

# Should members of ethics committee be trained and certified in ethics?

## Experiences and teaching programs

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**Background.** Over the years the work of the committees for medical research ethics has expanded considerably and the field of medical research has increasingly been regulated by international documents, often implemented in national law, in addition to independent national laws. This development has made the task of the committees very broad and complex, with many normative systems to consider as a basis for the ethical review. Up to this point we have had no formal requirements as to the training of members in ethics in Norway. With the complexity of the normative basis and of the range of research projects considered we have discussed now and then whether we should require some form of (obligatory) introductory training in ethics (and law) which at least covers the basics. The main objective of the paper is to consider these alternative points of view, namely learning ethics “by doing” *versus* formal training of the members of research ethics committees.

**Material and Methods.** The paper presents a thorough analysis of existing modules of training members of research ethics committees responsible for review of biomedical research projects. The experience of running different types of training courses is analysed qualitatively and compared with the traditional model of so-called “participatory learning”.

**Conclusions.** It seems that training cannot be achieved by establishing one type of the model. Training can enhance competence and skills, but at the same time it can reduce the multifaceted perspectives that are now brought into the committee solely on the basis of the variety of the composition of members. For these reasons it is worthwhile to hold on to the tension to the value of different contributions: training yes, but it is not necessary. It will in the future be more difficult to uphold this balance – between the trained members of ethics committees and the “unspoiled” normative perspectives of lay representatives or others – because of increased need for legal expertise in the review process of the committee. More than ethics, law presupposes knowledge and interpretative skills. This development follows from the fact that medical research is regulated by EU directives which are implemented in national laws (privacy and clinical trials) and also by national laws regulating parts of medical research.

**Key words:** medical research ethics, certification of members of RECs, teaching ethics

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### INTRODUCTION

In Norway, there have been regional committees for medical research ethics since 1987. It was then decided that the committees should be organized regionally and be composed with broad representation, with medical expertise in minority, and with obligatory legal and ethical expertise, as well as lay representation. The purpose of this was at least twofold: to assure the independence of the committees and to assure that the com-

position of the committee as a whole had sufficient ethical competency as a consortium of equals.

Over the years the work of the committees has expanded considerably (including *e.g.* biological material, personal information, psychology) and the field of medical research has increasingly been regulated by international conventions and directives, often implemented in national law, in addition to independent national laws. This development has made the task of the committees very broad and complex with many normative systems to consider as basis for the ethical review.

Up to this point we have had no formal requirements as to the training of members in ethics. With the complexity of the normative basis and of the range of

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research projects considered (from randomised clinical trials via qualitative research methods to studies of registries and journals) we have discussed now and then whether we should require some form of (obligatory) introductory training in ethics (and law) which at least covers the basics.

The main objective of the paper is to consider these alternative points of view, namely learning ethics “by doing” *versus* formal training of the members of research ethics committees.

## MATERIAL AND METHODS

The paper presents a thorough analysis of existing modules of training members of research ethics committees responsible for a review of biomedical research projects. The experience of running different types of training courses is analysed qualitatively and compared with the traditional model of so-called “participatory learning”.

## RESULTS AND DISCUSSION

### 1. Learning ethics by doing

The major opinion is that the committees have the necessary competency in ethics and law due to its composition. Despite this, I think the experience of many members is that the learning curve is steep when you are new to the committee. At the same time it is fascinating to see how fast people become confident and competent with ethical reasoning as a result of reviewing a large number of cases. They learn ethics by doing ethics in practice. This model of training seems to presuppose that there is some continuity in the membership (new members learn from old members, starting in a sense as apprentices) and that the committee can lean itself against the members with formal expertise in law and ethics when the going gets tough. Most of the time this model works rather well. It has, however, some weaknesses. It tends to favour the old and it tends to make the committee depend on the expert opinions of the representatives from law and ethics. With the increased legal regulation of research, the legal expertise on the committee is today of central importance as well as indispensable. It is easy to see tendencies towards considering some members as more important than others. These tendencies can undercut the rationale behind the understanding of the committee as a consortium of equals, in which each member has a unique contribution to make to the ethical competency of the committee as such.

In order to counter and reduce some of these tendencies, we have seen that when committees are newly appointed they organize ad hoc seminars on research ethics or participate as a group in an international conference on research ethics. I take it that the purpose of this, apart from the importance of building good group dynamics, is to make it possible for all members to have at least a common basis for their deliberations.

In addition to this, the committees have an annual two-day seminar for all members of all committees to discuss matters of common interest. Though the seminar doesn’t sail under the flag of training, there are obviously many elements of training in the seminars as such. Over the past few years we have set important topics of ethical review on the agenda, such as research on people with reduced competency, the methods of qualitative research and requirements for scientific standard as well as specific ethical issues, risk research in work environment, non-therapeutic research on children and on adults without ability to consent. Part of the purpose is also to enhance consciousness about particular issues and to assure some kind of harmonization in understanding and reasoning about such issues among the committees.

As a result of these experiences, it was also decided that it would be useful to develop teaching modules in research ethics in cooperation with the University of Oslo. These courses are offered on a regular voluntary basis for the secretariats of the committees as well as members of the committees, but not exclusively for them. As of today we have developed four semester courses: health care ethics (as of 2001), medical research ethics (as of 2003), research ethics in the humanities (as of 2003) and ethical considerations in clinical trials (offered for the first time in the spring of 2005) (1). All the courses are computer-based and make it possible to participate regardless of domicile.

In the following I will only discuss the basic course on medical research ethics, but before I do that I think it is pertinent to identify some of the issues that must be dealt with when deciding on the matter of training.

### 2. What is preferable in training?

There are important differences between the various kinds of training discussed.

- Should they be informal or formal or both?
- Should they be voluntary or obligatory or both?

This brings us to a larger question of quality assurance of the advice given by the committees, as well as to the question of accountability.

- Should the training be practical or theoretical or both? This brings us to the question which ethical tools are appropriate for the committees to master and utilize.

- Should the training require basic or high level competency or both?

- Should the committees themselves be providers of training or should someone be the provider, *e.g.*, a university, or both?

I think it is of utmost importance to clarify these issues as one plans training in ethics of secretariats and members of committees. It is a hard judgment call to say what is preferable. It depends on a large number of factors: feasibility, economy, academic resources and so forth.

It is, however, beyond doubt that the informal training implies being a member of the committee and

having to deal with concrete research projects of all types. The basics and high level competency and proficiency are learnt by doing ethical review. In addition come internal seminars as an important supplement. This, of course, the committees can provide themselves. It has been interesting to see that the large majority of members are very committed to participate in the meetings and also in a two-day seminar. It is not stated as obligatory, but it almost functions obligatory as a duty for the sake of the whole.

If training entails higher ambitions than learning by doing, I think it is a necessary prerequisite that the training is provided by others than the committees, *e.g.*, a university or a national institute of health (as it is in the US). Such providers have the resources and the teachers, as well as the power to issue credits or certification.

It seems that matters of quality assurance and accountability push to make some sort of certification obligatory. I am aware of at least two examples: one in the United States and one by the pharmaceutical industry.

I support the efforts of industry and, *e.g.*, research institutes to certify their constituency, be they clinical monitors or researchers. The certification is usually limited to obligatory participation in a series of seminars (over 2–3 days). It ensures some kind of basic knowledge of research requirements, including the basics of ethical review, as well as requirements of practical skills (site visits and application to ethics committees). Sometimes it also requires an exam (2). A similar “model” could of course be implemented for members of ethics committees. The basic course offered by the U.S. National Institutes of Health is different in the sense that it was based on self study (on line tutorial) and a true / false exam. It was set up in 2000. The purpose was to assure at least a minimum standard of knowledge and competency regarding the protection of human subjects in medical research. It required education for all investigators submitting research applications to NIH and also made obligatory for all members of the 14 ethics committees (Institutional Review Boards) that serve NIH. For the members of IRB the false / true exam is replaced by tracking participation through the lessons and by requiring participants to fill out an online evaluation form (3).

We never obtained support for requiring basic knowledge as a prerequisite for being a member of an ethics committee. There was, however, great enthusiasm for developing a more intensive study on a voluntary basis. It was this impetus that started the development of educational programs. We did consider offering educational programs provided by institutions in Europe or in the US. Some of these are of very good quality and available as online tutorials. It emerged, however, that it was seen as an important prerequisite that the educational program was offered in Norwegian. So it was. As of today and since the inception of the course in

2002, the course has been taken by four of the employees of the secretariats and by approximately five of the members of the committees. This is only a small fraction of the total number of members of the committees.

### **3. Computer-based university course on medical research ethics**

The course was initiated from The National Committee for Medical Research Ethics but developed in cooperation with the Center for Medical Ethics, the Institute of Philosophy, the Medical Association of Norway and the Faculty of Theology. Because the latter faculty had established an educational platform, partly computer-based, for continuing education for professionals within the health and social work sector, with a flexible and competent administration, it was decided that the course be offered by the Faculty of Theology.

It was decided that the course should be offered on a master level. The purpose of the course was to enhance knowledge of the principles of research ethics, strengthen the ability to interpret and analyze documents and cases, as well as to learn how to reason and justify decisions.

The main justification for a computer-based course was to make it available for a large range of possible participants without requirements for a particular place of study or domicile. With the first course we had participants from Porsanger in the north to Kristiansand in the south.

The course was also designed to be available for a variety of groups, both inside and outside of the university: members of ethics committees, students, professionals and researchers in relevant fields (medicine, pharmacy, nursing), clinical monitors, health authorities, data protection officials, students and professionals in the areas of law and ethics. With the first course we did actually attract participants from almost all of these groups. In hindsight the greatest benefit was the interaction among professionals, researchers and students that hardly ever meet in educational settings across the disciplines. This was also very clearly noted in the evaluations. The greatest surprise to us was the absence of students from medicine, philosophy and law. We have speculated about the reasons for this, and it seems that the most friendly explanation is that these studies are not organized to allow for external courses to be credited into their own studies.

The content of the course was laid out in five lessons (what we called reading assistance to the curriculum). It aimed at giving insight into the historical development of research ethics and the major documents that form the basis for the ethical review, from the Norwegian court case of Armauer Hansen (1880) via the Prussen directive (1900) to the most recent Declaration of Helsinki (2000). The lessons extracted and identified the most important ethical issues, such as the role of researchers and the responsibility for research

subjects, requirements for scientific standard and quality, the relation between risk and benefit, the question of consent, as well as alternative consent forms, conditions for doing research without consent, matters of confidentiality and protection of personal information. One lesson dealt with the procedures of ethical review by ethics committees. It has been acknowledged that many of the issues must be considered in relation to a growing number of laws, those decided nationally (such as The Health Registry Act, the Biobank Act and the Biotechnology Act) and those implementing EU directives (*e.g.*, the Personal Data Act and Clinical Trials). It seems reasonable that the committees cannot and should not recommend projects that are unlawful, but the course itself did not have focus on the legal issues.

We were asked by the organizers of the conference if it would be appropriate to have different modes of training for experts and lay. Our conclusion is no. It goes without saying when it comes to learning ethics by doing, but we think the same is true for a more intensive study at the master level. In effect, most members of the committee are lay in the area of ethics, at least when it comes to formal competency. The dividing line doesn't go between the educated expert and the uneducated lay member! Lay members are usually well educated within other areas than the ones asked for (medicine, nursing, psychology, law and ethics), *e.g.*, as teachers, policemen, managers, public servants, social workers, etc. And from the experience of having taught the course three times the evidence is clear: the lay members perform on an average better than the experts.

We also had to decide whether any kind of scientific evaluation should be included in the course as an integrated part of ethical thinking. We are aware that this is a contentious issue, but our experience is that many of the cases presented in the course, as well as in the ethical review proper, presuppose evaluation of methodology and study design as an integrated and prerequisite part of the ethical review. In line with modern theory of science, we are conscious that scientific evaluation is not a neutral value. It does also entail normative presuppositions and normative choices, *e.g.*, in answering questions about scientific need or value, relevance, what's new, criteria for effect and whether they are of clinical interest, recruitment bias, just comparisons, justification of placebo, the right number to be included, open post-marketing studies, etc.

### 3.1. Teaching methods

Computer-based teaching presents specific challenges to the teaching methods and the environment.

We decided on the following elements:

- one initial seminar to introduce the course and give hands on instructions to the use of the computer-based program "Classfronter",
- in the program we offered weekly lessons of reading assistance (4–8 pages) to facilitate reading of the

obligatory curriculum (see below), presentation of 2–6 authentic cases per lesson, specific tasks and a list of recommended supplemental reading,

- activities on the net should be group-driven to facilitate interactivity between the participants, partly through obligatory tasks to be performed in the discussion forum,
- use the internet possibilities as far as possible, *e.g.*, by links to available documents and cases, even original material from, *e.g.*, the Nuremberg trial and the video from Millgram's original study,
- exam in the form of an essay of maximum ten pages,
- each participant must present a disposition of the essay to be commented by the group,
- each participant was offered individual supervision and guidance by available teachers at fixed times.

The experiences have so far been very good, on the basis of course evaluations. Through evaluations of courses we became aware that participants did want to meet several times through the semester. We expanded to two full-day seminars, but we have ended up with three full-day seminars. These are voluntary but almost all participate in all of them even when they have to travel long distances. We have noted two important explanations: a good learning environment presupposes some close interaction among the students, especially when it requires that some of the activities are driven by the students. They seem to have a need to know with whom they are interacting. We also think that ethics needs the supplement of meetings in order to facilitate the dialogue, reasoning skills and to get a feel of discernment. This is not easily done in writing in discussion forums.

It was not easy to decide on the curriculum. Because we wanted to attract a wide group of possible participants, we decided that most of the curriculum should be available in Norwegian (or other Scandinavian languages) (4–10). We did, however, include one English-speaking textbook by T. Smith since it offered much valuable hand on reflections on ethical issues in medical research (11). Under recommended reading we listed the manual for research ethics committees published by King's College in Great Britain.

The course required 500 pages of obligatory reading. In addition, each student had to select an additional 250 pages drawn from the list of recommended reading or selected as relevant for the topic of the chosen essay.

Since cases play an important role in the course, to explain the development of ethical guidelines and to learn how to reason about concrete cases, we presented seminal historical cases and authentic cases presented to the committees over the past ten years. Among the historical cases the following were emphasized: Armauer Hansen, Norway, and the discovery of mycobacterium leprae (1880), Albert Neisser, Germany, and the search for a serum therapy against syphilis (1900), The Tuskegee Institute, USA, and the study of the natural

course of syphilis in colored men (1932–1972), Dachau and the hypothermia experiments, Germany (1942), Manchuria (China) and experiments developing bacteria to cause disease (1942), Vipeholm Mental Hospital, Sweden, and dental experiments (1945–1955), the use of thalidomide in pregnant women (1956–1961), Willowbrook State School, USA, and experiments with hepatitis (1954–1972), human radiation experiments, USA (post-war) and the Milgram studies on obedience, USA (1960s).

### 3.2. Course organization

The course was organized as a semester course. It offered five weekly lessons, including reading assistance. Participants were divided into groups of 4–5 students, which were given specific tasks (usually case resolution) as well as discussions of each other's dispositions for exam. The computer-based program has a function (called portfolio) which shows the activity of every student on the net in detail. I found it appropriate to inform them about the big-brother-sees-your-every-move function. The course is offered once a year and has the advantage that it can be credited to any (relevant) master program at universities, colleges and professional schools.

## CONCLUSIONS

It seems that training cannot be achieved by establishing one type of model, neither informal nor formal, especially if it requires some sort of obligatory certification, even the most minimal. I think it is of great value to offer a variety of training activities, knowing well that the most important training will be done as learning by doing. This should be supplemented by ad hoc seminars and annual meetings for all members of all committees organized and provided for by the committees themselves. They should also make the most pertinent material available to members of the committees, for their own perusal and study, *e.g.*, as The National Committee for Medical Research Ethics has done on their web site (12).

When it comes to more ambitious training, I don't think this can be the responsibility of the committees as such. It needs to be provided by larger institutions that have the resources and the capacity to do it, such as a university in our case, but it could also be a national research council or a national institute of health. Though it has been relatively few from the committees that have availed themselves of the course, it has been taken on a voluntary basis by employees of the secretariats. It has strengthened their competency which also contributes to the competency of the committees as such.

Though we have continuous discussions about the appropriate language, we have at present decided in favour of the local language, both in teaching as well as in the procedures of the committee. We are, however,

challenged because much research is multinational (in which all documents are produced in English) and cooperation between ethics committees is limited to compatible languages (for us Denmark and Sweden). The latter issue will be set on the agenda under the auspices of Nordic Research Board in an attempt to foster a viable network among research ethics committees in the Nordic and Baltic countries, also including Northwest Russia (13). The research will, among other things, explore the possibility of some common training possibilities. If this should prove feasible, it must be in English.

Training in ethics of members of ethics committees is a complex issue. As a starting point, we have considered a committee competent in ethics due only to its composition. There is, of course, a rather steep learning curve in the doing of ethics review in the committees. It creates skilled practitioners with experience. We have considered additional skills as an added value to the committee. All in all, it allows for a variety and difference which allows for various voices and perspectives to be heard. This seems to be a unique and valuable characteristic of an ethics committee. If we make too strenuous attempts to train everyone into the same mold, for the sake of quality assurance or accountability, there is a danger that we will lose the unique normative perspectives of each individual in the committee. From my own eight-year-long service in the committee I have used my experience with a lay member of the committee, who was a country-based policeman whom we called the cowboy. When he started on the committee he didn't have an inkling of what research ethics was – or medical research for that matter, but I was still impressed by his contributions drawn from common morality and common sense that over and over again proved very valuable and insightful. Most of the group was "socialized" into particular ways of approaching a case, but he saw many cases from a different perspective. It did happen that a comment from the cowboy changed the whole understanding of a case, and eventually, the opinion of the committee! The cowboy can at least stand as a warning. Training can of course enhance competence and skills, but at the same time, especially if it is made compulsory, it can reduce the multifaceted perspectives that are now brought into the committee solely on the basis of the variety of the composition of members. For these reasons I think it is worthwhile to hold on to the tension to the value of different contributions: training yes, but it is not necessary.

In my view, it will in the future be more difficult to uphold this balance – between the trained members of ethics committees and the "unspoiled" normative perspectives of lay representatives or others – because of increased need for legal expertise in the review process of the committee. More than ethics, law presupposes knowledge and interpretative skills. This development follows from the fact that medical research is regulated by EU directives which are implemented in national laws (privacy and clinical trials) and also by national

laws regulating parts of medical research (*e.g.*, in Norway, acts relating to health registry, biobanks, biotechnology). It raises interesting and complex issues for the committees regarding the legality of the committees and the need for legal representation in the committee, as well as in the secretariats. It also forces the committees to look at the relation between ethics and law and the common opinion that law stands over ethics, in the meaning that the committees ought not approve that which is unlawful (14). It can limit the area of ethics as well as the basis for discernment in deciding about particular projects. In this shift of emphasis – from ethics to law – there are important issues to be discussed, but in the context of this article it is of importance to see that it also has ramifications for training. We are already in the process of expanding the course by adding a lesson on relevant laws for medical research. Down the line, I am sure, we will offer a separate course on EU directives and national laws that intend to regulate the use of human subjects – and their biological material and personal information – in medical research.

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