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**Abstract:**

The pace of change and, indeed, the sheer number of clinical ethics committees (not to be confused with research ethics committees) has accelerated during the COVID-19 pandemic. Committees were formed to support healthcare professionals and to operationalise, interpret and compensate for gaps in national and professional guidance. But as the role of clinical ethics support becomes more prominent and visible, it becomes ever more important to address gaps in the support structure and misconceptions as to role and remit.

The recent case of *Great Ormond Street Hospital for Children NHS Foundation Trust v MX, FX and X* ([2020] EWHC 1958 (Fam), [21]-[23] and [58]) has highlighted the importance of patient / family representation at clinical ethics committee meetings. The court viewed these meetings as making decisions about such treatment. We argue that this misunderstands the role of ethics support, with treatment decisions remaining with the clinical team and those providing their consent. The considered review by clinical ethics committees of the moral issues surrounding complex treatment decisions is not a matter of determining a single ethical course of action.

In this article, we consider current legal understandings of clinical ethics committees, explore current concepts of ethics support and suggest how they may evolve, considering

the various mechanisms of the inclusion of patients and their representatives in ethics meetings which is not standard in the UK.

## **Introduction**

This paper aims to set out some of the misconceptions around clinical ethics support, focusing on the roles of clinical ethics committees and advisory groups (CECs). At a basic level, ethics support is the provision of assistance with regards to questions of morality in healthcare. It evolved as a system to aid healthcare professionals who were concerned about questions regarding the correct action in the care of their patients.<sup>1</sup> Such questions have classically included resuscitation and end of life decisions, issues of competence and capacity and equity of fair access to treatments.

Our focus is that of UK CECs. This is because the authors are familiar with their work, because the pandemic has exposed in a dramatic way the importance of their work but at the same time the ambiguity and uncertainty as to their proper role, and because of salient English law judgments as to who should attend meetings of CECs. This is not to say that we cannot learn from the experience of CECs from outside the UK. But our immediate focus is on those within the UK.

Many CECs utilise existing ethical guidance and frameworks whilst deliberating complex and challenging situations,<sup>2</sup> whether by regulatory bodies such as the GMC,<sup>3</sup> Royal Colleges such as the RCPCH,<sup>4</sup> or other bodies. Others have developed their own frameworks.<sup>5</sup>

COVID-19 has stimulated a significant expansion in the number of CECs<sup>6</sup> and provides both an opportunity and immediate context for considering what exactly CECs do. Early in the

pandemic, professional bodies in England and Wales recognised the need for clinical ethics support regarding difficult choices which professional or national guidance did not cover.

The Royal College of Physicians stated:

Support with difficult decisions

Medical ethicists (sometimes referred to as bioethicists) can help frontline staff with difficult decisions. Particularly where there is significant disagreement or a stakeholder might wish some form of external appeal other than a second opinion hospitals may wish to engage medical ethicists or form clinical ethics committees to help with such decisions.<sup>7</sup>

The British Medical Association said:

It is essential that employers take steps to provide appropriate support, including clinical ethics committee support and psychological support, to all health professionals working during the pandemic, many of whom may find working in the unfamiliar and strenuous conditions of a pandemic both practically difficult and morally and emotionally challenging.<sup>8</sup>

The UK Clinical Ethics Network, established in 2001, provided guidance and support both for established committees and for NHS Trusts and private hospitals setting up new ones.<sup>9</sup>

Questions of how CECs are constituted and trained are not considered here. They are important nevertheless, as is a recognition that membership of such committees is voluntary and unremunerated.

Calling upon established or new CECs and services to operationalise and fill in gaps in national and professional guidance that for moral, practical or political reasons cannot

immediately be addressed is admirable. It is essential that ethical dimensions of clinical decisions are given due consideration. But the ability of CECs as currently constituted to rise to the pandemic challenges is dependent on their function and form and the support they receive. Our aim is to articulate misconceptions, resolution of which would help to manage expectations and provide an impetus for improved support of clinical ethics services.

### **What clinical ethics committees are not**

There are within the UK ethics committees other than CECs – those of the BMA and the Royal Colleges, for instance – and there are CECs in other jurisdictions outside the UK that differ in their form and function from the UK ones. This can lead to confusion as to the role and the resources of UK CECs. First, we should separate CECs and RECs (research ethics committees). RECs consider the approval of research trials; CECs consider the ethics of clinical treatment. Of course, there can be overlap, if, for instance, possible treatment would involve enrolment in a clinical trial. Nevertheless, CECs and RECs have distinct and distinguishable functions.

Research ethics is managed and governed by a funded body, the Health Research Authority. One might assume that clinical ethics and research ethics have a similar provenance. Alas, clinical ethics lacks the well-funded governing authority and structure of research ethics.

It is useful to contrast UK CECs with CECs in the United States and many European countries, which have a more formalised structure and support system. The UK Clinical Ethics Network aims to set standards and has provided core competencies,<sup>10</sup> but not all UK CECs may avail themselves of the support offered by UKCEN.

A 2012 survey by Slowther et al. captured considerable variation in processes and form.<sup>11</sup>

Recently, new infrastructures, such as regional groups of committees have been established in some areas, so as to share frameworks and improve consistency.

### **Variation in function**

In 2001, Hendrick described three central functions of clinical ethics committees, 'notably education, policy development and case review'.<sup>12</sup> But there is variation as to how extensively these roles are embraced and understood, even by clinicians.<sup>13</sup> A 2009 study revealed that whilst the number of committees was rising, there was a paucity of cases that some committees reviewed due, in part, to 'low profile and lack of funding and support.'<sup>14</sup>

In 2012, Slowther noted that some *committees* were not clear as to their role and function.<sup>15</sup>

During the pandemic there has been emphasis on supporting clinicians through the development of frameworks<sup>16</sup> and operational guidance;<sup>17</sup> the newly constituted Devon committee is an excellent example of a newly formed CEC doing just this. It is less clear how far CECs have engaged in case consultation in the pandemic.

What *is* clear is that even before COVID-19, the role of some CECs was expanding. In 2020, the General Medical Council in its latest consent guidance mentioned for the first time the value in seeking advice from clinical ethics committees to resolve disagreements.<sup>18</sup> The courts, meanwhile, appear to perceive CECs as an alternative dispute resolution mechanism that can avoid the need for the courts to become involved in the care of patients - which after all is best resolved by those involved in the situation.<sup>19</sup> Some CECs have established

bioethics teams whose work extends beyond the committee in terms of supporting staff, patients and families going through very challenging periods; undertaking research into bioethical issues; and providing bioethics and law education, by relevant personnel where available, for staff.<sup>20</sup>

We argue there is a nuanced role for ethics support, that goes beyond a binary contrast between decision-making and discussions to help clinicians and, depending on the process, patients and their relatives think through ethical issues. It is conceivable that ethics support, in whatever format, could either make non-binding recommendations or indicate some ethically proper choices or indeed identify ethically problematic options.

#### **Case review: adjudication or advice?**

One of the functions of CECs and services is to consult on difficult cases and provide advice. The advisory function is in stark contrast to the RECs we mentioned above. If RECs decide not to give ethical approval to a research project, it cannot go ahead in that form. So too, in other countries, there are examples of CECs which go beyond the giving of advice. In the USA case *Re Quinlan*,<sup>21</sup> reliance was placed on ethics committee approval should the clinicians and family concur that treatment may be withdrawn. Some US states go further still and look to CECs to make decisions on behalf of patients lacking capacity to decide for themselves.<sup>22</sup>

Given these examples and the lack of formal guidance and standing operating procedures for UK CECs, it is understandable that some might assume that they have a decision-making function. Whilst the BMA in the above quote refers to *supporting* doctors, the RCP

references CECs helping staff with difficult decisions and providing a route to 'external appeal', which potentially goes beyond mere advice. The courts seem to take a similar view. In *Great Ormond Street Hospital for Children NHS Foundation Trust v MX, FX and X*<sup>23</sup> (MX) which concerned a dispute around the end-of-life treatment of a nine-year-old child, Russell J was highly critical of perceived failures of the relevant clinical ethics committee to involve the family in their discussions. MX is a paediatric case which urges parental involvement in CEC discussions of their child's case. The impact of the case, however, is likely to extend beyond paediatrics.<sup>24</sup> It may, for example, extend to family members of adults lacking capacity when complex decisions are being made about their care. Obviously, competent adults are entitled to give or to withhold consent to their own treatment. Evidently, they would have a say in what is done. Our sense is that the judgment has been taken up and understood in ways that suggest any patient with capacity, of whatever age, should be a party to the CEC discussions of cases involving their treatment.

There are good reasons to involve patients or representatives, which we will come to shortly, but it is apparent that the judicial criticism gave weight to the CEC view as though it was decisional rather than advisory. Wilkinson and Dunn have said of the case:

[S]ome of the suggestions made by the judge about how CECs should change how they work are potentially based on a mistaken conception of the function of a clinical ethics committee. And the broader idea that CECs should be conducting their business in a way that is more like a court room, with careful preparation and submission of evidence from both sides appears to be based on the idea that the aim of ethics review is to decide what should be done, and to arbitrate on what would be ethical.<sup>25</sup>

Instead, they argue, CEC case reviews aim to ‘help the clinicians think through the ethical considerations and their options’. In the UK, the decision to offer medical treatment is that of the clinical team and the decision whether to consent usually rests with the patient unless there is a loss of capacity or the patient is a younger child. Neither is the role of ethics support services, whatever their structure. In the UK, CECs, despite previous and current suggestions, do not perform a quasi-judicial process that determines treatment decisions. Doyle clarified this and hoped it might encourage clinicians to seek ethics support by reassuring them of no loss of clinical decision making.<sup>26</sup> It is, however, not clear if this perception has genuinely penetrated the judicial system or, indeed, the clinical sphere where, anecdotally, ethics referral can be perceived by clinicians as representing a failure in their relationship with patients or as a prelude to legal processes.

Whilst CECs can and often do reach a consensus on a recommended course of action, they are set up to advise clinicians rather than to make clinical decisions. UK CECs are neither constituted nor capable of clinical decision-making. There is potential for more CECs to expand their role in alternative dispute resolution, but if the courts seek to utilise CECs as a mechanism to avoid the necessarily oppositional nature of the legal process, then CECs will need to be formalised, and representation considered including legal support for those involved. The distinction of ethics from healthcare mediations would need to be formalised.

The number of contested cases in medicine, particularly for children, being played out in the public domain secondary to the change in confidentiality in the courts such as in the Family Division of the High Court has increased.<sup>27</sup> Mediation has emerged as an option for tackling disagreements in healthcare,<sup>28</sup> and family-centred care has entered the UK lexicon. Patients and (where the patient lacks capacity) family have a right to be consulted about treatment



such as the management of end-of-life care.<sup>29</sup> Bioethical mediation, which a CEC can sometimes facilitate, has been shown to lead to the resolution of seemingly intractable disagreements without recourse to the courts.<sup>30</sup> But there remains little standardisation, regulation or funding for this enterprise.

The advantage of a more inquisitional rather than adversarial approach to determine the best interests of either children, or adults with incapacity is attractive but would require structure and funding, as well as the granting of legal authority to any new body to make binding decisions, together with systems to ensure the voices of all interested parties are heard.

### **Patient representation**

A connected concern surrounds the relevance of patient representation. Patient and family representation can take many forms, from clinicians stating their interpretation of the patient viewpoint to patients/ family giving their opinion in ethics committee meetings. We have seen above that the court in *MX* seemed to ascribe the CEC a decision-making role as does the RCP COVID-19 guidance which says ‘a stakeholder might wish some form of external appeal other than a second opinion’. If the CEC was considered to be a decision-making body, then in line with the Court of Appeal decision in *Tracey*<sup>31</sup> the patient (or, if the patient lacks mental capacity, the family), may, depending on the nature of the decision, have a right to be consulted. The European Court of Human Rights has held that Article 8 of the European Convention on Human Rights requires a fair decision-making process ‘such as to afford due respect to the interests safeguarded by it’.<sup>32</sup>

If the CEC role is advisory, as per the standard formulation of CECs, then there is still a strong case for patient representation, but the aim, in this case, would be to advise *clinicians* in light of the patient or families wishes, preferences and values rather than to give requisite protection to the patient's article 8 interests through their involvement in the decision-making process. The High Court in *MX* did not highlight the distinction between the two goals. There Russell J said:

I consider that a lack of involvement by patients and / or their families is itself an issue of medical ethics and I am most surprised that there is not guidance in place to ensure their involvement and / or participation. ... [W]here the quality of life of a disabled child with complex medical needs is a central issue, the involvement of parents in the clinical ethics committee process is essential.<sup>33</sup>

If these words are used to improve patient participation in suitable cases then this is all for the good. With the ebbing of paternalism and emergence of a more consumerist model illustrated by choice of treating clinicians and the ready availability of private healthcare, the idea of a committee in a hospital discussing the ethical aspects of decision-making in the absence of the patient or their representatives seems archaic. Still, if patient representation is to be more widely advanced, the normative questions around the mechanisms for, extent of, and exceptions to patient involvement need to be clarified.<sup>34</sup>

If, on the other hand, the judge's dicta are interpreted as an endorsement of a CEC decision-making process in which patients are represented, then for two principal reasons, we would argue that CECs, as currently constituted, are not capable of its delivery. First, as was acknowledged in *MX*,<sup>35</sup> most committees discuss cases, issues or policies for the institution and its teams but do not engage directly with patients. Many are styled 'ethics advisory

groups' to make that clear. Ironically, the GOSH ethics committee at the heart of the criticism in *MX* for failing to represent the patient's parents in ethics committee discussions is one of the few committees to invite parents and sometimes children to ethics meetings routinely. Second, in those CECs where support is provided, there is little overarching standardisation, governance or funding. There is a risk, therefore of inconsistency and injustice to patients. In *MX*, Russell J's acknowledged:

I was told that there is no protocol or definitive guidance for the constitution and conduct of Ethics Committees, particularly as to the involvement of patients or their families in the meetings and decisions.<sup>36</sup>

There is potentially a role for CECs to engage more effectively in alternative dispute resolution (ADR) but for that to happen these deficiencies need to be addressed.

An important point that is not a feature of recent court rulings is the large number of multi-disciplinary clinical meetings that do feature the patient or their representatives. In complex paediatric cases, for example, daily meetings between the clinical team are frequent, as well as parent presence on ward rounds, though perhaps curtailed by recent COVID restrictions. Irrespective of this, the idea of a decisive ethics consultation occurring in the absence of prior discussion with a patient or their representatives is inaccurate.

However, there are undoubtedly many important healthcare meetings that do not usually occur with either the patient or their representatives. These include surgical planning meetings, radiology meetings, pathology meetings, theatre meetings, discharge planning meetings – the list could continue. Is it the case that all such meetings that directly influence patient care should always have the patient/their representatives invited?

This then begs the question of what is meant by patient representation? Considering ethics meetings, this might consist of a right to attend; a routine invitation to meetings unless there is a clear – and communicated – reason for not doing so; a right to enter a written statement/video recording. There is also the consideration about whether attendance is for all or only for a specific part of any meeting, and of whether patients/representative are notified of the meeting and/or notification of outcome.

One new issue that has been highlighted by COVID-19 is the role of video-conferencing. Patients and their relatives can now readily attend conferences about their care from their bedside or home, given the availability of adequate technology. What is, as yet, unclear is whether the nature of ethics or indeed other complex meetings, either with or without patients, are fundamentally changed by taking place in this novel way. Could professionals or patients/their families be intimidated or emboldened by this environment. Are non-verbal communications important or unnecessary?

The courts often do request information about ethics committee involvement in contested cases and receive it in the form of minutes, a meeting report or oral testimony. We are unaware of ethics committee members giving evidence in that role. Overall, this means that the courts receive what is often quite complex and nuanced ethical deliberation second hand and, in the context of an oppositional court process, potentially with a particular side's narrative.

## **Conclusion**

Pre-COVID, CECs were undergoing a transformation in response to a growing appreciation of their value both to support clinicians to make ethical decisions and to help to resolve disputes. We would support a role for ethics services in any UK ADR process, in conjunction with pastoral, mediation and legal expertise. This would require representation for patients and their relatives in a manner that current ethics support does not widely support.

The COVID-19 pandemic has highlighted the lack of formal ethics processes in most UK hospitals and by extension social care facilities, at a time of unprecedented need for such support. Some clinical ethics committees have been hastily assembled, with little standardisation or legal clarity on their operation.<sup>37</sup> Individual and regional groups have formed, but there is a lack of research as to how COVID-19 has impacted on composition and function of CECs and on the decision-making frameworks utilised.

We welcome recognition by the BMA and RCP that ethical support is pertinent to difficult clinical decisions. Expectations of CECs are high. The volunteers who rise to the challenges of COVID and non-pandemic related dilemmas such as end-of-life disputes that are subject to ever-increasing levels of, often inaccurate, media exposure<sup>38</sup> are deserving of praise and gratitude. We have referred to some assumptions and misconceptions about the role and function of ethics support, giving examples relating to our courts, professional bodies and clinicians. There is a danger that misconceptions could lead to unmet expectations. One option is to bring expectations into line with practice to maintain the flexibility and diversity of the current ethical support system. The other option is to bring the system in line with expectations through greater standardisation, governance and funding, albeit after a more fundamental reconsideration of the very function of ethics support. The question then is which expectations to prioritise.

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