internal Medicine*, Poehlman presented metabolic data on 35 women. Most of the women did not exist, according to a statement he later signed. Poehlman was among the most notorious fabricators of data, having authored or co-authored 204 articles cited in MEDLINE through March 2005. By then, the NLM policy of updating citations with retracted notices and linking them to retractions of publication was a well-known feature of MEDLINE. However, we suspected it was not routinely noticed by many users. There is really no way to tell how many MEDLINE users failed to notice the information; but it was possible to tell how many authors cited Poehlman's works before the official retractions were published in 2005. Moreover, because the *Annals of Internal Medicine* took the bold step of unilaterally retracting the 1995 article in 2003 before the NIH findings were complete, we can even tell how many authors cited this article after the retraction notice appeared.

Retracted articles continue to be cited

In an analysis we undertook using Web of Science, we determined that nearly every one of Poehlman's 204 articles was cited by others. The nine

MEDLINE articles Poehlman retracted were cited from 10 to 151 times through March 2005. Ironically, the Annals publication retracted in 2003 was cited the most of all the retracted articles – a total of 151 times, including sixteen times in 2004 and 2005 after the retraction notice was issued by Annals and added to the MEDLINE record. Worse yet, in August 2006, we examined the nine retracted citations again to see if any had been cited since our previous March 2005 analysis. Even after eliminating the citations to Poehlman's own retraction notices, all nine articles were cited by authors writing new, original papers. The *Annals* article, retracted in 2003, was cited 23 more times since 2005 with only three of the papers writing about Poehlman's scientific misconduct and 20 writing about obesity and post-menopausal women, Poehlman's research topic.

I have read most of the English translation of the incredibly thorough Sudbø Report from the Investigation Commission chaired by Prof. Ekbom. The report contains many excellent recommendations for the institutions, co-authors, and journals involved. There is little that I can add to the Sudbø story that has not already been documented. However, it does give me the opportunity to comment on two issues – the continued citing of Sudbø articles by innocent and unknowing authors and the use of the so-called 'Expression of Concern' by journal editors.

On September 18, 2006, 7 months after Jon Sudbø's article in *The Lancet* was retracted, NLM examined all 38 Sudbø articles indexed in MEDLINE to see how many were cited in other articles. As that time, only the *Lancet* article was retracted. The two *New England Journal of Medicine* articles for which the editor issued an 'Expression of Concern' were not yet retracted as that journal was still in discussions with Sudbø's co-authors regarding their retraction statements. The retracted *Lancet* article was cited 15 times, including 12 times after the appearance of the retraction notice. It makes me wonder how many researchers actually read the articles they cite, or if they ever read the popular press in which Sudbø's indiscretions were described.

The phrase 'Expression of Concern' was first used by Jeff Drazen, editor of *The New England Journal of Medicine,* and used since by the *Lancet, BMJ, Science* and a handful of other journals. It was used effectively in the Sudbø case by the *Lancet* as soon as it was informed by officials of the Radiumhospital that information strongly indicated that Sudbø's 2005 article was based on manipulated data. However, the *Lancet* knew that a published retraction statement would not be coming immediately so an 'Expression of Concern' was used to alert readers to be aware of this article. Any 'Expression of Concern' is linked electronically in both directions by

NLM to the original article. Once Professor Ekbom provided written confirmation that the paper was fabricated, the *Lancet* published a retraction notice that superseded the 'Expression of Concern' for the article.

Over the years, editors, deans, ethicists, and others have been quick to elaborate on the lessons learned from the various examples of tainted research. Prevention of fraud is important but so is identifying the damage and minimizing its effect. Full disclosure by all authors of their specific role, and acknowledgement that each has read and takes responsibility for the final paper is a good start. The adherence to established criteria for what constitutes authorship according to the guidelines of the *International Committee of Medical Journal Editors* is another prerequisite. NLM recently developed a new policy that addresses some examples of this lack of full disclosure. In order for the Library to index articles in funded journal supplements, each article must include a statement of full disclosure by its authors. Having disclosure information elsewhere in the publication is not sufficient because our users link to the full-text of the desired article and do not peruse the rest of the publication for this information.

Hal Sox and Drumond Rennie in their 2006 editorial about the Poehlman case (6), called on NLM to go further in trying to prevent the continual citing of retracted articles. They recommend the creation of a web-based program that would take a manuscript's list of references and compare it to NLM's master list of retracted articles, and when a match exists, send a message to the author. It's an intriguing idea but one we have rejected so far as we feel that it doesn't address the potential retrieval of retracted articles in any of the 900 million searches conducted against MEDLINE citations during the past year.

There are still only about 700 retracted publications among MEDLINE's 16 million citations. They can all be retrieved using a simple PubMed query of Retracted Publication [PT]. We also have an easy to use feature on PubMed's Special Queries page that allows a user to examine a list of all retracted articles in chronological order. Finally, we are cooperating with the makers of a major citation matching system used by many publishers. Currently, publishers use software to check the accuracy of references in a manuscript by matching them against MEDLINE citations. Unfortunately, their software does not identify the presence of a retraction notice in the MEDLINE record. If the products can be programmed to recognize this statement, then the journal will be alerted automatically to any citation that has been retracted. If this improvement can be made, it will go a long way towards eliminating the citing of retracted articles.

What have we learned?

What have we learned after more than 20 years of citing retractions and other forms of misconduct? Here are some signs that reviewers and editors can look for that should raise their suspicion about authors. If data seems too good to believe, too neat, too perfect, it probably is. If your scientific intuition makes you suspicious, follow up on it. If an author publishes so frequently that he literally has no time for good research, he probably doesn't practice good research. Co-authors must be familiar with all aspects of the research and must disclose that they are. Lab chiefs and others in supervisory or mentoring roles must oversee the research on an ongoing basis, not avoid responsibility while adding their names as co-authors of papers. If an author contends that her instance of fraud is an isolated, one-time indiscretion, better check further; it usually isn't. You can't afford to give a scientist the benefit of doubt, even someone of Sudbø's status, in any case where some fraud has been admitted. An audit or review must be undertaken and it should be done by persons outside of the immediate lab in which the scientist worked.

There are ways to minimize the damage done by dishonest people – and this is where NLM can help. But we also need to recognize that stringent procedures designed to prevent and detect wrong doing can be counter productive to the thousands of honest researchers. We cannot afford to damage the free exchange of ideas in trying to prevent the appearance of the next Sudbø. Trust has risks attached, which we must continue to strive to minimize by promoting an atmosphere in which authors, editors, research institutions, and NLM have clear responsibilities. When they are diligent in carrying out their responsibilities, misconduct will be reduced and the innocent use of fraudulent data may begin to disappear.

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Can editors police scientific misconduct?

Michael 2007;4:27–33

No universal definition exists of research misconduct but it generally includes fabrication or falsification of data, plagiarism, unethical treatment of research subjects and attempted or actual duplicate publication. Deceit, rather than honest error or naivety is the key.

Over the decades, editors of science journals have had the wool pulled over their eyes by numerous serial fraudsters. For example, 17 papers published between 1979 and 1981 by John Darsee were retracted because investigations showed the data had been invented or dishonestly manipulated. They had been published in high impact journals including the *New England Journal of Medicine, American Journal of Physiology, American Journal of Cardiology* and several others. Also in the eighties, Robert Slutsky was found to have published 12 definitely and 49 questionably fraudulent papers in radiological and cardiological journals before his activities were discovered. In 2003, *Nature* and *Science* retracted eight papers by Schon and others at Bell Laboratories on superconductivity. Hwang Woo-suk, at the time considered a pioneer in stem cell research, provoked an international outcry when he was discovered to have published fraudulent work in *Science* during 2004 and 2005.

Together with Jon Sudbø, they represent some of the most publicised scientific fraudsters. But ask any experienced editor of a medical peer-reviewed journal and he or she will tell you of many more, less high profile papers, about whom they have grave suspicions.

Editors' dilemmas

However, editors are probably the least likely persons to first raise an alarm: colleagues of the researcher – often junior, reviewers, readers and statisticians are more likely to do so, although the mere fact that so much spuri-

ous research has been published does not speak well for the skills of many of those who review or read scientific papers.

The main problem for editors is that the whole system of science publishing is based on trust. They do not expect authors to commit fraud, even if now more alert to other areas of misconduct such as failure to declare competing financial interests, guest and ghost authorship and the more subtle attempts at redundant publication ('salami slicing'). Moreover, editors of general medical journals cannot be expert in the many fields of research which come their way. To a lesser extent, the same is true of editors of major speciality journals. Only in particularly small and esoteric fields can the editor be his own expert reviewer.

Initial triage in journals receiving a large number of submissions looks for such criteria as originality, concordance with the journal's vision and likely citability, rather than giving close attention to the methodology or statistical analysis – a process usually outsourced to reviewers and biostatisticians.

Editors may have a conflict of interest over and above their desire to enhance the reputation of their journal, for example a connection with the author or author's institution, which may override necessary scepticism. Hunger for high impact papers might also influence judgement. An example is a fraudulent paper published in the *British Journal of Obstetrics & Gynaecology* where the potential importance of the findings (had they been true) may have led to the submission (on which the editor-in-chief, from the same institution as the perpetrator was invited to be a co-author) to be dealt with in a way which avoided the normal checks and balances of the editorial and peer review process (1).

Peer review may not protect

Despite the filter of the peer review process, papers in which data have been manipulated improperly continue to find their way into the literature. Given the problem even 'trained' reviewers have in detecting major errors in papers, it is unsurprising that suspicions may not be aroused (2).Reviewers are likely to be more effective where their specialty is a small one so that their chance of recognising a pattern of misconduct in the work of an individual or a team is greater. Indeed the *Committee on Publication Ethics (COPE)* has been alerted by such a reviewer, so concerned about several papers by the same group sent to him from different journals, that he undertook a MEDLINE© search of their publications. The total was extremely high (itself a matter for concern) and the scatter between numerous low impact journals was great. Statistical analysis by his colleague of a

random selection of the group's publications suggests a possibility of wholesale fraud.

Misconduct of the types often assumed to be less serious – redundant publication and plagiarism, for example - is more likely to be noticed by experienced reviewers. Searching the databases when conducting systematic reviews is an obvious route (3). A short cut might be to type a series of words from a suspicious paper into Google to see if they have been used before (4). 'Less serious' may be a dangerous classification, however. Those experienced in dealing with dishonest persons frequently discover that their dishonesty is rarely circumscribed and recurs in various areas of their personal and professional lives. Thus, detecting plagiarism could be a first step to detecting other misconduct.

Skilled fraudsters may manipulate data in a manner which may elude detection unless specific techniques are deployed. Al-Marzouk et al used baseline comparisons of means and variances in baseline data and examination of patterns of digit preference to detect fabricated or falsified data in a randomised controlled trial where referees had raised concerns about suspicious inconsistencies (5). Unfortunately, routine use of such analyses are likely to be beyond the resources of most journals.

How editors can be on guard

Information from the database of cases discussed at the regular meetings of COPE (6) suggest there are warning signs which suggest editors should perform extra scrutiny:

- Submissions where it seems unlikely that the authors could have the resources to undertake the reported trial: a group of authors, widely scattered geographically through the developing world, reported a large, multicentre prospective randomised trial but without being able to provide evidence of the necessary funding. MEDLINE© search revealed a previous similar exercise.

- Data 'too good to be true': Two authors submitted a study on 15 000 newborn babies born in a socially deprived area of a large city. They claimed 97 % follow up at age 18 months – an impossible target given the proportion of residents who were known to move out of the area each year, the expected number which traditionally avoids follow-up and the scanty details of the system used to trace patients.

- Findings that are hard to believe: a study producing a counterintuitive result is always likely to spark an editor's interest, especially if the topic

is one where there is otherwise a consensus. While such a finding may be true or the result of a methodological or computational error, the possibility of fraud needs to be considered.

- Authorial pressure: in a competitive arena, editors often welcome approaches by researchers with an interesting story to tell. But they should have a degree of scepticism about those whose entreaties are persistent, repetitive or even threatening. Bullying is a well-recognised method of covering up for dishonesty.

Following a review of the journal's procedures after the withdrawal of the fabricated papers by Hwang Woo-suk, the editor of *Science* described the journal's development of criteria for being alert to submissions needing special attention. These included "papers that are of substantial public interest, present results that are unexpected and/or counterintuitive, or touch on areas of high political controversy…" (7). The last is exemplified by a recent COPE case involved publication in a high impact journal of a survey of household violence following a coup against a country's elected president showing high levels of violence and human rights abuse. Complaints followed that the author had not declared knowing and supporting the deposed president and may not have reported similar violent acts conducted by his supporters.

Avoiding trouble

There are many general tasks which editors can carry out in an attempt to reduce misconduct. Clear instructions to authors, requiring them to complete a checklist, may not deflect determined fraudsters but at least offers editors evidence of dishonesty in their declarations to offer to any investigatory authority subsequently involved. For example, insistence on a clear account of any conflicting interest which might prejudice a reasonable reader as to whether the interpretation of data is likely to be reliable (8). Similarly a requirement to declare if the paper has been submitted elsewhere and for sight of any related papers by the authors may help deal with deliberate or unwitting redundant publication. There should be precisely stated rules on authorship or contributorship, ethical approval and trial registration as laid down in guidelines such as those from the *International Committee of Medical Journal Editors (ICJME)* (9).

One major academic publisher has produced guidelines for its journal editors on handling breaches of publication ethics (10) including access to COPE's flowcharts on dealing with commonly encountered issues.

Editors need to be aware that new techniques may bring new problems. For example, not only text and figures can be manipulated: images such as photomicrographs can be altered using standard software such as Photoshop®. A 2006 report from the *Council of Science Editors* states that 'clear guidelines are important because some level of image manipulation is accepted practice, (for example image cropping or limited adjustment of brightness and contrast…' Production editors (technical editors) may become suspicious when conducting a forensic analysis to check figures for compliance with journal requirements (11). The *Rockefeller University Press* has defined digital-image related misconduct and provides pertinent examples (12).

Post-hoc action

ICJME guidelines state that editors have a responsibility to ensure that any question of misconduct is pursued, usually by the author's institution [9] COPE requires of its members that they must follow the principle of their prime duty being to maintain the integrity of the scientific record. This must take precedence over their other duties – for example, making sure their publication is readable and profitable (or, at least not a financial burden for the society, academic institution, government body or publisher to whom they are responsible). Because they take final responsibility for everything in the publication they edit, they have a duty to detect and investigate misconduct.

This duty is initially carried out by communication with the authors, all of whom should be copied into the correspondence. In many cases, misconduct has not occurred and innocent or understandable errors or misunderstandings aroused initial concern. Where an editor remains unsure after any exchange of correspondence, he or she may be helped by consulting others, such as his journal's or publisher's ethical committee or an outside body, such as COPE. Being able to quote advice from an external source can be powerful support, particularly for a relatively junior editor or one who feels professionally vulnerable. Do not be too hopeful of reaching a satisfactory outcome, however. In 1992, the *BMJ* published a paper by Ram B Singh. Subsequently doubts were raised about the paper and others by the same author published elsewhere. Despite 7 years of effort by the editor, no legitimate authority was prepared to investigate the case (13). An analysis of the first 79 cases reported to COPE as showing prima facie evidence of misconduct showed that 15 reached an impasse where no resolution proved possible and a further 36 took over a year to resolve (14). A current cause célèbre involving fierce argument between a principal

investigator, his previous employer the University of Sheffield, the editor of the journal publishing the papers involved and the pharmaceutical giant Proctor & Gamble over alleged manipulation of properly acquired data, is unresolved after 5 years. [15].

Most editors would agree that while they have a duty to be whistleblowers, investigating cases should be in the hands of others so that due process and a fair hearing may be ensured. Where the author's explanation is unsatisfactory, this involves alerting the author's employer or funder and requesting they investigate. Experience dictates that it may be necessary to enquire regularly, perhaps 6 monthly, as to the outcome of any investigation. Where no institution can be identified, for example in the field of private practice, any regulatory body having control over the author's professional accreditation should be contacted. Formal governmental mechanisms exist in some countries, especially Scandinavia and the USA while others have more ad hoc processes (16).

Once an investigative body has issued its report, editors should be prompt in correcting the literature. *The National Library of Medicine* uses three indexing terms: *correction* (generally where there is no element of deception but rather an error in the publication process or methodology); *retraction*, where the author, editor, publisher or academic or institutional sponsor requires it because of pervasive error or unsubstantiated or irreproducible data (regardless of deliberate dishonesty); or an *expression of concern* where the editor wishes to draw attention to a possible problem short of correction or retraction (17).

Meanwhile, alas, corrected and retracted papers continue to be cited without drawing attention to the original error or fraud.

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Playing by the rules - Scientific misconduct in a legal perspective

Michael 2007;4:35–42

A simple lesson to learn from the recent Norwegian research scandal is that there are rules that need to be observed and appreciated. This requires knowledge, understanding and awareness both at the individual level and institutional level.

Given the increasingly complex framework for research, it may sound a tall order, but it is nevertheless reasonable. Contrary to popular belief, rules are not meant to be an inappropriate hindrance for good research. They are meant to foster good research. Ethical, professional and legally acceptable research is crucial for public trust and the legitimacy of science.

Fortunately the awareness of and attitude towards this normative framework is changing. The recent case has speeded things up in Norway, and it has certainly made it easier to explain why we do have and must have rules. For in order to play by the rules, one must know the rules.

This paper concentrates on the rules and regulations governing medical and health related research in general, in the wake of the hereinafter called Norwegian research scandal. Three questions can be raised:

- Are there rules?
- Is there a problem with regard to the rules and regulations?
- If so, what should be done to address the problem?

Are there rules?

In March, 2006, I was asked to talk about whether fraud in science is illegal or not? I was a bit surprised by that request. Is anyone in doubt, I thought.

My answer was of course a simple but clear yes. There are rules. Medical and health related research is subject to a magnitude of rules, just like any other activity (1,2) (tables 1, 2, 3).

Table 1 Significant international "legal" instruments regulating biomedical research

- The Nuremberg Code of 1947
- UN Universal Declaration on Human Rights of 1948 (UDHR)
- CoE European Convention on Human Rights of 1952 (ECHR)
- UN International Covenant on Civil and Political Rights of 1966 (ICCPR)
- UN International Covenant on Economic, Social and Cultural Rights of 1966 (ICESCR)
- CoE Convention for the Protection of Individuals with regard to Automatic Processing of Personal Data of 1981
- EU Directive on Personal Data of 1995
- CoE Convention on Human Rights and Biomedicine of 1997 (CHRB)
- UNESCO Universal Declaration on the Human Genome and Human Rights of 1997.
- EU Directive on Clinical Trials of 2001
- CoE Additional Protocol Concerning Biomedical Research to the CHRB of 2005 (AP)
- EU Directive on Good Clinical Practice Directive of 2005.
- UNESCO Universal Declaration on Bioethics and Human Rights of 2005

Table 2 Relevant Norwegian legislation regulating biomedical research

- Law of torts
- Criminal code of 1902
- Transplantation Act of 1976
- Human rights Act of 1999
- Patients rights Act of 1999
- Health personnel Act of 1999
- Personal Data Act of 2000
- Health register Act of 2001
- Biobank Act of 2003
- Biotechnology Act of 2003
- Clinical trials directive of 2003
- Research ethics Act of 2006

There are a variety of behavioural norms governing the conduct of scientists, from social and ethical norms to more specific and binding professional and legal norms. These norms may be unwritten (e.g. custom based) or text based. They concern anything from prior ethical review, choice of method, risk assessment, consent and confidentiality to publication and authorship. And fraud in science is immoral and illegal, as in any other sector. Moreover we all have a duty of care; ethically, professionally, and

Table 3 Significant international professional and non-governmental guidelines regulating biomedical research

- WMA's Declaration of Helsinki of 1964
- CIOMS International guidelines for ethical review of epidemiological studies of 1991
- EMEA ICH Guidelines for Good Clinical Practice of 1996
- CIOMS International ethical guidelines for biomedical research involving human subjects of 2002.
- International Committee of Medical Journal Editors. Uniform Requirements for Manuscripts Submitted to Biomedical Journals: Writing and Editing for Biomedical Publication of 2005.

legally. Breaches of that duty may for example constitute liability for negligence.

Additionally there are established agencies or procedures to oversee and ensure that the rules are observed. These may be internal or external, prior or afterwards. An internal revision board at research institutions is one example. Multidisciplinary ethical committees and governmental agencies, such as data inspectorates and health authorities are other examples. Scientific journal peer-review may also be added. Courts or investigating agencies have a more reactive role in this control or quality assurance system.

Tables 1, 2 and 3 (which are incomplete) also illustrate that the regulation of medical research has been increasing at the international level during the past decade, as it has on the national level in several countries. Furthermore, we see an ongoing shift from professional guidelines to statutory rules (2).

A broad comparative analysis of common basic principles in this field revealed an anticipated intimate relationship between ethics, professional guidelines, and the law (2). Together these norms create a normative framework which any researcher is expected to know and adhere to.

The intention of this framework is to protect human subjects and to state which behaviour is acceptable or not; hence, to foster ethical and professional research. Simultaneously the intentions are then to prevent unethical, unprofessional and bad science. Thus the framework is meant to benefit the interest of human subjects, society, science, and scientists. The Declaration of Helsinki and the Oviedo-Convention both state that the "interests and welfare of the human being shall prevail over the sole interest of society or science" (4, 5 see Article 2). The rules are however obviously not meant to hinder good research, although some researchers seemingly suspect them of precisely that.

Generally speaking, regulations are, in this as in any other field, intended "to codify accepted modes of behaviour; good law is then facilitative, not prohibitive" (5). It is important to stress that although the framework is meant to be guiding, many of current rules, certainly the legal ones, are binding. Thus despite the fundamental character of academic freedom, it is by no means voluntary for researchers to comply or not with the existing framework (4 see Article 15). Bluntly speaking: researchers can appreciate and adapt, or close their eyes and hope for the best.

Another simple point to be made is that there is a gradual scale of wrongdoing. Deviations from existing rules occur in many shades – from the trivial to the conspicuous (6). A similar scale may describe the gradual degree of guilt – from honest errors via indifference and carelessness to intentional fraud. These are all wrongdoings, i.e. unwanted behaviour. Even unintended wrongdoings may be blameworthy and for example constitute liability. Although the intentions are the best, indifference to or ignorance of the law is seldom a valid excuse in a court of law; nor should it be within the scientific community.

Is there a problem with regard to the rules and regulation – a case study

The Investigating Commission's Report

The Norwegian research scandal may be illustrative of existing challenges or problems with regard to the rules and regulation of medical research.

The Commission concluded in its investigative report that "the bulk of Jon Sudbø's scientific publications, are invalid due to the fabrication and manipulation of the underlying data material" (7 p. 5). Furthermore the Commission "…found that there are no reasons to believe that other persons than Jon Sudbø, either intentionally or with gross negligence, have contributed to the fabrication of data or committed similar gross and serious breaches of good scientific practice" (7 p. 117). However, the Commission "discovered a series of minor breaches, which in aggregate have contributed to a system in which the breaches of good scientific practice have been allowed to increase without being discovered earlier" (7 p. 106).

The Commission observed that "…co-authors mainly appeared as sub-suppliers or as senior guarantors…" (7 p. 99). Although that may be legitimate, "…there are, as the Commission sees it, certain descriptions in the articles which more people should have reacted to. This may be co-authors, supervisors, superiors, critics, colleagues and others" (7 p. 99). The Commission went as far as stating that "[r]esearchers associated with the department indeed seem to have had a relatively relaxed relationship with the for-

malities. This applies in relation to the retrieval, delivery and treatment of human biological material and sensitive patient information, recommendations from the Regional Committee for Medical Research Ethics, and licenses for data processing and dispensation from the duty of secrecy" (7 p. 98). In its concluding remarks the Commission states: "A general characteristic seems to be that many of the co-authors did not have a very conscious relationship to the responsibility inherent in being listed as a co-author of a scientific publication. In other words, they have taken this role and responsibility too lightly" (7 p. 118). The researcher's supervisor was, however, the only individual named and blamed for negligence in the report. The Commission also criticized the primary institution, mainly for:

- "Insufficient advance control and organization of Sudbø's PhD project, including specification of distribution of responsibility.
- Insufficient training and consciousness-raising of Sudbø and other employees about the rules for handling patient material, advance assessment of research projects and authorship.
- Insufficient management and routines for discovering and handling deviations from internal instructions, etc" (7 p. 114-5)

Three additional research institutions where also criticized for breaches of confidentiality when handing out sensitive patient material and data without patient consent and/or necessary permission.

Finally, the Commission observed that scientific journals could probably have done more to include the co-authors and make them more conscious of their responsibilities.

The failure in all segments from bottom to top added up to what the Commission calls a systematic fault – a malfunction of the research community at large. Thus, interestingly, from a legal perspective, the Commission asserted that it was not "the lack of rules which is the problem, but rather the individual researcher's and institution's knowledge and practicing of the rules which actually exists (p. 106)… [and] a lack of measures to prevent breaches of good scientific practice through the implementation of simple and effective routines" (7 p. 107).

Complex, inaccessible, or too rigid rules?

Lack of knowledge *and* negligence or indifference when it comes to practicing existing rules is worrying. One might ask if lack of knowledge and awareness is due to complex, inaccessible, or too rigid rules.

As shown the regulatory framework is indeed complex and somewhat inaccessible (tables 1, 2, 3). In Norway, a governmental appointed committee (the Nylenna-committee) undertook an investigation of the Nor-

wegian framework for medical and healthrelated research (8). The Nylenna-committee recommended a simplification and improvement of the Norwegian framework in order to make it more comprehensible and accessible.

However, it must be noted that complexity is hardly ever an acceptable excuse for not knowing at least the basics. The Investigative Commission stated for example that the "prohibition against improper manipulation and fabrication of data is embedded in rules that all researchers must be assumed to be well acquainted with" (7 p. 106). The same can be said about other basic rules governing research. Furthermore, saying that the rules are too rigid – or even worse, not likeable - is also a rather poor excuse for negligence.

A troubling awareness or attitude towards the framework?

Since lack of knowledge therefore appears to be only part of the problem, the Commission report can be read as suggesting that there is a troubling awareness or even attitude towards existing rules within the scientific community. The Commission noted that testimonies indicated "… a disturbing lack of awareness of the prevailing rules for good research practice. This applies in particular to rules on secrecy, protection of personal data, authorship and advance assessments of research projects …" (7 p.114).

Although adherence by the rules is first and foremost an individual responsibility, the Commission also stresses the institutional responsibility when it states that "there has been a lack of measures to prevent breaches of good scientific practice through the implementation of simple and effective routines" (7 p. 107). In this regard, the Commission goes as far as stating that "… the deviations to a certain degree must have been known to and therefore apparently accepted by management" (7 p. 110).

These observations by the Commission indicate a problem of awareness and attitude towards the framework at all levels. Moreover, it poses the question: do we all actually understand and value the governing and facilitating function of the existing normative framework?

What should be done?

The Commission's investigating report echoes the findings in a broader survey of US scientists (n= 3 247), which revealed that 33 % of the respondents had engaged in conduct likely to be sanctionable (9). This finding led to the conclusion that "…mundane 'regular' misbehaviours represent greater threats to the scientific enterprise than those caused by high-profile misconduct cases such as fraud." Thus the "bad apple-theory/excuse" must

be abandoned and replaced by a culture of prevention and increased awareness at all levels.

Not unexpectedly, one of the Commission's recommendations is that "Research institutions must to a larger extent make all researchers and supervisors aware of the prevailing rules and the liability attached to breaches of the rules." (7 p. 119). From a legal perspective this implies education, implementation and a certain degree of follow up (control). These are preventive measures and should of course be aimed at the management and all researchers, not only the "bad apples" (the others).

Scientists cannot be expected to be professional lawyers able to manoeuvre in a complex framework and bureaucracy by themselves. It takes time and demands qualifications. That is the reason why it is an institutional responsibility to make the rules readily available for researchers and arrange for effective and professional research. Simple checklists, adequate schooling and accessible assistance when more complicated issues need to be addressed appear necessary. An adequate and proper quality assurance system is obviously mandatory in professional institutions responsible for research on human subjects and sensitive material.

Several research institutions in Norway have already adopted such measures, and the Commission notes optimistically in its report that "The medical research community is in a transition phase as regards the organization and formalities relating to medical research" (7 p.115). An additional point is accountability. Laboratory personnel, project leaders, authors, co-authors, supervisors, and management, from bottom to top, must be aware of their responsibility.

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Can research institutions live up to expectations?

Michael 2007;4:43–7

The Sudbø case is a tragedy for all involved but also represents a thought provoking event of great potential value. The investigations set in motion have pointed out a number of measures that either are lacking or where practice of existing rules and regulations must be improved. These actions will lead to a better, more stream-lined and quality – based research education. The most difficult problem in the wake of this scandal is to find the point where control is sufficient to secure quality, but not so heavy-handed that it represents a hindrance to research. I have expressed doubts as to whether we have found this equilibrium yet. So far, university and hospital have faced this scandal back-to - back and with considerable success. Only the future will show whether we will reach the right balance between control and preventive measures, where I have declared myself clearly in support of actions dominated by preventive measures. Rigorous control systems will lead to less research, less joy, more frustration, much higher administrative costs and probably not better research. We will never manage to root out fraud by control, but we can improve quality considerably and prevent some researchers from temptation to make shortcuts.

The Sudbø case deals with a man who at a point decided to fabricate scientific data and subsequently published them in high-ranking journals. He made elaborate manoeuvres to evade control agencies such as the Regional Committee for Medical Research Ethics, The Data Inspectorate and The Board of Health. Eventually his fraud was disclosed, but many have asked why it took such a long time to discover what was going on. The Ekbom commission (1) showed with painful clarity that a number of people failed to do what was expected of them. Sudbø's supervisor believed blindly in his research scholar who collected astonishingly large and complete data in a hurry, a number of co-authors took their responsibilities too lightly, and

the few with a gnawing suspicion afterwards admitted that they avoided the whistleblower position. The commission also uncovered a number of weaknesses in the prevailing set of rules related to research in the involved institutions. Sudbø was not employed at the university while he committed fraud. However, he worked as a research scholar in one of the four university hospitals in Oslo and parts of his PhD defended at the Medical faculty was apparently based on fraudulent research. For these reasons the University of Oslo and the university hospital in question decided from day one to deal with the Sudbø case as a common problem.

So, what to expect of us? How did we handle the situation? First I must make some reservations. I present my personal view and not necessarily the position of the University of Oslo. Secondly, the mopping-up operation initiated by the university is still not finished at the time of writing. Thirdly, in Norway also the hospitals are by law imposed to perform research. A number of similar measures to prevent scientific fraud have been initiated or are in planning in hospitals. These I will not comment on. The main actions taken at the University of Oslo after the irregularities were discovered and Sudbø had admitted to fraud, were the following.

1. The Rector decided that the handling of the personal matters should be delegated to the medical faculty.
2. Sudbø was within weeks invited to resign his post and did so without preconditions.
3. The University of Oslo and the university hospital jointly appointed the Ekbom commission (1) which within 5 months concluded that the scientific fraud involved more articles than Sudbø had admitted to, and also included papers that were part of his thesis which he had defended successfully in 2001.
4. The medical faculty subsequently appointed a special adjudication committee given the mandate to investigate whether Sudbø's PhD thesis contained fraud. The committee came to the same conclusion as the Ekbom Commission.
5. The University of Oslo in parallel appointed seven working groups with a mandate to look into all aspects of quality assurance related to research, including the role of supervisors and existing rules and regulations relevant to the case.
6. In December, 2006, approximately 11 months after the fraud was revealed, the Faculty Board of the medical faculty decided unanimously that Sudbø should lose his PhD and that his PhD diploma should be returned to the University of Oslo.

I still remember how quickly a number of people both inside and outside the university decided that they knew enough to call for a number of strict control measures for research in general based on the Sudbø's admittance of fraud. The Sudbø case is indeed a serious and painful experience for the university, and I have no problems with taking full responsibility for a number of the weaknesses discovered. Still I found several of the demands for stricter control short-sighted and potentially harmful for research. My first reaction was to underline that the results of a very thorough and independent investigation had to be made public in order to regain the trust of other researchers and society at large. But I also made it clear that one of the main duties of a dean is to *stimulate* my colleagues to research of good quality. It should not be the goal of a research institution to do whatever it takes to hunt down fraud. I decided rather early on that apart from ensuring that research is done in accordance with rules and regulations, positive preventive measures are better than controls that have never proved to be a creative measure.

This balancing act between control and preventive measures is in my opinion still the most challenging problem in the wake of the Sudbø case. The University of Oslo initiated a rather large mop-up operation and similar efforts were set in motion at the university hospital. We still have not seen the full impact of this operation, but a preliminary listing of recommended measures is shown in Table 1.

These proposals represent wall-to-wall responses to the various deficiencies met, but are they helpful in the long run? Rules and regulations do not stop persons who have decided to cheat. A handbook where everything can be collected is a fine idea, but who shall revise it? And concerning expectations: who is formulating them? There are no doubt differences between what research scholars expect and what authorities having the power to give or withhold grants would prioritise. I would think researchers in training for their PhD want better training courses in methodology and science philosophy, easier access to data and above all: experienced supervisors aware of their responsibilities and with ample time to guide the candidates and prevent them from falling into research-ethical potholes. On the other hand we have representatives of the research authorities – mainly hospital and university administrators, high-ranking persons in ministries and research foundations who recommend that research institutions must have a clear overview of and control over all research projects and impose a number of obligatory courses on research scholars, supervisors, and project leaders to ensure that all regulations are met.

This difference in priorities should not surprise anyone, but it puts decision-makers in a delicate situation. The higher up in the pyramid of

Table 1. Recommended measures at the University of Oslo after the Sudbø case

Handbook for research
Course for project leaders
Necessary permits granted
Overview and control with research projects
Certified protocols
Traceability from published to original data
Storing of research data
Enforcement of Vancouver rules of authorship
Obligatory course for research scholars
Course for supervisors
Agreements regulating university/hospital cooperation in research
Commission of research ethics
Ombudsman for research

power you come, the clearer the responsibility issue comes in focus. No one will disagree that compliance with law and regulations is to a dominant degree an institutional system and management responsibility. This is in full accordance with the Nylenna committee's report (2) and has received full support by the university. Thus it came as no surprise that within hours after the Sudbø case became public the news media asked who was responsible for this mess and for good reasons. It is in the implementation of necessary measures that we must balance control and prevention. For example, rumours have circulated that it would be recommended that all manuscripts must be read and accepted by department heads before being sent to a journal. This, and similar measures like it, would indeed make research more difficult than it already is, and represent an unacceptable encroachment on academic freedom. A listing of all projects within an institution is perhaps not very useful as a control measure and invites for more administrative work. Are obligatory courses for supervisors a smart idea, or a way to discourage interested researchers?

I see no reason why administrative demands for overview and control can not be reconciled with core values of academic freedom. One has to distinguish between the research institutions' responsibility for development of an environment where research can take place within the scope of good ethical practice, and the demand for an exciting and creative atmosphere within a research group where project leaders and supervisors can accept and set in motion new projects or submit papers without waiting for a nod from an administrative head.

So, where are we a year after the Sudbø case broke into the open?

Do we agree on how to handle the situation or have we experienced a rift between persons, institutions, and authorities? I am pleased to state the fact that so far the involved research institutions have tackled the situation in full accord. We jointly appointed the Ekbom commission, accepted its conclusions and have been busy implementing the necessary revisions afterwards.

But some problems remain as described above. My recommendation is a balanced regimen favouring preventive measures like:

- more emphasis on the supervisor/mentor role,
- better theoretical training courses including more information on the rules and regulations that researchers must follow,
- improved possibilities for research scholars to present their projects for research groups and
- commitment of all authors to the Vancouver rules.

One task remains: the scientific institutions involved must as soon as possible harmonize their rules and regulations in order to avoid researchers working in university hospitals having to cope with two systems.

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Will anything really change? Views from a representative of the health authorities

Michael 2007;4:49–52

Beyond any doubt, the Sudbø case has had multiple effects. It has contributed both to an increased awareness and debate, to further development of systems for handling fraud, to a new law, and it has stated clearly the consequences and the seriousness of fraud in medical research.

Awareness about uncertainties of scientific results

Results from research have to be handled with caution. This has become especially clear after the extreme case of scientific misconduct by Jon Sudbø. As part of the Norwegian Health Authorities, the Norwegian Directorate for Health and Social Affairs is in its work highly dependent on scientifically based knowledge. The Directorate commissions such knowledge to a substantial extent. The handling of the results from investigation and research has hitherto not necessarily been subject to enough critical consideration. Not only conscious fraud, but also more or less unconscious mistakes, misinterpretations, or faults can occur throughout the whole process of commissioning, planning, and conducting a study to the reporting and implementation of the results. Attention and better understanding of the uncertainties connected to all scientific results are beneficial effects.

Critical approach to authorities' own administrative work

Health authorities, again speaking on behalf of the Directorate, have become more aware of their own contribution to quality assurance of scientifically based knowledge. Both commissioning, assessment and implementation of scientific results in practice or administration has to be subject to critical thinking. The directorate has started establishing better routines aimed at achieving better quality.

In addition, the case has also contributed to a more critical approach to the directorate's other administrative work and a better understanding of the fact that this kind of critical approach is necessary for achieving better quality.

Responsibility for reliability of research and the results

Authorities abruptly have become aware of the fact that control mechanisms for securing the quality of research and the reliability of results have not been sufficient. Those who really go for cheating might not be hindered in any case, but still the Sudbø case uncovered weaknesses in the system for handling fraud in science. The Investigation Commission recommended in its report "that institutions take more responsibility for raising awareness and instructing their researchers about the rules that apply, and that they engage in at least a minimum of verification and control, taking appropriate account of academic freedom."

Simultaneously, the long discussed question of responsibility has found an answer: There is no longer any doubt about institutions being responsible. This is true both for prevention of fraud, for education of scientists, and for the handling of misconduct in science.

Pushing for better routines in research institutions

The initiative for developing better routines is left to the research institutions, although authorities are critically following the progress. There is no doubt that the reliability of science in general and of the responsible institution in particular is weakened after the Sudbø case, and that the handling must be observed with great attention.

The National Committee for Research Ethics in Norway is investigating what measures now are taken by research institutions. They have developed a check list on research ethics to be used by scientists. Guidelines, contracts, and other tools are made more easily accessible. A new contract for commissioned research is developed by the Ministry for Knowledge.

Legal instruments

Some years before the Sudbø case, a new Act legalizing The National Committees for Research Ethics in Norway and an Investigating Committee for Ethics in Research was proposed (Ot.prp. nr.58 (2005-06). This work was quickly resumed and the law was passed this year.

Before the Sudbø case became public, the Official Norwegian Report "Good Research, Better Health" by the Nylenna Committee (NOU 2005:1) had proposed a new Act related to medical and health research, aiming at promoting and improving research and simplifying the approval. By making the system more transparent and by establishing defined rights for researchers and requests to research organisations, the intention was to promote good, ethically justifiable medical and health research. The Ministry's process connected to this new Act is in progress and the Sudbø case has emphasized its importance.

Factors influencing ethical behaviour in research

Scientists are under pressure and this may influence their behaviour. As an example, the funding of the scientists' own careers and also their host institutions' economy, is today dependent on the publication of articles based on results from research and on the prestige of journals. This situation must be considered as a strong incentive for short cuts, pushing towards more and quicker publication and co-authorships.

The Sudbø case has emphasized the great responsibility for quality assurance lying on the coauthors and the obstacles connected to this system. Research today is to a great extent based on team work, both across institutions and nations. The recent debate has drawn attention to the fact that often the only way to compensate for contributions in a scientific project is to offer a co-authorship, although the contribution might not have been sufficient according to the Vancouver guidelines.

Authorities ought to consider how to implement incentives and provide working conditions for scientists such that ethical behaviour is promoted. They need to ensure that this is not counteracted by the financing systems.

Serious consequences of fraud

Health authorities, represented by the Norwegian Board of Health, now have stated how seriously they consider fraud in medical research. Sudbø has not only lost his professional honour, but also his working place, his Ph.D. and the right to practice as a doctor and dentist for the rest of his life. The sentence is putting an end to his professional career, is covered by great public interest both nationwide and internationally, and seems irreversible.

The sentence over Sudbø seems unusually tough, compared to crimes and mistakes in other parts of society. This underlines the great responsibility lying on the shoulders of scientists and health personal and the ab-

solute need for reliability. Implementation of false results from research can endanger patients. Implementation of false results into politics can lead to wrong decisions and waste of substantial resources.

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Will anything really change? Views from a journal editor

Michael 2007;4:53–56

The title of this conference is "*Research misconduct: learning the lessons"*. However, the organizers seem to be somewhat confused, because the title of this last session today is: "Will anything really change?" If you really have learnt your lessons, then things *will* change. However, as we all know, that is not always the case. A familiar example is the fact that although we know a lot of things in medical practice, it is often a huge step from knowledge to implementation.

I will skip to the conclusion right away: Will anything really change? My answer is: No. I will try to explain why this is the most likely answer, as seen from an editor's point of view.

Two examples–no consequences

In 2005, a paper in *The Journal of the Norwegian Medical Association* was retracted (1). I was the medical editor for that manuscript, and I remember I was thinking that this was a pretty good paper. A few months later, I realized why. The paper had been plagiarized from another paper published two years earlier in *The Lancet*. This was the first retraction in the 125-year history of *The Journal of the Norwegian Medical Association* (2). As a matter of standard procedure, The Editor-in-Chief informed all the authors' employers. However, to our surprise, almost nothing happened.

In the autumn of 2006, Iain Chalmers presented us with another case of scientific misconduct: the case of the Croatian professor Asim Kurjak (3). Kurjak had plagiarized on at least two occasions – but with almost no personal consequences. There seems to be a pattern here, and Chalmers put it accurately: unless perpetrators face greater sanctions, the problem is unlikely to go away. But what about Jon Sudbø? He has really experienced serious sanctions. True, but why? To me, the reason is obvious: it was not

possible to get away with fraud. When he admitted to having fabricated data in *The Lancet* paper, the international research community looked – for a while – to Norway, and his employers had to do something in order to retain this country's credibility in the international research community (4).

Reasons why things won't change

There are many examples like the two cases I have briefly described. The point should be clear: the crux of the matter for the perpetrators and their employers is: is it possible to get away with it? And as long as the answer more often than not is "Yes", then why should anything really change?

The second reason why nothing will change is that research is based on trust. There is no alternative; and in relationships based on confidence, you always run the risk that someone will cheat you.

Moreover, misconduct may be difficult to detect. Jon Sudbø was caught because his fraud finally became obvious. His paper in *The Lancet* was reckless. If he had been more careful, I guess that today he would still be a star in the scientific community.

Finally, the counter forces are strong; and they are all pervasive. For example: publish or perish: in order to survive in the scientific community today, you have to publish – extensively. It is then of course tempting to take short cuts to achieve this. Moreover, the perpetrators often deny what they have done. Neither Kurjak nor Sudbø has admitted (nor possibly even regretted) what they have done. These are only examples of what I mean when talking about counter forces.

Let's go on as before

In my opinion, the main reason why nothing will change is that fraud is unpleasant. I have two images of this: no one likes to be cheated. We all know that. Moreover, when someone is caught with their trousers down, it is unpleasant not only for the owner of the trousers, but also for others around them. The plagiarism in the Norwegian journal that I mentioned earlier is an example: it was obviously unpleasant for the authors, or more precisely, for those who pretended to be the authors – and it was also unpleasant for us at the journal – and everyone else. So why bother?

The obvious conclusion is: let's go on as if nothing has happened: that is to the benefit of all of us. I'm sorry to bring you this unfortunate conclusion.

Final remark

Despite all my pessimism – or maybe it is realism? – I will point to some ways out of this mess, again primarily from an editor's point of view. The problem would be solved if researchers became honest; that is, if they became better human beings. That is not very likely, is it? We have a few thousand years of observation of mankind now, and there are not too many signs of progress.

The journal's role is important but limited. In the past, editors would simply reject papers that were suspected of being fraudulent. Now, the Committee of Publication Ethics clearly states that editors have an obligation not to ignore suspicions of fraud. Journals are important whistle-blowers, because they, their reviewers, or readers are often the first to suspect research misconduct (5). However, at what time does one blow the whistle? How much evidence is necessary?

Investigating cases of suspected fraud may be very demanding on resources and time consuming. An illustrative case was presented in the *BMJ* in 2005 (6). After a publication of a paper in the *BMJ* in 1992, Dr Ram B. Singh became the focus of an investigation into suspicion of scientific misconduct, spanning well over a decade.

The journals have a duty to notify their readers if a paper proves to be fraudulent. However, usually it must depend on others – that is, a legitimate authority such as an employer, university, or funding body – to hold an investigation and reach a conclusion on the status of the work. However, what should be done when there is no authority, or when the authority doesn't see it as its task to investigate or doesn't even want to investigate?

The largest responsibility has to be put on the institutions. When they are informed about the suspected fraud, then they have to respond. They have to investigate. And they have to reach a conclusion.

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Research misconduct: learning the lessons

Michael 2007;4:57–61

It is only with perverse nostalgia that I now hold the September, 2005, letter from Jon Sudbø. His letter accompanied a paper *The Lancet* published on October 15, 2005. It is the letter that prompted an expression of concern published on January 21, 2006. It is the letter that eventually led to a retraction notice being issued on February 4, 2006.

Sudbø's first communication with us refers to the "double-edged sword" of cancer therapy. There is also a double-edged sword to research and publication. On January 13, 2006, news of Sudbø's fraud broke in the Norwegian media. It was too late for the American *Journal of the National Cancer Institute.* In their January 18 issue, they reported the start of a clinical trial based on Sudbø's work. The headline ran: "Years of research come to fruition with launch of oral cancer prevention trial." Eight days later I received a message from Anders Ekbom confirming that one key element of this long-term research programme had been fabricated.

Does the Sudbø affair represent a series of extraordinary acts by one man, indicative of a single individual's aberrant behaviour? Or does it reveal a catastrophic failure of an entire multidisciplinary, polyinstitutional, and international system of science? Fortunately, we have the investigation of Anders Ekbom to guide us. Here, the facts of the case are lucidly laid out. The Ekbom Commission thoughtfully reflects on the nature of justice in cases of research misconduct; the difficulty of finding the right judgment between error, incompetence, and outright dishonesty; and the task of defining a correct standard of proof against which to measure individuals and institutions.

In Britain, we have adopted a less intellectual attitude. We ask only whether a person has been a jerk or a crook. But the blunt simplicity of this question is no joke. For fraud leaves a shadow of desolation and betrayal be-

hind it: in Sudbø's case, and most acutely, for one research fellow whom he had both supervised and deceived.

The Ekbom Commission's conclusions were devastating. "Several people should have reacted", they wrote. Ekbom meant co-authors, supervisors, superiors, opponents, colleagues, and perhaps even editors (although, politely, he does not say so). Why? Because there were warning signs.

It is important that we do not overreact. Bad cases make bad law. We do not need more regulation of research. We need intelligent regulation. A light touch. Regulation better coordinated and better enforced. Indeed, one could make the case that the discovery of Sudbø's fraud was a stunning success. A lie detected quickly, investigated appropriately, and corrected immediately.

Still, it is right to ask: why was the Sudbø fraud not detected earlier? What arrangements might be put in place to make sure such a fraud would be detected in the future? In answer to the first question, the Commission alludes to several possibilities. First, the presentation of Sudbø's data was so elegant that it possessed some kind of bewitching quality on all those who saw it. Second, the possibility of fraud seemed beyond the limits of rational belief. Third, there was "boundless trust" in Sudbø, a man who had become a "favourite son" of the research community. Fourth, his co-authors were cleverly manipulated, disabling their critical faculties. And finally, this was, after all, "sensational research" – who was going to swim against such a strong tide of success? None of these explanations is especially satisfactory.

In truth, few procedures were in place for the quality assurance of Sudbø's research. Insufficient care was taken over the preparation of his work for publication. There were inadequate institutional arrangements with respect to the training of scientists and the management of research. And there was "a disturbing lack of awareness" among scientists "of the prevailing rules for good research practice." There is also an astonishing paragraph in the Ekbom report, a paragraph that should be elaborated on if we are to understand this case fully. Ekbom mentions one person, an individual with suspicions, who retained documents and who knew that something was wrong. Out of fear, this person stayed silent.

The medical journal is also a neglected source of scrutiny. A journal is the final common path for acts of scientific dishonesty. It bears a great responsibility for protecting not only the record of research, but also the conscience of the research community. Sudbø's fraud reveals the strength but also the fragility of the research community. There are parallels here with the cloning scandal, perpetrated by Dr WS Hwang from South Korea. The

journal *Science* commissioned an independent review of this monstrous episode of misconduct. The *Science* panel concluded that:

- the journal had been intentionally deceived
- no peer review procedure is fool proof
- but procedures can reasonably be strengthened
- after all, existing procedures clearly failed
- incomplete answers to reviewers' questions should have triggered concerns
- editors were sometimes too easily persuaded by the beguiling rhetoric of authors
- the nature of the collaboration should have been explored more deeply and not accepted at face value
- worse, "the cachet of publishing in *Science* can be an incentive not to follow the rules"
- editors should start from a position of "a healthy level of concern", not blind trust
- there should be a "formal risk-assessment" of papers by editors to calculate the probability of deception and the consequences (if misconduct was discovered) for the reputation of the journal, science, and policy-making
- high-visibility papers should receive greater scrutiny
- journals should tighten their rules on co-authorship
- more primary data should be made publicly available

Each of these conclusions has a direct corollary in the Sudbø case. The Ekbom Commission, for example, had some sharp remarks about the wider inclusion of co-authors in the review and publication process. And about the risks of fast-tracking papers. I can think of five hypothetical reforms that would have prevented the frauds of Sudbø, Hwang, and many others. They are extreme. But I know that they would have worked.

Hypothetical Reform 1: Slow down the peer-review process. Ignore the calls to speed up peer review by scientists aggrieved at its snail-like pace. Let us take time to document warning signs. Let us raise the bar for publication of high-risk papers. Let us have a higher index of suspicion for fraud. Plainly, trust does not work.

Hypothetical Reform 2: Follow the example of clinical trials: insist on an independent data and safety monitoring board for all research studies. Create

in-built checks and balances: an oversight mechanism that does not exist today.

Hypothetical Reform 3: Change the culture of our research institutions. Have fewer rules but stronger values. A research career should be seen as a privilege that demands a set of very specific duties. Scientists should be rewarded for the total life of what it means to be a scientist – mentorship, education, training – and not merely the products of that life, whether measured in grants or published papers.

Hypothetical Reform 4: In both the Sudbø and Hwang cases, at least one reviewer dissented from the majority. Yet by a simple democratic vote, both papers won through to publication. The authors' responses to queries from reviewers appeared plausible. This approach to peer review is clearly flawed. Instead, we should demand absolute concordance between reviewers if publication is to proceed.

Hypothetical Reform 5: Until we take the responsibilities of authorship more seriously, we will not be taking research misconduct anywhere seriously enough. Wringing our hands over fraud without being clear that one should take credit only when a contribution has been serious and substantial, and without recognising that as an author one has a responsibility to check the integrity of one's colleagues, is like complaining about climate change as we drive our SUVs to the Vinmonopol. Curbing fraud means smartening up our own behaviour.

(Note: The Ekbom Commission is surprisingly soft on authorship. For cost-benefit reasons Ekbom and his team did not fully investigate the roles of Sudbø's co-authors. The Commission viewed gift authorship, the absence of data checks, and a lack of internal review of authorial roles as "not uncommon". Deviation from the norms of authorship were "of less importance in relation to the main issue in this case." Indeed, Ekbom and his associates saw authorship transgressions as "less gross and serious." I disagree.)

These five measures seem draconian. Yet how bad does the next case of research misconduct have to be, how damaged does public trust in science have to become, before we do what we know in our hearts and our heads is necessary to strengthen the integrity of research? The lessons of Sudbø seem agreed. We must all adhere to existing guidelines. We must not introduce more regulations. We must not disable research. Fraud will happen again.

As an editor, who feels sincere responsibility for the accuracy and honesty of the scientific record, I do not believe this response is sufficient. In an era when deference and trust are under challenge, we have to recalibrate our procedures to match public and societal expectations of transparency, accountability, and willingness to strive continuously to improve the quality of what we do in a demonstrable way. Put simply, journals have to raise their game. Editors must supplement trust with vigilance. Each peer-reviewing editor should see himself or herself as a critical guardian of research integrity. Editors must work to strengthen the collective responsibility of co-authors. Journals should revise their pre and post acceptance processes to reflect these changes in attitude.

The Ekbom Commission raised some particularly troubling questions as it closed its inquiries. Would the Sudbø case diminish the interest of scientists outside Norway from collaborating with Norwegian researchers? Would the institutions caught up in this latest fraud have their names forever and "inevitably" linked to Sudbø?

I do not believe so on either count. Norwegian science is not defined by one man or one incident. The institutions affected are complex and diverse organisations. They support excellent research of high national and international standard. The wound created by Sudbø will heal. But the speed with which it will heal and the risk of its recurrence will depend on the conclusions of conferences such as that which we are reporting in this issue of *Michael.* Our greatest enemy is silence.

The Dream Life of Sukhanov by Olga Grushin is the story of a depressed, beleaguered, middle-aged editor who is reviewing the sad course of his life and the mistakes he has made. He is arriving at the end of his career. The novel is about the way he tries to edit his experience. This is hard because his life seems to consist of a series of failures and betrayals. Yet his conclusion is clear: "true wisdom could be distilled only in the retort of suffering". Not a bad epitaph for an editor. Not a bad lesson to be drawn from the extraordinary case of Jon Sudbø.

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Research misconduct: learning the lessons

Friday 8 December 2006

International one day conference

The Norwegian Directorate for Health and Social Affairs, Universitetsgata 2, Oslo

Chair: Prof. Magne Nylenna, Editor, Norwegian Electronic Health Library

From 09:30: Registration/Coffee

10:30: *Introduction* (Dr. Richard Horton, Editor-in-Chief, The Lancet)

10:45: *The Sudbø-case* (Prof. Anders Ekbom, Chairman, The Sudbø-commission). Discussion

11:30: *Lessons to learn for journals* (Dr. Harvey Marcovitch, Chairman COPE, Committee of publication ethics, London, UK). Discussion

12:10: *Darsee to Sudbø: MEDLINE's role in the retraction process* (Mr. Sheldon Kotzin, Associate director for library operations, Executive editor of Medline, National Library of Medicine, Bethesda, MD, USA). Discussion

13:00: Lunch

14:00: *Researchers' responsibilities* (Dr. Camilla Stoltenberg, Division Director,The Norwegian Institute of Public Health). Discussion

14:35: *Can research institutions live up to expectations?* (Prof. Stein A Evensen, Dean, University of Oslo, Medical School). Discussion

15:10: Coffee

15:30: *Will anything really change?* Panel discussion
Dr. Erlend Hem, Medical editor, The Journal of the Norwegian Medical Association
Mr. Sigmund Simonsen, Lawyer, Research fellow, Norwegian University of Science and Technology
Dr. Hans Petter Aarseth, The Norwegian Directorate for Health and Social Affairs

16:15: *Summing up* (Richard Horton, Magne Nylenna)

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Norwegian Knowledge Centre for the Health Services

From the left Mr. Sheldon Kotzin, Dr. Richard Horton, Prof. Magne Nylenna, Prof. Anders Ekbom and Dr. Harvey Marcovitch (photo: Kjell Tjensvoll).

Michael

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2. *Michael* is named after Michael Skjelderup (1769-1852), the first medical professor in Norway and one of the founding fathers of the Society.

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