

# Medical investigators' views about ethics and fraud in medical research

**ABSTRACT**—The objective of this study was to ascertain the views and attitudes of medical investigators on medical ethics, and ethics and fraud in medical research. We sent postal questionnaires to all principal investigators whose study protocols had been assessed by their regional medical ethics committee for biomedical research (mid-Norway) in the years 1986-92 ( $n = 159$ ). The response rate was 70% ( $n = 119$ ). Some 80% agreed that ethical considerations had influenced their research and 12% that they would have had ethical scruples today about some of their previous projects. One in ten agreed that they might have achieved better results if they could have paid less attention to ethics. About 70% of the respondents found that the committee's comments were useful and relevant, but most agreed only in part. Around 85% agreed fully or in part that scientific quality is an important ethical element of any project and that researchers put more effort into their study protocol when they knew it would be evaluated by an ethics committee. One in six (18%) respondents agreed fully or in part that they had been exposed to scientific misconduct. Also, 27% knew about one or more cases of fraud or misconduct while 42% stated that this knowledge was not public. We concluded that ethics in medicine and medical research have an important and increasing role among investigators with little or no theoretical background and training in ethics. Scientific fraud and misconduct in medicine is a growing concern among researchers, who welcome a professional body that can manage allegations and cases of fraud.

Ethics and value questions have received increasing attention over the past 10-15 years, in Norway as well as in other countries. In medical research such interest has been enhanced by the recent public and legislative involvement in genetic and biotechnological advances.

Over 20 years ago the Medical Research Council established an ethics committee to assess projects sponsored by the Norwegian Council for Science and the Humanities. Local *ad hoc* committees were also set up for studies financed by a foreign agency [1]. In 1985, the Norwegian Department for Social Affairs established an ethics committee for medical research in each of the country's five health regions. Later, these were organised under the Department for Education and Research who, every four years, appoint their seven members: two physicians, one registered nurse, one jurist, one ethicist (philosopher

or theologian), one layman, and one representative of the hospital owners in the region. The last is most often a politician. The committees are administered by the four medical schools in Norway. The committee mandate states that they shall evaluate all biomedical studies that involve human subjects, based on the revised Helsinki declaration [2].

The committee in health region IV (mid-Norway) started work in 1986. Up to the end of 1992, it had assessed 346 study protocols, most of them clinical comparative studies in adults in general hospitals. Despite this experience, it became evident that little was known about Norwegian investigators' attitudes and knowledge of medical and research ethics or about their attitudes to the work of the ethics committees. Further, there has been concern over scientific fraud and misconduct over the past few years and in 1992 the Medical Research Council established a separate committee against such dishonesty based on the Danish model [3]. Little documentation existed of the extent of such misconduct, and hence we wanted to obtain this from the scientific community as well as ascertaining its views on fraud and misconduct in medical research.

This study was approved and endorsed by the regional research ethics committee.

## Material and methods

A survey was conducted through a postal questionnaire in 1992 which included all 159 project leaders (principal investigators) whose study protocols had been assessed and evaluated by the ethics committee for medical research in health region IV between 1986 and 1992.

The questionnaires offered 69 statements to which responses were invited in one of five alternatives ranging from 'fully agree' to 'fully disagree'. Fraud and misconduct was defined as any occurrence from forgery and plagiarism of data on the one hand to uncollegiate publication procedures on the other.

Data were analysed with the PC version of SAS (SAS Institute Inc. 1987). Parametric and non-parametric tests were used for continuous data, the chi square statistics for categorical ones, and Pearson's 'r' for correlation analyses, all with 5% as the level of statistical significance.

## Results

A total of 159 questionnaires were sent out and after one postal reminder, 119 (70%) were returned; another two were returned incompletely. Among the

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40 investigators who did not respond, there were five women (12.5%), and 23 (63%) were chairmen and/or professors of a hospital department.

#### *Gender differences between respondents*

There were more male ( $n = 99$ , ie 83%) than female ( $n = 20$ ) investigators among the respondents ( $p < 0.001$ ). The men were significantly older (45.9 vs 40.7 years;  $p < 0.05$ ). Whereas 63 (63%) of the men were chairmen and/or professors, only three (15%) of the women were at that level ( $p < 0.001$ ). On the other hand, there were no such differences for investigators at intermediate or junior levels which included assistant professors, grant recipients, doctoral students and junior hospital staff members.

Men also had longer experience than women in full time (6.7 vs 2.4 years;  $p < 0.05$ ) as well as part time research (10.3 vs 4.3 years;  $p < 0.01$ ).

Significantly more of the men (80% vs 50%) characterised their activity as clinical research ( $p < 0.01$ ). For basic and community medicine research there were no such gender or other differences. Almost half of the men had been engaged in more than one kind of medical research.

#### *Statements about medical ethics*

Table 1 shows the responses to ten statements. About half agreed that in certain cases it may be necessary to withhold scientific data or results and that the scientist should hold back data if he/she would feel responsible for their potential abuse. Over a third of investigators agreed in part that ethical objections were 'sand in the machinery', while far fewer fully agreed to that statement. One out of four fully or partly agreed that the present level of medical knowledge would have been considerably lower if today's ethical guidelines had been in place over the past 100 years.

Almost 80% agreed that ethical considerations had influenced their own research, while 12% claimed that they would have ethical objections today to some of their previous work (Table 1). A majority paid more attention to ethics today than when they had first started medical research, while every tenth investigator agreed fully or partly that they might have achieved better results if they could have paid less attention to ethical considerations. Very few agreed that ethics were given too much attention and had influenced their work negatively, while almost half stated that they would never publish scientific data obtained from studies that were ethically unacceptable.

Stratified analyses showed few differences among the respondents, and these were only of borderline significance ( $0.10 > p > 0.05$ ). However, relatively more men than women agreed that ethical considerations had influenced their scientific work and fewer basic research investigators agreed that they paid more

**Table 1. Proportion (%) of medical researchers who fully or partly agreed to ten statements about medical ethics.**

Statements	Fully agree	Partly agree
In certain cases it may be both necessary and desirable to withhold scientific data or results	17	33
If a scientist has a responsibility for potential use and abuse of scientific results, he/she must have the right to withhold data	20	36
Ethical objections may at times be 'sand in the machinery' and a hindrance in obtaining useful data	6	37
If the ethical principles we follow today had been the (ruling) guidelines over the past 100 years, the present level of medical knowledge would have been considerably lower	5	20
Ethical considerations have influenced my own work as a scientist	48	29
I would have ethical objections today about some of the projects I have previously completed	3	9
I pay more attention to ethical considerations today than I did when I first started as a scientist	31	29
I believe I could have achieved better results if I did not have to pay so much attention to ethical considerations	2	8
I believe that too much attention is given to ethical considerations and that it has influenced my work in a negative way	1	4
I would never publish scientific data obtained from studies that were ethically unacceptable	20	23

attention to ethics today than earlier. More of the older (ie 45 years or above) investigators agreed with today's ethical objections about some of their previous studies.

#### *Statements about the research ethics committee*

Responses to the ten most characteristic statements about the research ethics committee are shown in Table 2. Over 90% of the investigators agreed fully or in part that the regional research ethics committees are important and necessary for evaluating medical research projects. Conversely, very few stated that the committee is a threat to the freedom of science; nevertheless, more than a third agreed, mostly in part, that the scientists themselves are in the best position to



assess the ethical implications of their studies. On the other hand, a majority (60%) agreed that it is important for the committee to evaluate both the scientific and ethical aspects of the studies (data not shown).

Agreement ranged from 75% to 85% for most statements with a few exceptions regarding the usefulness of the committee's work for the individual investigator. Whereas one in ten agreed that they found the evaluation and comments from the committee to be of use or benefit, a similar proportion stated that the comments were imprecise and not well founded (Table 2). More men than women agreed that the committee's comments had been useful ( $p < 0.01$ ) and more of the older investigators agreed to that statement than younger ones ( $0.10 > p > 0.05$ ).

Fewer community medicine investigators agreed that the committee is important in medical research and that scientific validity is an important ethical element of a research project ( $p < 0.05$ ), while relatively more in the same category agreed that the scientists themselves are in the best position to assess the ethical implications of their research ( $0.10 > p > 0.05$ ). More clinical researchers agreed that today the interests of patients and volunteers are better taken care of than before the committees were established ( $p < 0.05$ ). Fewer community medicine investigators found the committees' comments useful and relevant ( $p < 0.05$ ). And, while fewer clinical researchers agreed that the comments were of little use to them as project leaders ( $p < 0.01$ ), more basic researchers held that the comments were too imprecise and ill-founded ( $0.10 > p > 0.05$ ).

#### *Statements about scientific fraud and misconduct*

About 40% of the respondents agreed to some extent that manipulation of medical data is a problem in Norway, yet almost half stated that it is less of a problem here than in other parts of the world (Table 3). One in four knew of one or more incidents of fraud or misconduct, and a similar proportion stated that the incident they knew about was well known in the scientific community, whereas 42% held that probably very little was publicly known. One of every six investigators agreed fully or in part to have experienced or have been personally exposed to incidents of scientific fraud; and most of them agreed that a set of rules to manage cases of fraud and misconduct, with a special body to investigate and assess alleged cases of fraud, should be established (Table 3).

The stratified analyses showed very few significant differences among respondents. However, knowledge about one or more incidents of fraud was observed more often among investigators aged over 45 ( $p < 0.05$ ). And, regardless of gender and kind of research, older investigators tended to agree more to all statements than younger ones.

More of the basic researchers agreed that manipulation of scientific data is a problem in Norway and that

**Table 2. Proportion (%) of medical researchers who fully or partly agreed to ten statements about the medical research ethics committee.**

Statements	Fully agree	Partly agree
The (regional) research ethics committees are an important and necessary tool to evaluate medical research projects	58	33
The scientists themselves are in the best position to consider and evaluate the ethical implications of their studies	4	33
It is an advantage for the scientists that the ethical considerations or implications of a project are evaluated by others than the scientist himself/herself	74	22
Scientific validity is an important ethical element of a research project	68	17
Scientists should always notify the research ethics committee about the final outcome of their study	31	22
The work of the research ethics committee is a threat to the freedom of science	1	1
The interests of patients and volunteers are better taken care of now than before the research ethics committees were established	42	38
The committee's evaluation and comments have been useful and relevant	32	41
As a project leader, I did not find the evaluation and comments by the committee were of any use or benefit to me	5	6
The comments made by the committee were imprecise and the conclusions were not well founded	1	11

rules and a body to manage alleged cases of fraud are needed. This group tended to agree less about their own knowledge of fraud and that cases known to the scientific community were unknown to the public. Community medicine investigators gave replies in the opposite direction and also claimed that they had more often been exposed to fraud and misconduct than the other two categories ( $0.10 > p > 0.05$ ).

#### **Discussion**

The number of papers, review articles and books addressing medical ethics in general, and medical research ethics in particular, has grown considerably over the past few years. An electronic search of the



**Table 3. Proportion (%) of medical researchers who fully or partly agreed to seven statements about scientific fraud and misconduct in medicine.**

Statements	Fully agree	Partly agree
Manipulation of medical data is also a problem in Norway	10	29
Scientific fraud in medicine is less of a problem in Norway than in other parts of the world	18	27
I know of one or more incidents or examples of scientific fraud in medicine in Norway	18	8
The incidents of fraud that I know about are well known in the scientific community	12	12
Probably very little of scientific fraud in Norway is known or revealed to the public	10	31
I have myself experienced or been exposed to incidents that I would characterise as scientific fraud. This includes eg plagiarism and/or uncollegiate publishing practices	7	10
A set of rules should be established to manage such cases and allegations, and a special body that can investigate and assess alleged cases of scientific fraud	35	25

most recent edition of MEDLINE for 1992–4 yielded over 5,000 references catalogued under the heading of 'ethics'. However, most of them were largely theoretical discussions and only few data enable one to evaluate or estimate the true impact of ethical considerations on ordinary medical scientists. We therefore aimed to obtain numerical data on how Norwegian medical scientists feel about the role of ethics and the work of the ethics committee in their day to day research activities and how their relations with patients and colleagues are influenced by such considerations, as well as to obtain data on a subject that has largely received theoretical attention.

To go more thoroughly into ethical perceptions, we might have followed a previous Norwegian study on research ethics using a structured interview [4]. But as those results did not differ from ours, and we included the entire population of principal investigators in the catchment area, our study can be taken to be representative of the whole country.

Despite presenting a fairly comprehensive questionnaire, we achieved a 70% response rate. As there was no difference in age, sex and status between responders and non-responders and there is no indication that investigators in our region have attitudes that differ from those in other regions of Norway, we

believe that our findings are valid for the whole community of Norwegian medical scientists. The differences observed in the stratified analyses broadly reflect the predominance of older, male clinicians among the respondents.

#### *Medical ethics and the ethics committee*

There are few other studies to corroborate or contradict our data. The results of an Australian study published in 1992 were much the same as ours and concluded, like us, that ethics committees are accepted and found useful by medical investigators [5]. Only 5% of our respondents fully or in part agreed that too much attention is given to ethical considerations, and almost 80% stated that such considerations had influenced their work as scientists. In view of that, we are disturbed that in our study less than half (43%) agreed that they would never publish scientific data obtained from studies that were ethically unacceptable and that a similar proportion felt that ethical considerations could be regarded as 'sand in the machinery'. We think that questions about ethical considerations and how they influence the work of scientists are so basic that they might merit a separate study.

Our perceptions of good and bad or right and wrong have changed over time. Still, we ourselves do not entirely agree with those who claim that had today's ethics been applied in the past it would have set back medical knowledge, or that ethical standards now are higher than they were 100 years ago. On the contrary, we do not believe that high ethical standards are an obstacle to achieving good scientific results. Thus, after his successful identification of *Mycobacterium leprae*, the Norwegian Armauer Hansen in 1879 inoculated material taken from a node from a leprosy patient into the eye of a healthy woman. His scientific objective, ie to show the contagious nature of the disease, was unexceptionable. Yet, three years later Hansen was charged and convicted for committing a personal offence against the woman.

The fact that new and valuable progress has resulted from ethically unacceptable projects does not prove that the same insight could not have been achieved through other studies based on acceptable standards. Many studies that took place during the first half of this century would never have been carried out at the time if medical ethics had been in the public eye in the same way that it is today.

We found the responses to our statements about the role and work of the ethics committee more positive and less critical than we had expected. Thus, almost everyone stated that it is an advantage for a project to be evaluated beforehand by others than the scientists themselves. Most investigators also agreed that it is unethical to carry out a study of dubious scientific value. We disagree that 'Scientific validity is not primarily an ethical issue. It is technical' [6], on the



grounds that if a research protocol is not set up according to accepted scientific principles, the lack of scientific validity becomes the most important ethical element.

Based on our data, we are confident that the committees make an essential contribution to quality assessment in medical science. Another indication is that a majority agreed that the committee should also assess the scientific validity of studies (data not shown). Quality assessment is a growing concern in medical research in Norway [7] and Britain [8]. The main responsibility for quality in medical science clearly rests outside the ethics committee, but since most of the projects involving human subjects come to them for evaluation, it is natural that many regard the committee as an important part of quality assessment. In the report following a 1992 conference on local research ethics committees arranged by the Royal College of Physicians the question was asked if the committee should be 'an ethics committee' or a 'research ethics committee' [19]. No definite answers were given, but for us, evaluation of ethics and of scientific validity are inseparable elements of good science.

#### *Scientific fraud and misconduct*

When our data on this aspect first appeared in a Norwegian medical journal [10], they caught the attention of the media. Even given our wide definitions, there was considerable reaction to the fact that 18% of the respondents agreed fully or in part that they had experienced or were aware of incidents of scientific fraud. The extent of fraud can hardly be estimated with any degree of accuracy [11,12], and only the most striking allegations and cases come to the attention of the medical community and hit the headlines [13-19]. Thus, we must emphasise that our study has *proved* nothing about the nature of scientific fraud and misconduct or how widespread it is among medical investigators in this country. On the other hand, our results indicate that the problem should be addressed in a prudent and systematic way. With 60% agreement from our respondents, we believe that the national board that has now started work in Norway has the general support and backing of the scientific establishment. Support for this view is also found from the discussions in the first two annual reports of the Danish Board against Scientific Misconduct [3,19,20]. Most important, though, is the preventive role and impact of both the Danish and Norwegian boards, with their emphasis on healthy scientific attitudes and

the preparation of high quality study protocols as preeminent features.

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