Ethics Committee Consultation and Extracorporeal Membrane Oxygenation

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Abstract

Rationale: The clinical ethics literature on extracorporeal membrane oxygenation (ECMO) has been focused primarily on identifying hypothetical ethical dilemmas that may arise with the use of this technology. Little has been written on the actual experience with ECMO-related ethical questions.

Objectives: To describe the role of an ethics consultation service during the expansion of a single-center ECMO program in a cardiothoracic surgery intensive care unit (CSICU) and to identify common ethical themes surrounding the use of ECMO.

Methods: We conducted a retrospective, descriptive cohort study of all ECMO ethics consultation cases in the CSICU at a large academic hospital between 2013 and 2015.

Measurements and Main Results: During the study period, 113 patients were placed on ECMO in the CSICU, 45 (39.5%) of whom were seen by the ethics committee. In 2013, 10 of 46 (21.7%) patients received ethics consults. By 2015, 28 of 30 (93.3%) of patients were seen by ethics consultants. Initial consultation occurred at a median of 2 days (interquartile range, 1–6 d) following initiation of ECMO. The most common ethical issue involved disagreement about the ongoing use of ECMO, which included multiple axes: Disagreement among health care providers, disagreement among surrogates, and disagreement between health care providers and surrogates over stopping or continuing ECMO.

Conclusions: In our experience with integrating ethics consultation into the routine care of ECMO patients, most of the ethical questions more closely resembled traditional concerns about the appropriate use of any life-sustaining treatment rather than the novel dilemmas imagined in the current literature.

Keywords: ethics; extracorporeal membrane oxygenation; life-sustaining treatment; mechanical circulatory support

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Extracorporeal membrane oxygenation (ECMO) is a type of mechanical circulatory support for cardiac or pulmonary function. A pump is used to pull blood from the patient's large vessels, carbon dioxide is removed, and oxygen is added externally, and the blood is returned to a large vein or artery, depending on the indication. Although ECMO is an effective therapy in neonates, the historical experience with ECMO in adults has not been as successful (1, 2). Significant improvements in the ECMO circuit allowed for more aggressive ECMO use during the H1N1 influenza epidemic in 2009 (3). As a consequence, there has been sustained interest in adult ECMO, with an over 400% increase in U.S. cases from 2006 to 2011 (4, 5).

The bioethics literature on ECMO has been focused primarily on identifying novel ethical dilemmas that arise with the use of this technology (6). Which patients should be considered candidates for extracorporeal cardiopulmonary resuscitation (CPR) (7)? Should all code status conversations include a discussion about ECMO? What should happen with patients who are "stranded"

on ECMO without hope for end-organ recovery or permanent therapy such as transplant? Who decides when to stop the circuit and under what circumstances? Should a patient whose heart is not beating but whose blood is still circulating via ECMO be automatically considered a patient with a Do Not Resuscitate order?

Other questions raised in the bioethics literature include appropriate resource allocation, given the expense and personnel required for this therapy; whether discussions of ECMO candidacy should involve patients and their surrogates or whether these decisions can be made without their explicit input; whether it is justified to have patients or their surrogates sign documents stating that the circuit will be withdrawn if the ECMO-specific goals are not met; whether it is appropriate to continue ECMO in brain-dead potential organ donors; and whether hospitals without ECMO capability have an obligation to transfer patients to regional ECMO centers (8, 9)

Despite ongoing discussions of the unique ethical dimensions of ECMO, little has been written about the role of hospital ethics committees in navigating the actual clinical ECMO experience (10). In their case consultation and organizational ethics roles, ethics committees are an important and underused resource in addressing the predictable consequences of introducing a new life-sustaining medical technology. In this article, we report the experiences of the Massachusetts General Hospital (MGH) ethics committee, known as the Edwin H. Cassem Optimum Care Committee, with ECMO during its growth at our institution. We discuss the decision to have the ethics committee involved in ECMO cases, regardless of whether there was a particular ethical issue, and the types of ethical questions that emerged from these consults. In reviewing our experience, we hypothesized that most of the ethical questions involving ECMO would more closely resemble traditional concerns about the appropriate use of any life-sustaining treatment rather than novel dilemmas.

Methods

Ethics Committee Consultation Process

Any health professional, patient, or family member can consult an ethics committee. In most cases, a team of two or three ethics committee members, led by a senior consultant with training according to the American Society for Bioethics and Humanities guidelines, responds to the request (11). Consultants aim to understand the patient's expected prognosis, values, wishes, and treatment preferences; the ethical questions that led to the consultation being placed; and what goals of care have been agreed upon. Consultants provide an ethical analysis and give an assessment that is entered into the medical record.

The ethics committee approached ECMO-related consultations similarly to other requests until 2013, when the volume of ECMO cases at MGH grew substantially. Knowing the potential ethical challenges of ECMO and acknowledging that ethics involvement had previously been requested only as the burdens of treatment intensified, there were multidisciplinary meetings about the best mechanism for addressing ECMO-related ethical questions. To give ethics consultants a more balanced view of the ranges of outcomes with ECMO, nursing and physician leadership in the cardiothoracic surgery intensive care unit (CSICU) coordinated with ethics committee leadership to integrate ethics consultation into the routine care of ECMO patients. This approach allowed for timely ethics support for clinical care teams, patients, and families and gave ethics consultants the opportunity to observe a spectrum of clinical trajectories. By consensus, it was decided that senior intensive care unit nursing staff would formally contact the ethics committee when ECMO was initiated for a new patient. In practice, however, the process and timing of consulting the ethics committee remained open to any health professional or family member.

Ethics Committee Database

We reviewed all ethics committee consultations that occurred between January 1, 2013, and December 31, 2015, and included those involving ECMO patients seen in the CSICU as part of the routine ethics consultation program. We excluded ECMO patients who were cared for outside the CSICU.

We obtained sociodemographic and clinical data from ethics consultation notes and MGH medical records. Functional status and comorbidities prior to admission were defined as previously described (12). Indications for ECMO were divided into bridge to cardiac recovery, bridge to cardiac transplant or ventricular assist device, bridge to pulmonary recovery (which included pulmonary embolism), bridge to lung transplant, or extracorporeal CPR. Life-sustaining treatments at the time of consultation were defined as medical interventions necessary to prevent or to treat multiorgan dysfunction as previously described (13).

The study authors, all of whom are involved in the clinical care of ECMO patients, ethics consultation, or both, reviewed ethics consultation notes and the medical record to identify central themes. This required an iterative process in which authors identified, critiqued, revised, discarded, and finally agreed upon broad thematic categories. Study data were collected and managed using Research Electronic Data Capture ("REDCap"), a database tool hosted at MGH (14). The institutional review board at MGH approved the study.

Results

During the study period, 113 patients were placed on ECMO in the CSICU, 45 (39.5%) of whom were seen by the ethics committee. In 2013, the first year of the program, 10 of 46 (21.7%) patients received ethics consults. By 2015, however, 28 of 30 (93.3%) patients were seen by ethics consultants. There was no significant difference in sex (64.4% vs. 72.4% male; $P = 0.41$), age (47.5 ± 16.2 vs. 54.7 ± 13.3 yr), or in-hospital mortality (51.1% vs. 52.2%; $P = 1.00$) between patients who were and those who were not seen by the ethics consultants.

Clinical and Consultation Characteristics

The clinical characteristics of the ECMO consultation patients are listed in Table 1. The patients were predominately white, middle-aged men who were living independently in the community with few medical comorbidities at the time of admission. The primary indication for ECMO was bridge to cardiac or pulmonary recovery. Patients in the cohort were receiving multiple life-sustaining treatments in addition to ECMO at the time of consultation (median, 6; interquartile range [IQR], 5–8). These treatments included renal replacement therapy (55.6%)

Table 1. Clinical characteristics of ethics committee extracorporeal membrane oxygenation consultations

Characteristic	Data for 45 Total Consults
Age, yr, mean ± SD	47.5 ± 16.2
Male sex, n (%)	29 (64.4)
Race, n (%)	
White	34 (75.6)
Black	3 (6.7)
Asian	2 (4.4)
Other/unknown	6 (13.3)
Number of admission comorbidities, median (interquartile range)	2 (1–3)
Functional status prior to admission, n (%)	
Complete independence	38 (84.4)
Modified dependence	6 (13.3)
Complete dependence	1 (2.2)
Indication for ECMO, n (%)	
Bridge to cardiac recovery	15 (33.3)
Bridge to pulmonary recovery (including pulmonary embolism)	14 (31.1)
Bridge to heart transplant or ventricular assist device	13 (28.9)
Bridge to lung transplant	3 (6.7)
Extracorporeal cardiopulmonary resuscitation*	3 (6.7)
Number of other life-sustaining treatments at the time of consultation, median (interquartile range)	6 (5–8)
Renal replacement therapy during hospitalization, n (%)	25 (55.6)
Tracheotomy performed during hospitalization, n (%)	17 (37.8)
Gastric feeding tube placed during hospitalization, n (%)	7 (15.6)
Total length of hospitalization, d, median (interquartile range)	29 (10–54)

Definition of abbreviation: ECMO = extracorporeal membrane oxygenation.
*Three patients underwent extracorporeal cardiopulmonary resuscitation and were maintained on ECMO as a bridge to a cardiac recovery or ventricular assist device. They are counted in both categories.

or tracheostomy for mechanical ventilation (37.8%). The consultation characteristics of the patients are listed in Table 2. Consultations occurred at a median of 4 days from admission (IQR, 2–18 d) and a median of 2 days from initiation of ECMO (IQR, 1–6 d). In 2013, however, consultations occurred at a median of 10 days from initiation of ECMO compared with a median of 1 day by 2015.

Consultation Themes

There were 21 cases (46.7%) in which there was no specific ethical question identified by the treatment team or the ethics consultants. We identified two primary themes in the remaining cases. The first theme was needed for guidance in clarifying the patient's goals of care and the role of ECMO support. In these 11 cases, the ethics committee was asked to help develop a better understanding of how to assess the burdens and potential benefits of ECMO and what would be an acceptable quality of life for the patient. In one case, the patient himself relayed certain "'intolerable states,' which include permanent dialysis, prolonged life support, stroke and disability," to the ethics consultants. This conversation helped frame the later decision to withdraw ECMO when the patient had a progressive decline and lost decision-making capacity. In a second case, the ethics committee worked with the ECMO team to interpret a young patient's request to "not let me die" (as a result of viral cardiomyopathy) as the apparent burdens of ECMO intensified.

The second theme was disagreement about the ongoing use of ECMO, which included multiple axes: disagreement among health care providers, among surrogates, and between health care providers and surrogates over stopping or continuing ECMO. In contrast to the first category, in which the ethics committee was involved to help clarify the patients' goals of care in the setting of an uncertain benefit of ECMO, there was not consensus about which course—continuing or stopping therapy—would be in the patient's best interest.

There were two cases in which there was disagreement within the health care team. In both cases, the patients' nurses felt that a "technology imperative" was driving ongoing aggressive intervention despite the patient's progressive decline and suffering. This was particularly true for a patient awaiting lung transplant who required deep sedation to tolerate ongoing ECMO. In both cases, the ethics consultant's role was primarily to provide support to the nursing staff, helping to identify and discuss the source of their distress and to facilitate, where possible, conversations with physicians on the burdens of ongoing interventions.

There was one case in which there was disagreement between the patient's family members about whether to continue ECMO. The patient's wife believed that enough time had passed without neurological recovery after a cardiac arrest to believe that her husband would not want to continue ECMO. She noted, "He would not want to live in a state without awareness where he could not communicate or be active." The patient's parents, however, believed that not enough time had passed. The ethics committee was involved to help achieve family consensus, which was also very important to the patient's spouse.

There were two cases in which patients or their surrogates requested discontinuation of ECMO despite health care professional recommendations to continue. In one case, the request came from a patient who was started on ECMO as a bridge to lung transplant but whose anxiety and pain could not be controlled, leading her to request withdrawal of ECMO. When she fell into a state of diminished decision-making capacity, her husband began to reiterate her wishes. In the second case, the patient's sister, who focused on "how he liked to live his life," felt pressured to continue to consent for procedures and interventions such as dialysis once it became clear to her that he would not have the quality of life she believed he would want. In this setting, she began to discuss stopping ECMO.

There were three cases in which surrogates refused to accept recommendations to discontinue ECMO. In two of these cases, physicians determined that the patient was no longer a candidate for destination therapy and recommended stopping ECMO. One family refused this recommendation because of mistrust in the health care team. They suggested that their family member was not receiving the same level

Table 2. Consultation characteristics of ethics committee extracorporeal membrane oxygenation consultations

Characteristic	Data for 45 Total Consults
Time between admission and consultation, d, median (interquartile range)	4 (2–18)
Time between ECMO initiation and consultation, d, median (interquartile range)	2 (1–6)
Role of requestor	
Attending nurse	31 (68.9)
Attending physician	5 (11.1)
Nurse director or clinical nurse specialist	6 (13.3)
Staff nurse	2 (4.4)
Family	1 (2.2)
Additional reason for consultation (identified by requestor),* n (%)	
Request for moral support/affirmation of actions	37 (82.2)
Clarification of patient's values and preferences	14 (31.1)
Assistance with setting goals of care	12 (26.7)
Disagreement between clinicians and surrogates	4 (8.9)
Interpreting advance care planning documents	4 (8.9)
Disagreement among family members or surrogates	3 (6.7)
Disagreement among clinicians	3 (6.7)
Question about allocation or stewardship of resources	3 (6.7)
Team desired more care than patient or surrogate	1 (2.2)
Identification of appropriate surrogate	1 (2.2)
Consultation themes, n (%)	
Discussion of goals of care	11 (24.4)
Disagreement about ongoing use of ECMO	
Surrogate refused to stop ECMO	3 (6.7)
Disagreement among health team members	2 (4.4)
Disagreement among surrogates	2 (4.4)
Patient or surrogate request to stop ECMO	2 (4.4)
Other	4 (8.9)
No specific ethical issue identified	21 (46.7)

Definition of abbreviation: ECMO = extracorporeal membrane oxygenation.
*Multiple reasons allowed for each consult.

of intervention as other patients and that "necessary care [was] being withheld." The other family refused to withdrawal ECMO because they felt that their family member could still get better. They argued that he "would want to pursue therapy to prolong his life, and, if he had to go through a prolonged rehabilitation, that he would be 'disciplined' to work hard on his recovery." In the third case, physicians recommended stopping ECMO initiated because of progressive circulatory collapse. They argued that there was "very little chance of meaningful cardiac and more importantly neurologic recovery." The family felt that their loved one should continue ECMO to give him "every chance" of getting better.

A strong secondary theme in almost all of the disagreement cases was whether sufficient time had passed to decide whether a reasonable trial of ECMO had been attempted. For example, one surrogate felt that discussing stopping ECMO for her son who had biventricular failure and anoxic brain injury was premature. She argued that "[we] are 'in it for the long haul.' … [We] don't understand how people can 'give up' on him so quickly when he was 'just stabilized.'" In a case of disagreement between health care providers, one physician argued that enough time had passed to establish that there was only a "very small chance that the patient will improve to the point where he can [undergo a transplant]." Another physician, however, argued that "without catastrophic complications like stroke, or gut or limb ischemia, it is not appropriate to consider discontinuing mechanical support." Finally, in a case in which surrogates requested ECMO withdrawal when physicians felt that not enough time had elapsed, the patient's family believed that they already had enough evidence that treatment was "setting [the patient] up for a life of debilitating, chronic illness that he would not want."

Four cases involved themes that could not be categorized as easily. These included a case in which a delay in treatment potentially would contribute to the patient's need for ECMO and whether this would change the threshold for when to discontinue ECMO as the patient declined. A second case involved a patient who had survived ECMO and who was left chronically critically ill. Nursing staff and the patient's family were concerned about the fact that she had survived ECMO was changing the threshold at which refusal of other life-sustaining treatment was considered appropriate. In the third case, the ethics committee was asked to consider whether ECMO should be offered to a patient with a progressive postsurgical decline if he were to need it. The patient did not require ECMO support, but the ethics committee eventually assisted the family in deciding on other goals of care. Finally, a fourth case involved interpreting whether continuing ECMO was consistent with a patient's living will.

Ethics Committee Recommendations in Cases of Disagreement

In all cases in which surrogates refused to consent to stopping ECMO, ethics consultants framed their recommendations around the idea that ECMO was intended as a bridge to recovery. A consultant wrote, "The 'bridge' function of ECMO [sets it] apart from routine life sustaining treatments.… [ECMO] is instituted with the understanding that there must be an acceptable 'destination.'… When there is no acceptable destination, … it becomes a clinical decision to discontinue the therapy—not a patient or surrogate decision." References to a health professional's moral obligations were also common: "[P]hysicians and nurses cannot in good conscience continue treating a patient who is clearly at end of life, rather, they are obligated as a first ethical principle to 'do no harm,' which, in the case of [this patient], means allowing [him] to die with peace and dignity."

In cases in which surrogates requested to stop ECMO, ethics consultants generally recommended time-limited trials of ongoing treatments "with the inclusion of evaluation criteria against which the achievement of physiological milestones could be measured." Absent clear improvement, they suggested that "[the] team is ethically obligated to consider, advise and support

family in reevaluating goals of care to allow the patient to die with dignity." In cases in which there was disagreement among health care professionals or among family members, the ethics consultants urged all parties to focus on what the patient would want while acknowledging the limits of prognostication for novel therapies such as ECMO. They wrote in one such case, "[I]t is a complex process, fraught with uncertainty, to establish consensus about prognosis, particularly as we gain familiarity [with] observed clinical outcomes, and to integrate values and preferences of the patient to come to a decision."

Discussion

Increased use of ECMO in adults has been accompanied by a parallel conversation in bioethics about ethical challenges in this population. The majority of this literature has been focused on potential novel ethical dilemmas. We report on the actual experiences of an ethics committee in a large ECMO referral center where physician, nursing, and ethics leadership made a conscientious decision to have ethics consultants routinely involved as the ECMO program expanded. We found that, rather than novel ethical dilemmas, the majority of consults involved very similar questions—including various permutations of disagreement between patients, surrogates, and health care professionals—posed in ethics consultations about other life-sustaining treatments (15).

There were no cases in which the ethics committee was asked to comment specifically on the role of CPR in an ECMO patient, nor were there consults about whether ECMO should be an option for periarrest patients as imagined with extracorporeal CPR. The latter cases likely occurred in time-pressured situations in which ethics consultation was not immediately available. As such, the ECMO team relied on a multidisciplinary consensus in assessing these patients, in accordance with consensus and institutional guidelines on ECMO candidacy (16). Similarly, there was only one case in which the ethics consultants were explicitly involved in a discussion of a patient's candidacy for ECMO, although members of the ethics committee were involved in the broader organizational discussion of absolute and relative ECMO contraindications.

Even the cases that could be interpreted as being about patients "stranded" on ECMO bore a closer resemblance to common ethics consultant cases about the role of providing ongoing interventions such as mechanical ventilation that are merely sustaining life in patients with irreversible underlying diseases (17, 18). Importantly, there were more references to the "bridge" role of ECMO in ethics consultant recommendations than are typical in our center, suggesting that consultants agreed with the broadly accepted though potentially controversial argument that ECMO is not a destination therapy (17).

In cases where ECMO was a bridge to recovery, however, the ethics consultants did not distinguish it from other life-sustaining treatments that are also aimed at recovery, such as tracheostomy for a patient with slow-to-resolve acute respiratory distress syndrome (19). Although the patients in our cohort were relatively healthy at the time of admission and had few comorbidities, ECMO was never the sole life-sustaining treatment. Most patients needed multiple life-sustaining treatments, with half requiring tracheostomy or dialysis and almost one-fifth requiring permanent feeding tube placement. This suggests that ECMO is part of a package of interventions, an aspect that may be important to clarify with patients and surrogates during the consent process (20).

In contrast to other life-sustaining treatments such as mechanical ventilation, where there is a large literature on using advance care planning to help avoid nonbeneficial treatment, there were fewer "upstream" points during which a clearer conversation may have avoided disagreement about ongoing ECMO support (21). ECMO was typically initiated in a time-sensitive manner, leaving little room for a sustained conversation about "stopping conditions" or acceptable duration of a time-limited trial from the patient's perspective. Early clarification, however, about acceptable functional outcomes following ECMO may be helpful in contextualizing later changes in the patient's clinical trajectory.

We note that, despite a commitment to routine ethics consultation, it took over 1 year to reduce the consultation time to within 48 hours of ECMO initiation. By 2015, however, more than 90% of ECMO patients had an ethics consult.

Unsurprisingly, given the initial consensus that nurses would contact the ethics committee with new consults for ECMO patients, the majority of consults came from a member of the nursing staff. As other authors have suggested, however, the burdens of providing interventions believed to be nonbeneficial fall more heavily on "bedside" health professionals such as nurses (22). This appears to be particularly true in the case of ECMO, in which nurses appeared more willing to raise the possibility that the burdens of continuing ECMO were intensifying. Navigating the moral distress of bedside providers is an essential part of the ethics consultation process and involves helping to formulate specific ethical concerns and, where appropriate, facilitating a discussion between all members of the health care team about those concerns (23, 24).

Somewhat surprisingly, we found that the majority of disagreements about continuing ECMO were less about whether the treatment was more burdensome than beneficial but whether enough time had passed to decide that the patient had had a reasonable trial of ECMO. The epistemic focus of these disagreements emphasizes the importance of clear initial communication about identifying milestones that suggest appropriate progress. In cases in which clinicians and ethics consultants recommended withdrawing ECMO despite surrogate demands, the consultants were able to rely on a broader institutional policy about limiting or not offering nonbeneficial treatment despite surrogate requests (13). Although the policy was not formally invoked in any case, ethics consultants noted the availability of the policy in several cases if consensus could not be reached. Having a policy for clinician-guided limitation of life-sustaining treatment in combination with setting clear expectations may have helped avoid cases of intractable conflict as some authors have described (25).

Finally, in more than half of cases, ethics consultants identified and addressed a specific ethical issue, including clarifications of goals of care that helped shape later clinical trajectories. This suggests that treatment teams may underappreciate the frequency with which ethical questions arise in the use of a new life-sustaining treatment. Having ethics consultants routinely involved also allows them to develop a better

understanding of the range of possible outcomes with this technology, which is particularly important when they are called for cases in which there are concerns that the burdens of treatment are intensifying.

Limitations

Our study has several limitations. First, MGH has a large and active ethics committee and was able to provide the requested routine consultations. Hospitals with smaller committees may not have the resources needed to expand beyond consultations in which there is a specific ethical concern. Second, because the ethics consults did not become truly routine until the last year of the study, we do not know if there were cases that the ethics consultants did not review but that involved specific ethical concerns. Third, because our aim in this article was to describe our routinized approach to ethics consultation and ECMO in the CSICU, we did not capture every MGH ECMO patient, such as those in the medical intensive care unit, during the study period. Fourth, we did not capture quantitative survey data from clinicians and surrogates about the helpfulness of ethics consultations, although we believe that the continued existence of the program suggests that clinicians find some utility in ethics involvement.

Conclusions

In this single-center experience, routine integration of ethics consultation into the care of ECMO patients revealed that most of the ethical questions involving ECMO more closely resembled traditional concerns about the appropriate use of any life-sustaining treatment rather than the novel dilemmas imagined in the current literature. Future research should be focused on prospective survey studies to quantify the impact of this type of collaboration on surrogates, clinicians, and ethics consultants. ■

Author disclosures are available with the text of this article at www.atsjournals.org.

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