What can Clinical Ethics Committees learn from Research Ethics Committees?

By Emma Cave

Summary: In the UK, research ethics committees (RECs) have historically been prioritised over the development of clinical ethics committees (CECs). Today, the importance of CECs is receiving increasingly wide recognition. But whilst the regulation, coordination and support of RECs provides a relevant comparator for CECs there are differences in role, remit and function that warrant variations in approach.

Contrasting the development of CECs and RECs

Two forms of local NHS healthcare-related ethics committees have evolved in the UK: research ethics committees (RECs) review research on human participants and clinical ethics committees (CECs) consider an array of moral issues in healthcare. There is potentially overlap between the two, and in some countries, ethics committees once considered both research and clinical matters.

There are substantive reasons for the separation of research and clinical matters given that research is broadly concerned with the pursuit of knowledge and clinical ethics with medical benefits for patients, which might require different expertise and skills of committee members. But there are also procedural explanations for the prioritisation of the development of RECs which flowed from emphasis on research governance in the 1964 Helsinki Declaration and, in Europe, the Clinical Trials Directive 2001/20/EC which led to formalisation and central support of RECs for certain functions.

In the UK, the support given to research ethics was not extended to clinical ethics. Where RECs are regulated, co-ordinated and supported centrally through the provision of guidance, standard operating procedures and training, CECs remain unregulated, heterogenous in structure, remit and constitution and without any need for formal training.

RECs were not always well supported. The first formal guidance for local research ethics committees (LRECs) issued in 1991 (HSG(91)5) did little to improve LREC's reputation for bureaucracy, inconsistency and as an impediment to research. My first academic post, funded by the NHS between 1998 and 2000, was to help develop and deliver regional training for RECs. We envisaged that training would help reduce inconsistency and give REC members much needed support. We organised networking sessions, developed a training manual and ran on-site sessions utilising case studies. Today, the Health Research Authority requires members to undertake induction and annual training.

CECs in the limelight

Recently, the importance of CECs has been accentuated by judicial decisions and professional guidance. The courts emphasise the potential for CECs to help resolve disputes (eg Re X (a child) [2020] [21]) and to guide clinicians so as to safeguard patients' best interests (eg AB v CD [2021] [110]). Professional guidance has recently recommended CEC involvement to resolve disagreement (GMC 2020 para 92), and guidance in the COVID-19

pandemic recommending reliance on ethics committees where the law was unclear and national guidance was lacking (RCP 2020, BMA 2020). Can CECs learn from the development of governance and support for RECs?

Lessons to be learned

Caution is required in the transferral of the REC model to CECs. The ethical goals of balancing the value of research and harm reduction in research can be contrasted with a focus on medical interests in clinical practice. Whilst there are internationally agreed laws and codes in research, there is less agreement in the more variable clinical environment. These factors impact on the nature and quality of ethical advice the committees offer.

The purpose of advice in RECs and CECs is also quite different. NHS REC approval is a requirement for most NHS research, but CECs *advise* clinicians rather than making decisions. The nature of CEC advice varies widely depending on the needs of the population served. A 2019 USA Delphi study suggests that there is a high level of agreement on objectives to 'mediate, educate, develop policy, improve the moral quality of a decision or action, counsel, create a moral space and manage moral distress'. Other objectives such as empowerment, transforming the institution or improving patient quality of life received only moderate agreement. In the UK too, variations in the form of ethical advice provided by CECs should not be assumed to be a negative product of a lack of central organisation, but can flow from the different needs of the relevant population.

Centralisation in place of the bottom-up system that currently operates for CECs does offer several advantages. In Italy, the Italian National Bioethics Committee in 2017 called for clinical bioethics committees to be set up in relevant settings and set out guidance as to functions, structures, compositions, tasks, training and competencies. In Norway too, by 2011 all trusts were reported to have at least one committee, supported and coordinated by the Centre for Medical Ethics at the University of Oslo. A 2007 comparative European study, however, found that a central mechanism was preferable but that it should be weak rather than strong in order to support the independence of CECs. The strong top-down approach applied to NHS RECs may not be appropriate for CECs.

Indeed the UK Clinical Ethics Network was established to support ethics provisions and to provide training of members. It became an independent charity in 2007 and produced advice on core competencies the same year. But it is unclear how far this guidance is followed and not all committees are members of the network. The CEN website provides valuable resources and was a source of support to established CECs and newly formed CECs in the pandemic. But here, as in many countries, educational needs remain poorly defined and accommodated. Greater centralised funding and support, including the development of central training for members may be an area where lessons can be learned from the REC model.

But even then, the goals of training will vary. In our 1990s training for RECs, we hoped to improve consistency in outcome by generating a better understanding of ethical and legal principles. This goal would be inappropriate in CEC deliberations where advice should be shaped by the particular facts of the case. Consistency of *process* is, however, important. In

Re X (a child) [2020] [21], for example, Russell J emphasised the current variability in the representation of the patient or family members in ethical deliberations.

Russell J [22] also lamented the lack of guidance for CECs. RECs have the benefit of governance arrangements describing how NHS RECs function. Similar advice for CECs on composition, membership, purpose and scope would help establish clinical ethics as a core part of the NHS. Given the proliferation of professional guidance and legal cases suggesting reliance on CECs, it is time to consider how we might better support them.