How can we provide effective training for research ethics committee members? A European assessment

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ABSTRACT

Training for members of research ethics committees (RECs) varies from state to state in Europe. To follow this up, the European Forum for Good Clinical Practice organised a workshop in March 2007 to explore these issues and look for solutions. This article summarises the discussion, providing ways forward to develop REC training.

The expectation of the workshop of the European Forum for Good Clinical Practice (EFGCP) was that the European Union Clinical Trials Directive would bring about a consistent approach to medicinal trials in the EU. Alas, this has not turned out to be the case. The EFGCP ethics working party's report[1] shows that countries have implemented the directive in different ways and, among many aspects of clinical trials, training for members of research ethics committees (RECs) varies from state to state.

Only three of the 26 countries reported training requirements for REC members, although 19 reported some form of training provision. Fifteen had a quality assurance process but it was unclear whether this included training of REC members.

To follow up this apparent lack of training provision, the EFGCP organised a workshop to explore these issues and look for solutions. Twenty-three delegates from 19 countries attended, and this article summarises the discussion.

THE ARGUMENTS FOR INVESTMENT IN TRAINING

Being fit for purpose (competence)

While research is the primary activity, research ethics is not an "optional extra" nor a subject to be bolted on at the end. Consequently, all those involved in research, its review or its regulation need to have an understanding of research methodology, research ethics, its application to patients and populations and the broader regulatory, legal and moral environment.

The EU Clinical Trials Directive places greater responsibility upon RECs and REC members to protect research subjects and facilitate ethical research. It is difficult to see any way to develop this other than by training. While governments are directed to establish RECs and members must be fit for purpose, either or both could be morally and legally liable for deficiencies. Training provides a moral and legal defence.

The benefits of competence

At a national level, if governments wish to attract pharmaceutical industries, a robust review process that will stand up to scrutiny will encourage ethical pharmaceutical industry investment. Inexpert, easily persuaded review is not in the interests of such companies. If anything, it may attract companies with a poor record.

Within our communities, competence will help RECs gain the trust of researchers and patients alike. Expert research review will promote public trust in review and in research, improve recruitment and support research-based improvements in health care.

The argument therefore is not "Do we need training?" but rather "Is it being provided in the most effective way?" This question needs to be answered.

PROBLEMS AND POSSIBLE SOLUTIONS

National problems

Some states lack the organisation of a national process. In relatively few is there a co-ordinated system. For many states, resources are very limited. However, reports from some delegates demonstrated that a lack of funds need not prohibit training. It can be built into review and the most successful training is probably best situated within everyday processes. A Portuguese initiative shows that training can take place within routine committee business. In the UK, learning is shared between RECs and is incorporated into the "process" by circulation and analysis of a "dummy protocol". Electronic discussion groups could allow RECs to exchange views and ask for help on particular problems with small initial investment.

Local problems

Training must meet local needs. Only local expertise can define these and design a process to meet them. In addition, while there is a huge amount of material available, it is often in the wrong language and not easily accessible. Furthermore, part of the purpose of training is to create a group of REC members who support and motivate each other. Such training can be developed only locally, by local "champions".

Individual problems

It was reported that some REC members perceive no need for training. Personal reward is central to motivation and there is a clear need for courses to meet individuals' needs or aspirations. These may include professional continuing education or academic qualifications. Courses also need to be an appropriate length. Many members will not be able to attend more than a one-day meeting. For those who cannot attend, self-directed learning using such resources as e-learning and edited, regulated

discussion groups might provide some parts of the training.

At a committee level, accreditation of RECs might depend upon completion of training for all members, and training starting at appointment could be mandatory or prior training could be a condition of appointment to a committee.

Educational problems

Members are more likely to attend training of a quality that requires good teaching, and expertise is available for such work. The University of Maastricht has established a course for Dutch REC members. Such an initiative could also address other educational problems such as the multidisciplinary nature of RECs and the consequent variability of knowledge and expertise. Training such multidisciplinary groups requires particular educational skills.

Developing the idea of the competent committee, a committee that together decides its needs for process and hence training, could encourage all to contribute. This could be addressed by a training needs analysis at national, committee and individual levels. Ongoing training might be based on the "competent committee" and members may be more willing to attend if they are nominated as committee representatives to feed back and be designated as a committee's source of information and expertise on a particular topic.

TRAINING NEEDS

The fundamental need was recognised to be commitment. At a national level this depends on a clear argument that will persuade responsible authorities to provide resources. The effectiveness of training also needs to be assessed. On its own, its uptake will be variable and benefit will be limited. Committee accreditation is needed and should include a record of REC member training and a process to evaluate the committee's deliberations and decisions.

Locally, committees need easy access to regulations, directives and guidance published in the local language. They should draw up their own training needs analysis and syllabus. Broadly speaking, it was felt that early training should include the following topics:

- the purpose and history of medical research
- the history of research ethics
- working together in the modern regulatory environment
- basic ethical principles
- critical appraisal of a project
- ethical analysis
- group working
- reaching consensus
- fraud and misconduct.

CONCLUSIONS

- All those involved in human research must have a knowledge of research ethics. Training is central to the development of competence, and providing a cogent and conclusive justification for training REC members is central to resourcing.
- Training on its own will not achieve the aims of fair, commensurate and consistent review; it must be supported by a process of accreditation and evaluation.
- A lack of national co-ordination need not hinder training. Local initiatives and "training within process" have been shown to be possible even with limited resources.
- Training must meet members' motivations and be guided by local needs. The material needs to be easily accessible and in the local language. Part of the purpose of training is to create local groups who support and motivate each other.
- The necessary subjects extend well beyond traditional ethics and research ethics and extend into skills that can be used in many walks of life.
- E-learning has a place in teaching research ethics but further work is needed to define this. The creation of edited, resourced discussion groups might be the first step.

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REFERENCE

1. The procedure for the ethical review of protocols for clinical research in the European Union International. *Int J Pharm Med* 2007;**1**:1–113