Fraud, misconduct or normal science in medical research— an empirical study of demarcation

Niels Lynøe, Lars Jacobsson and Erik Lundgren Umeå University, Sweden

Abstract
Objectives—To study and describe how a group of senior researchers and a group of postgraduate students perceived the so-called “grey zone” between normal scientific practice and obvious misconduct.
Design—A questionnaire concerning various practices including dishonesty and obvious misconduct. The answers were obtained by means of a visual analogue scale (VAS). The central (two quarters) of the VAS were designated as a grey zone.
Setting—A Swedish medical faculty.
Survey sample—30 senior researchers and 30 postgraduate students
Results—Twenty of the senior researchers and 25 of the postgraduate students answered the questionnaire. In five cases out of 14 the senior researchers’ median was found to be clearly within the interval of the grey zone, compared with three cases for the postgraduate students. Three examples of experienced misconduct were provided. Compared with postgraduate students, established researchers do not call for more research ethical guidelines and restrictions.
Conclusion—Although the results indicate that consensus exists regarding certain obvious types of misconduct the response pattern also indicates that there is no general consensus on several procedures.

Keywords: Empirical ethics; misconduct; research ethics

Introduction
According to Robert Merton, an ideal quality of a scientist is to have a passion for the truth. Thus fraud, misconduct and dishonesty in the scientific research process are seen as contrary to the whole enterprise of scientific research. Nevertheless fraud, misconduct and dishonesty evidently exist and the problem has attracted increasing attention during the last few decades, especially in the USA, Great Britain and Denmark. Particularly within the field of medicine, certain historic as well as contemporary cases have been classified as fraud or misconduct. It seems reasonable to distinguish fraud and obvious misconduct from simply poor or sloppy scientific practice. In the latter case the researcher is perceived to act in good faith. Forgery, piracy and plagiarism are typical examples of fraud or obvious misconduct. According to the Danish approach, dishonesty may include: manipulating data, suppressing inconvenient facts, so-called “salami publication” and gift authorship. These procedures have also been described as “trimming and cooking”. If intent to deceive is an important criterion for obvious misconduct, it is relevant to distinguish between scientifically experienced senior researchers and young inexperienced ones.

Despite the ultimate goal of scientific advance and the concept of good scientific practices, and despite the existence of well-defined criteria for what is meant by fraud, obvious misconduct and dishonesty it might, nevertheless, be difficult to distinguish between obvious misconduct and normal scientific practice. If the distinction is not clear-cut it might be reasonable to talk about a “grey zone”. Is it normal scientific practice or misconduct, for example, to remove what is perceived as an outlier from an otherwise smooth curve? Is it obvious misconduct or part of normal scientific practice to retouch an electron-microscopic picture to remove what is perceived as an artefact, or to show the “best” figure as one representative example out of five experiments?

Inspired by Broad and Wade’s concept of an “epistemological free-trade area” to describe a possible grey zone, we have conducted an empirical study of the possible grey zone within the field of medical research.

There are a few empirical studies concerning the attitudes of students and the experience of researchers with regard to the existence of research fraud and misconduct and to our knowledge no previous studies concerning the demarcation problem have been performed. The purpose of the present study was primarily to ascertain whether or not the researchers perceive a grey zone and if there is a difference between experienced and non-experienced researchers.
Subjects
Thirty senior researchers were selected from professors and associate professors in different fields (clinical and pre-clinical) from the same medical faculty in northern Sweden. Twenty of the senior researchers responded (16 men and 4 women). The senior researchers were selected according to the following criteria: 1) they should be active researchers, 2) they should be typical representatives of the scientific community, and 3) they should have a high degree of scientific autonomy. For reasons of confidentiality, no reminders were distributed. Thirty postgraduate students were recruited in connection with a research course (including research ethics) for postgraduate students at the medical faculty of a Swedish university. Twenty-five (9 men and 16 women) responded. No reminders were dispatched.

There are six universities in Sweden (none are private) and there is no reason to believe that the one we used for our study differs from the other five. At the time this study was conducted (spring of 1996) nobody had received guidelines for good medical research practice, either from the Swedish Medical Research Council (Swedish acronym: MFR) or the local medical faculty. Guidelines were introduced by MFR in late 1996.  

Methods
In order to study the demarcation problem we used a questionnaire containing statements of different kinds. The questionnaire was distributed in the spring of 1996. The statements were developed within the framework of three main themes: 1) manipulation of results when analysing and presenting them, 2) manipulation of data in connection with observation, and 3) sociological aspects of research, for example, dilemmas of authorship.

The statements were answered by means of a visual analogue scale (VAS). The two extremes of the scale were no misconduct (=0 cm), and obvious misconduct (11.4 cm). The questions/statements were:

1. To use short quotations without referring to the source is

   Not misconduct
   | | |
   Gr 1 | Gr 2

2. When presenting results, to exclude data that do not agree with the hypothesis is

   Obvious misconduct
   | | |
   Gr 1 | Gr 2

3. When discussing results, to ignore results that contradict your own is

4. To choose a statistical analysis method that brings out the results in a better way is

5. To make use of advanced statistical methods when presenting trivial results in order to make them look more interesting is

The distribution of responses by the postgraduate student (group 1, n=25) and senior researchers (group 2, n=20) to the general questions below concerning observation data and literature. The results are presented as a box-plot where the bold line represents the median; the box contains 50% of the respondents. The grey zone represents the central two quarters of the middle of the visual analogous scale from 2.9-8.6 cm. The area 0-2.9 cm = not misconduct, and the area 8.6-11.4 cm = obvious misconduct.

freq = frequency, C = common, RC = rather common and RU = rather uncommon

Figure 1: The distribution of responses by the postgraduate student (group 1, n=25) and senior researchers (group 2, n=20) to the general questions below concerning observation data and literature. The results are presented as a box-plot where the bold line represents the median; the box contains 50% of the respondents. The grey zone represents the central two quarters of the middle of the visual analogous scale from 2.9-8.6 cm. The area 0-2.9 cm = not misconduct, and the area 8.6-11.4 cm = obvious misconduct.

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are listed in figures 1-3. The questionnaire was distributed anonymously.

The reasoning behind the different zones is that the inter-quartile variation was found to be within a quarter of the end of the scale when we asked questions concerning obvious misconduct or obvious good conduct. Because the answers to clear-cut cases were found to be unanimously within the upper or lower quartiles, the inter-quartile range may be regarded as a grey zone. Only obvious cases, i.e., with the median value within the middle of the grey zone, were classified as a grey-zone cases. Thus we defined the area of no misconduct as 1/4 of the scale, corresponding to 0 - 2.9 cm, and the area of obvious misconduct as 1/4 of the other end of the scale, corresponding to 8.6 - 11.4 cm. The “grey zone” is an operational definition and corresponds to the central 2/4 (two quarters) (2.9 - 8.6 cm) part of the scale. The distribution of responses has been presented as box-plot diagrams.

Since certain procedures may be regarded as more or less acceptable (or as more or less good science) even if classified as no misconduct, we used a VAS to assess each procedure as either acceptable (0 cm) or not acceptable (11.4 cm). The reason for using this scale was to focus the misconduct scale. We also asked how common the procedure in question was. Here too we used a VAS, but afterwards we divided this scale into four parts: uncommon, rather uncommon, rather common and common.

Finally we asked for knowledge of research misconduct within the subject’s own department or a related department, and the possible need for regulation and control. When asking about knowledge of misconduct, we gave examples of obvious misconduct.

The study is primarily descriptive, where the distribution of responses has been presented by using a box-plot technique (median values and quartiles).

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**Figure 2**  The distribution of responses by the postgraduate student (group 1, n=25) and senior researchers (group 2, n=20) to the general questions below concerning specific laboratory procedures. The results are presented as a box-plot where the bold line represents the median; the box contains 50% of the respondents. The grey zone represents the central two quarters of the visual analogous scale from 2.9-8.6 cm. The area 0-2.9 cm = not misconduct, and the area 8.6-11.4 cm = obvious misconduct. Freq = frequency, RC = rather common and RU = rather uncommon.
Results
We have divided the presentation of results into three sections. The first section deals with general statements regarding the view of analysing and presenting the results.
Figure 1 shows that in three of the five statements one can see that one or both of the groups answered within the grey zone. Concerning statement 3, both groups find the procedure to be within the grey zone.

EXPERIMENTAL OBSERVATION DATA
The second section deals with statements regarding the attitudes towards manipulating different observation procedures.
Figure 2 shows that the response pattern is obviously within the grey zone concerning three of the four statements. There was a tendency for the postgraduate students to regard the occurrence of all the scenarios as rather common whereas the senior researchers saw these as rather uncommon.

ITEMS CONCERNING THE SOCIOLOGY OF SCIENCE
The third theme concerned questions on some sociological aspects of research, for example dilemmas of authorship.
In only one statement in figure 3 did the senior researchers find the procedure to be within the grey zone.

EXAMPLES OF FRAUD/MISCONDUCT IN RESEARCH
Three examples of fraud/misconduct in research were given. Two senior researchers gave examples from their own department or an associated department. One example concerned discarding research data laundered and reappearing on another project. One postgraduate student described how a research supervisor had misused his authority in connection with improper changes of observation data.

<table>
<thead>
<tr>
<th>Not misconduct</th>
<th>Obvious misconduct</th>
<th>Frequent misconduct</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. To use one's authority as head of department to silence criticism of a study is</td>
<td>Gr 1</td>
<td>Gr 2</td>
</tr>
<tr>
<td>2. To put one's name down as co-author when one has only carried out observations (i.e. provided clinical data) is</td>
<td>Gr 1</td>
<td>Gr 2</td>
</tr>
<tr>
<td>3. That the research team agree that the one who recruits most subjects will have his/her name printed first on the list of co-authors of a paper is</td>
<td>Gr 1</td>
<td>Gr 2</td>
</tr>
<tr>
<td>4. That the head of department is named as co-author of works published by his/her department, even if he/she has not qualified intellectually for this, is</td>
<td>Gr 1</td>
<td>Gr 2</td>
</tr>
<tr>
<td>5. That a research director, with a view to launching new ideas, presents these ideas as his/her own when they come from a junior researcher without external recognition is</td>
<td>Gr 1</td>
<td>Gr 2</td>
</tr>
</tbody>
</table>

Figure 3 The distribution of responses by the postgraduate student (group 1, n=25) and senior researchers (group 2, n=20) to the general questions below concerning factors in the scientific community. The results are presented as a box-plot where the bold line represents the median; the box contains 50% of the respondents. The grey zone represents the central two quarters of the visual analogous scale from 2.9-8.6 cm. The area 0-2.9 cm = not misconduct, and the area 8.6-11.4 cm = obvious misconduct. Freq = frequency; RC = rather common and RU = rather uncommon

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This text appears to be a part of a research paper discussing the sociology of science, focusing on the attitudes towards manipulating different observation procedures and examples of fraud/misconduct in research. The text suggests a division of the presentation into three sections, with the second section dealing with experimental observation data and the third theme concerning sociological aspects of research, such as dilemmas of authorship. The figure 3, which is likely a box-plot, shows the distribution of responses by postgraduate students and senior researchers to general questions about factors in scientific communities, with categories of not misconduct, obvious misconduct, and frequent misconduct.
NEED FOR RULES

The two groups disagreed on the need for more rules. Five postgraduate students wanted more rules, four did not find it necessary, and sixteen did not answer the question. None of the senior researchers wanted more rules. Two claimed that open discussions and good role-models suffice, eight were satisfied with the current system (ie prior to the introduction of research ethical guidelines in Sweden(1) and one maintained that there should be fewer rules despite the fact that no rules for good practice existed at the time in Sweden (spring of 1996).

Discussion

VALIDITY ASPECT

The response rate among senior researchers was relatively low, and they did not constitute a random sample. The senior researchers originally selected were, however, considered to be typical representatives of the scientific community and rather uniform. Thus it seemed appropriate to use this group of senior researchers as a contrast group vis-à-vis the group of postgraduate students.

The inter-quartile variation is in some cases remarkably high, indicating that no consensus exists. Certain respondents, especially among the senior researchers, consistently placed their marks on extreme values on the VAS, while others were more hesitant and answered in the middle of the scale. The high inter-quartile variation may also have been due to the possibility of researchers within the field of clinical research being insufficiently confident about the assessment of preclinical procedures and vice versa.

THE GREY ZONE

Some types of procedures are fairly generally agreed to constitute obvious misconduct, whereas others are classified as not misconduct. However, in half of the presented statements at least one of the groups perceived that there is some uncertainty and that no general consensus exists regarding the procedure. Only in one statement did both groups answer within the grey zone. A common denominator for most of the cases was “trimming and cooking” consistent with the grey-zone phenomenon presented by Stephen Lock.7 The fact that the response patterns in eight statements out of fourteen were found within the grey zone also indicates that Broad and Wade’s discussion of “the epistemological free trade area” has a certain relevance.8

Concerning the estimated frequency of the procedures presented there was a tendency for the two groups to disagree. For example, compared with the group of senior researchers, the postgraduate students believed it to be more common that a research supervisor presented the ideas of a junior researcher as his own. The senior researchers, on the contrary, regarded this as rather unusual. An embarrassing question here is whether the postgraduate students are influenced by a pessimistic outlook or whether they describe what is actually the case.

EXPERIENCES OF MISCONDUCT

Three of the 45 respondents said they knew of instances of what could be regarded as fraud/misconduct at their own or a related department. In a Norwegian study, 18% of the senior researchers said they knew of cases of research fraud/misconduct.10 In an American study 36% of biomedical trainees said they had observed some kind of scientific misconduct.11 The differences might to some degree reflect that, in some of the studies, the respondents are referring to the same cases, but they might also depend on how one defines a procedure or act as misconduct.

NEED FOR RULES

There was a clear difference between the two groups concerning the question of the need for rules and regulations. Even if only a minority (five) of the postgraduate students called for rules, none of the senior researchers was actually of the opinion that this is necessary. The response pattern may thus reflect how deeply rooted the established senior researcher is in the norms and values of the research community, in contrast to the non-established junior researcher’s uncertainty of the rules that apply. The response pattern may also reflect that some postgraduate students have a weak status, and sometimes are dependent on a senior researcher who seemingly acts in an unpredictable manner.

Concluding remarks

This study indicated that it is not always clearly apparent what one should classify as obvious misconduct. The study showed that in some cases a grey zone exists both among researchers belonging to the same group and between groups with different experiences.

The question of the existence of a grey zone is of importance when discussing how narrow or broad a definition of misconduct should be. The variation in the response pattern of the study presented indicates that it seems a matter of importance who should conduct an investigation into suspected misconduct and draw conclusions.
Three cases of experienced misconduct are reported but in contrast to postgraduate students, established researchers did not call for more research ethical guidelines.

This investigation should be followed by both qualitative and quantitative studies using larger samples. One purpose of this study was to identify outer limits for what should be classified as a grey zone. In future studies one could designate the grey zone in advance.

Niels Lynøe, MD, PhD, is Associate Professor in the Department of Social Medicine, Umeå University, Sweden. Lars Jacobsson, MD, PhD, is Professor in the Department of Psychiatry, Umeå University, Sweden. Erik Lundgren, MD, PhD, is Professor in the Department of Cell and Molecular Biology, Umeå University, Sweden. Correspondence to Niels Lynøe.

References
5 Riss P. Fraud in medical research: the Danish scene. See reference 2.
7 Lock S. Fraud and the editor. See reference 2.

News and notes

Ethics and Palliative Care

An Advanced European Bioethics Course, Ethics and Palliative Care, will be held from 6 - 8 April 2000, in Nijmegen, the Netherlands.

Subjects will include: Evolution of palliative care; Ethics and pain management and the Limits of palliative care. The conference will be held in English.

For further information please contact: Dr B Gordijn, University of Nijmegen, Dept 232 Ethics, Philosophy and History of Medicine, PO Box 9101, 6500 HB Nijmegen, the Netherlands. Tel: 0031 24 3615320; fax: 0031 24 3540254; email: b.gordijn@efg.kun.nl.

To visit the website go to: http://www.azn.nl/scientist/departments/departments.html and choose: Ethics, Philosophy and History of Medicine from the list of non-clinical departments.