JME Online First, published on September 20, 2011 as 10.1136/medethics-2011-100064

A syllabus for research ethics committees: training needs and resources in different European countries

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Received 25 June 2011
Accepted 12 July 2011

ABSTRACT

This paper reports a European Forum for Good Clinical Practice workshop held in 2011 to consider a research ethics committee training syllabus, subsequent training needs and resources. The syllabus that was developed was divided into four competencies: committee working; scientific method; ethical analysis and the regulatory framework. Appropriate training needs for each, with possible resources, were discussed. Lack of funding for training was reported as a major problem but affordable alternatives were debated. Strengths and weaknesses of this approach were discussed and the resultant proposal will be disseminated through the European Forum for Good Clinical Practice and the research ethics committees of member states.

The European Forum for Good Clinical Practice[1] is one of the most active bodies in research ethics in the European Union (EU) and aims to promote consistent, high quality ethical review. Two previous workshops discussed standards and training for research ethics committees (RECs),[2 3] and this paper reports a further workshop with 30 participants from 12 countries held in Stuttgart in April 2011 to consider a possible training syllabus for RECs and their members.

WHY TRAINING, AND WHY A SYLLABUS?

It is self-evident that RECs require expertise to review research so that they may hold the confidence of all involved, public; patients; researchers and other regulators. This need is clearly reflected in international guidance.[4–6] Other than undirected 'learning on the job' (the efficiency and reliability of which is questionable) or appointing those who already have the necessary skills, training is the only way REC can acquire expertise for review.

What is being debated, therefore, is not whether RECs need training, but how this might best be provided. There is little current guidance on this,[7–9] although there is recent work for clinical ethics committees.[10–12] We propose that a syllabus, built on a realistic analysis of the work of REC and drawn up by REC members themselves, will help define educational aims and objectives.

WHAT SHOULD BE IN THE SYLLABUS, AND HOW SHOULD IT BE STRUCTURED?

The syllabus that was developed was divided into four broad competencies, synthesised in the boxes below. The first was 'committee working' (box 1).

The second area of competency was scientific method (box 2). Fair and accurate review can only be built on an accurate picture of the study, which will centre around its scientific justification.

The third was ethical analysis (box 3).

The fourth area was an understanding of the regulatory framework (box 4).

Delegates named a number of training methods and resources that might suit the present syllabus.

Box 1 Competencies in committee working

Outside the committee—capacity to work with all involved—public, patients, researchers and other regulators:
- understand the place of research in health care, and how researchers plan, seek funding and conduct research;
- present and describe the authority, purposes and processes of REC to others;
- consider and promote the public understanding of research and health care.

In committee—capacity to review proposals, debate an application and reach consensus:
- prepare for the committee meeting by:
  - reading documents;
  - developing and using critical appraisal skills;
- have the skills and attitudes (empathy, humility, courage) to work together, present one's own views and accommodate those of others;
- skills to debate issues in committee;
- to be open to questioning and comments;
- to be able to handle differences of views and opinions.

Training—capacity to:
- commit to continuing training;
- determine what the committee needs to know;
- match training needs with possible resources.

International, national or regional training days

While expensive and time consuming to organise, training days are an excellent opportunity to provide efficient access to expertise and can be used to promote a consistent approach. They are also an opportunity for REC members to network so they do not become entrenched in one way of working or seeing research. It is, however, necessary to consider how to spread this learning to those who cannot attend.

REC break-out session/away days

These sessions allow the REC to talk without the pressure of applications to review, helping members to get to know each other and therefore work together more effectively. Groups that know each

Box 2 Competencies in scientific method

Capacity to review the scientific standing of a project, according to national guidance:
- analyse research questions and appropriate methods to answer them;
- understand different research designs (quantitative and qualitative) and their appropriate application, including statistics that are relevant for REC, equipoise and the fair use of placebo;
- know about modern development of drugs and medical devices.

Capacity to review the suitability of the applicant and the validity of the research:
- consider the researchers' role, constraints and motives;
- consider how the research team is assessed: CV, good clinical practice training, resources, experience, skills, empathy with subjects;
- consider and understand how 'conflicts of interest' may arise and how they should be handled.

other will find it easier to discuss issues openly, agree, disagree and strive for consensus.

Visiting a research site or volunteer for research

This would provide the opportunity for REC members to gain an understanding of research procedures.

Tutoring/coaching or mentoring in committee

More experienced members or REC officers might be able to provide directions and access to resources for members.

Box 3 Competencies in ethical analysis

Capacity to maintain a balanced view of health care and research, recognising its benefits and harms:
- know about research history, the benefits research has brought and its attendant risks.

Capacity in (research) ethics:
- be able to apply the common ethical models (eg, duty based, rights based and consequentialism);
- be able to analyse the ethical aspects of:
  - recruitment of participants and inclusion/exclusion criteria;
  - consent (patient autonomy, principles of informed consent, information provided to participants);
  - judging the burden of the study and its risks compared with its benefits;
  - payments to subjects, both volunteers and patients;
  - confidentiality and data management;
  - data and sample storage;
  - end of study and publication policy;
  - research involving particular groups (children, elderly, mental health patients);
  - insurance and compensation arrangements (according to national guidance).

Capacity to make a judgement upon the ethical standing of a research project:
- understand how to reach judgements on research projects;
- reflect on one's own decisions and how they are reached.

Box 4 Competencies in the regulatory framework

Capacity to understand the functioning and role of REC and other bodies involved in the regulation of research:
- understand the Declaration of Helsinki;
- have access to, and understanding of European clinical trials directive, good clinical practice guidelines and national legislation relevant to research and REC;
- understand the REC' and other bodies' roles in protecting research subjects and facilitating research;
- understand and have access to the committees' governance and standard operating procedures;
- understand the role of other regulators, how this links to the role of REC and how differences can be resolved.

Training by members for members

Committees will contain a wide range of professional expertise so meetings are an obvious opportunity to share knowledge and expertise. Presentations could be arranged during breaks between application reviews or after the agenda items, which will also help the committee members appreciate and value each others' talents and work together. This makes it an affordable and effective resource that all REC could benefit from.

E-learning

Once developed, it can be economical but the financial resources and expertise needed to establish a course and update it are often underestimated.

HOW COULD THIS SYLLABUS BE PRESENTED AND PROVIDED?

Training must recognise and accommodate the REC members' honorary, voluntary status. A central principle and unanimous conclusion was therefore that any syllabus must kindle enthusiasm. Were it to extinguish members' motivation, it would clearly have failed. It was also stressed that it is not the role of overarching bodies to dictate to REC or tell them how to think or learn; their independence is a central and crucial aspect of their deliberation.

CONCLUSIONS

Limitations

The use of any syllabus requires judgement. These are broad guidelines and could be considered a syllabus for a REC rather than one for REC members. An individual member should not be expected to meet all the expectations within a syllabus, at least on appointment. REC members will obviously acquire competencies during their time on a committee. One of the strengths (and reasons for) RECs is that they provide complementary and cumulative experience. Assessment will need to be addressed although current initiatives such as e-learning modules[13] could help.

What does this report add?

The workshop provided an opportunity to share European initiatives for training of RECs, allowing us to incorporate ideas from all delegates at the meeting. It could serve as a guide for committees to assess their competency and training needs, and as a route to develop training material for REC members and trainers.

It is also a first step in developing a central record of training resources available across the EU and elsewhere. The meeting report[14] was deliberately designed to allow member states to enter their own resources, so that a European compendium of

Cairoli E, Davies HT, Helm J, *et al*. *J Med Ethics* (2011). doi:10.1136/medethics-2011-100064

research ethics training resources could evolve. The European Forum for Good Clinical Practice is committed to updating it in the light of feedback from REC in the EU.

Competing interests The meeting was an initiative of the European Forum for Good Clinical Practice. The authors declare they have no competing interests.

Provenance and peer review Not commissioned; externally peer reviewed.

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Notes