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Ethical Dilemmas in Extracorporeal Membrane Oxygenation (ECMO)

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By

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M.D., Virginia Commonwealth University/Medical College of Virginia, 2005

Advisor: Kathy Kinlaw, M.Div.

An abstract of a thesis submitted to the Faculty of the James T. Laney School of Graduate Studies of Emory University in partial fulfillment of the requirements for the degree of Master of Arts in Bioethics in 2021

Abstract

The ethics of medical decision making can be complex. Modern medicine has the ability to keep patients alive for extended amounts of time on maximal support. One such technology that is being used with increased frequency is Extracorporeal Membrane Oxygenation (ECMO). ECMO is a potentially life-saving technology that is used to provide artificial cardiac and pulmonary support to patients. ECMO use in the United States in on the rise, since 2006 there has been a 400% increase in the use of ECMO in intensive care units (Mosier, 2015). According to the Extracorporeal Life Support Organization **(**ESLO) registry, ECMO was used in over 5,000 cases in 2014 (Makdisi, 2015). This substantial increase of patients treated with ECMO and the expansion of indications for its use raises many questions about the use of ECMO some of which will be surveyed in this paper (Makdisi,2015). It should be noted that ECMO is supportive therapy, meaning that it acts to sustain life and that it does not necessarily cure the underlying pathology.

Over the last 50 years, medical technology has outpaced the understanding of most patients and their families; yet they are the primary decision makers. This presents ethical dilemmas for patients, surrogates, and health care teams; many of the dilemmas that ECMO poses are novel in that they are specific to this technology. My thesis approach will involve identifying ethical dilemmas that arise in caring for ECMO patients. My recommendations will involve creation of an ECMO Physician Orders for Life Sustaining Treatment (ECMO-POLST) and rigorous use of ethics committees prior to the initiation of treatment and throughout the patient's trial of ECMO. In instances in which extraordinary care or newer medical technologies are being used, a different approach is required in order to mitigate ethical dilemmas and provide quality care for patients.

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Yours,

Michele
2021

TABLE OF CONTENTS

Appendix: Figures/Forms

Abbreviations

AATS - American Association for Thoracic Surgery

AMA - American Medical Association

ARDS - Acute respiratory distress syndrome

CCPR- Conventional cardiopulmonary resuscitation

CESAR – Conventional ventilatory support vs extracorporeal membrane oxygenation for severe adult respiratory failure

CO2 - carbon dioxide

COVID 19 - Coronavirus 19

CPB - Cardiopulmonary Bypass

EACTS - European Association for Cardio-Thoracic Surgery

ECMO - Extracorporeal Membrane Oxygenation

ECPR – Extracorporeal Cardiopulmonary Resuscitation

ELSO - Extracorporeal Life Support Organization

ICU - Intensive Care Unit

QALY - quality adjusted life years

PEA - pulseless electrical activity

POLST - Physician Orders for Life Sustaining Treatment

STS - Society of Thoracic Surgeons

VAD - ventricular assist device

V-A ECMO - Veno-Arterial Extracorporeal Membrane Oxygenation

V-V ECMO - Veno-Venous Extracorporeal Membrane Oxygenation

CHAPTER I: INTRODUCTION AND EVOLUTION OF ECMO

Medicine has made major strides in technological advancement and has the ability to keep patients alive longer than previously anticipated. Although these advances have some positive effects on healthcare, they have also required physicians to reevaluate goals of medicine and present many new ethical challenges. One such example of a medical advancement that is becoming more commonplace at most major academic centers is Extracorporeal Membrane Oxygenation (ECMO). Many patients now have the ability to survive illnesses and injuries that would have been insurmountable years ago as a result of such technology. In instances in which advanced technology is being used, a delicate balance of multiple medical ethical principles must often occur in order to provide appropriate medical care. Modern medical care, especially those that involve heroic efforts such as ECMO, sometimes present the following ethical problems:

- Moral distress
- Resource Allocation
- Decision Making Quandaries
- Informed Consent
- Appropriateness Extracorporeal Membrane Resuscitation (ECPR)

As medicine, its technology and possible interventions continue to progress, the medical field will have to solve the ethical problems that accompany such advancements.

Extracorporeal Membrane Oxygenation has dramatically evolved over the last 40 years. ECMO is a potential life-saving technology that is used to provide artificial cardiac and pulmonary support to patients. This technology is usually reserved for patients who have severe cardiac and or pulmonary disease that is refractory to traditional treatment (Makdisi, 2015) . As ECMO technology has improved over the last 40 years, so has its use and indications in patients.

Use of ECMO is drastically increasing. In in 2014 the ELSO reported that ECMO was used in over 65,000 cases internationally (Makdisi, 2015). ECMO use in the United States is on the rise. Since 2006 there has been a 400% increase in the use of ECMO in intensive care units and an increase in the number of ECMO centers, see figure 1 (ELSO annual report 2020, Mosier, 2015). The Extracorporeal Life Support Organization (ELSO) is the nonprofit multidisciplinary international organizational body that maintains a registry for use of ECMO at medical centers, supports research and creates guidelines for use of ECMO. According to the Extracorporeal Life Support Organization (ESLO), ECMO was used in over 133,000 cases internationally in 2020 with 52% of patients surviving to discharge or transfer to another facility, see Figure 2 (ELSO annual report, 2020). This technology has even been widely used in the treatment of patients with COVID-19 during the current global pandemic. This substantial increase of patients treated with ECMO and the extension of indications raise many questions about the use of this technology to treat critically ill patients (Makdisi, 2015).

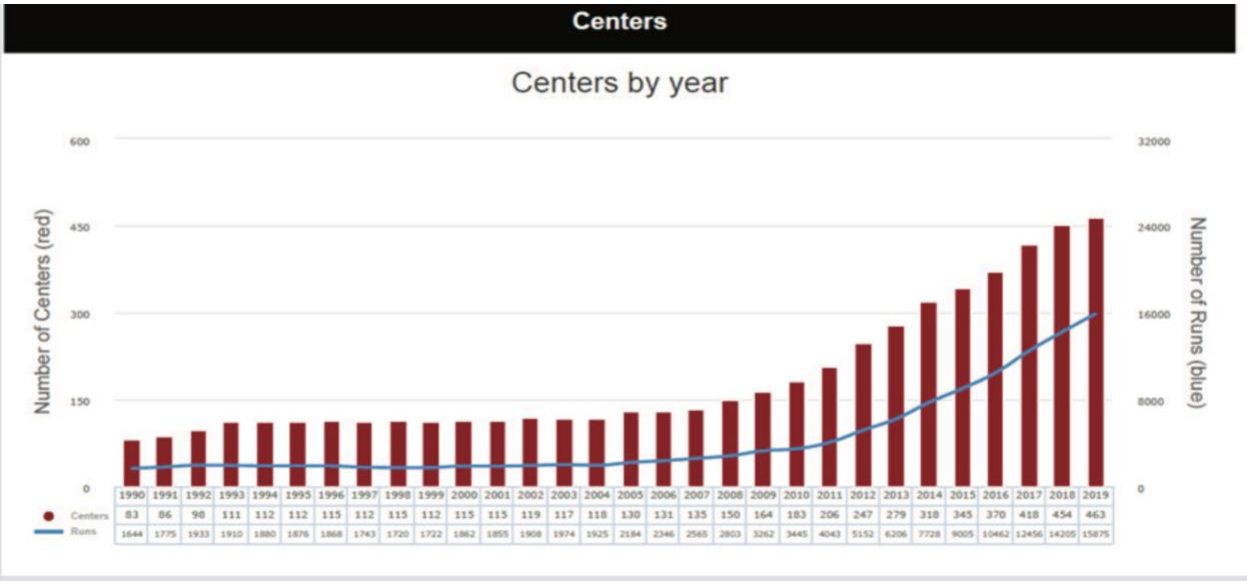

Figure 1: The number of centers contributing to the ELSO registry and cases per year (ELSO annual report, 2020)

Overall Outcomes from 2015 to Present					
	Total Runs	Survived ECLS		Survived to DC or Transfer	
Neonatal					
Pulmonary	4,072	3,361	82%	2,781	68%
Cardiac	2,574	1,837	71%	1,293	50%
ECPR	811	553	68%	359	44%
Pediatric					
Pulmonary	3,502	2,656	75%	2,321	66%
Cardiac	4,651	3,534	75%	2,756	59%
ECPR	2,350	1,344	57%	1,007	42%
Adult					
Pulmonary	17,460	12,211	69%	10,795	61%
Cardiac	20,055	11,931	59%	9,062	45%
ECPR	6,528	2,714	41%	1,948	29%
Total	62,003	40,141	64%	32,322	52%

Figure 2: Recent ECMO outcomes for all patient subgroups (ELSO annual report, 2020)

Basic Principles of ECMO

The basic concept and goal in the use of ECMO is the successful gas exchange of both oxygen and carbon dioxide (CO2). Oxygen exchange across the membrane oxygenator is determined by several variables including thickness of blood film, membrane material, fraction of inspired oxygen, and blood level; carbon dioxide exchange is based mostly on surface area, blood flow, and the gas flow rate (Allen, 2011). The role of the membrane oxygenator is the basis of ECMO and has been the source of complications as well as many improvements of the technology. There are two types of ECMO, Veno-Arterial (V-A) ECMO and Veno-Venous (V-

V) ECMO. V-A ECMO provides respiratory and cardiac support (Makdisi, 2015). Patients are usually placed on V-A ECMO for severe cardiac failure with or without concurrent respiratory problems, whereas V-V ECMO is reserved for those with isolated respiratory failure. During V-A ECMO, blood is drained from a vein and bypasses both the heart and lungs. The blood is oxygenated and carbon dioxide is removed and then sent back to the patient via an artery. Put simply, in this instance ECMO functions as the patient's heart and lungs. Initiation of V-V ECMO blood involves blood being drained from a patient, sent to the ECMO machine, oxygenated and carbon dioxide removed and returned to the patient via a vein. Stable hemodynamics are required for V-V ECMO. It should be noted that ECMO has the ability to act as the patient's heart and/or lungs, meaning that it is supportive care and that it does not treat the underlying pathology.

History of Extracorporeal Membrane Oxygenation

The theory that artificial oxygenation and perfusion can be used to support a patient during a heart operation was first used by Dr. John Gibbon in 1953 when he performed the first open heart surgery using cardiopulmonary bypass (Vuylsetke, 2017). Extracorporeal membrane oxygenation can be viewed as an extension of cardiopulmonary bypass, although there are differences between the two. Other pediatric cardiac surgeons furthered the work that Gibbons performed. Initial use of ECMO in 1970, by Dr. Thomas Baffes, was primarily in infants with congenital heart defects (Makdisi, 2015). Use of ECMO in adults occurred the following year in the setting of a trauma. After a motor vehicle accident, the first adult patient who was placed on ECMO for three days in 1971 survived (Vuylsetke, 2017). Use of this technology without clinical trials led to many questions regarding safety and efficacy and the medical community realized that a research trial was necessary. In 1979, the results from the first National Institutes

of Health trial were published, and the results showed a 10% survival rate in patients placed on ECMO (Zapol, 1979). The patients in the study had the same survival rate as those treated with the conventional medical treatment of the time (Zapol, 1979). Although initial research failed to show any real benefit of V-V ECMO in patients with respiratory failure over conventional treatment modalities, many centers in the United States and Europe, continued to use ECMO as last resort with promising results (Makdisi, 2015).

In 2006, the CESAR trial was published. The aim of this randomized controlled trial was to assess whether, for patients with severe, but potentially reversible respiratory failure, extracorporeal membrane oxygenation would increase the rate of survival without severe disability. Severe disability was defined as inability to dress or bathe and confinement to bed. Patients were randomized to 2 groups; an ECMO group and conventional ventilator group. Trial aim was to assess whether severe disability occurred six months post randomization, and whether ECMO was cost effective compared to conventional ventilator support (Peek, 2009). The results of this trial showed a decrease in severe disability 6 months after randomization, dropping from 63% to 47%, for patients with severe respiratory failure treated with extracorporeal support (Mao, 2016). The presence of the CESAR trial was associated with significant increase in the utilization of ECMO in clinical practice and in the research activities related to ECMO (Mao, 2016). Moreover, the indications for the use of ECMO have been greatly expanded and it has since been used in patients of older age and that have higher comorbidities (Mao, 2016).

Technological Advancement in ECMO and patient care

With the increased use of Extracorporeal Membrane Oxygenation globally, technological advances have occurred which ultimately decreased complications and improved overall patient

safety. Although the basic fundamentals of ECMO have not changed over the last 30 years, the technical elements continue to improve and have evolved from an assemblage of individual components to more integrated systems with added features, enhanced safety, and improved maneuverability (Betit, 2018).

ECMO systems have also become more integrated making transport of patients between facilities easier and safer (Betit, 2018). Many of the advancements have allowed for an expansion of the indications for the use of ECMO, including for patients awaiting lung transplantation (Betit, 2018). The change in the use of ECMO to longer term support has prompted a different approach to the clinical management of these patients, including weaning from mechanical ventilation, ambulation, and other rehabilitative care (Betit, 2018).

ECMO Candidacy

Similar to how extracorporeal membrane oxygenation technology has evolved since its advent, so has its use and who is considered a candidate for such care. Traditional criteria for ECMO use have evolved into a broader use of the technology as a final effort to save a life, often times without consideration of the consequences. Again, ECMO is supportive therapy, not curative. It is indicated for those with cardiac or respiratory failure or a combination of both. From an ethical standpoint prior to institution of ECMO, consideration should be given to the likelihood of patient recovery as well as the length of time that ECMO will be provided to the patient before discontinuing the use of ECMO (Allen, 2011). One of the most common indications for V-A ECMO for cardiac failure is failure to wean from cardiopulmonary bypass after cardiac surgery (Allen, 2011). Other instances in which V-A ECMO may be indicated is primary graft/organ failure after a heart transplant, cardiogenic shock as a result of acute

coronary syndrome/myocardial infarction, myocarditis, and decompensated cardiomyopathy (Allen, 2011). Although serious deliberation should occur prior to the initiation of ECMO in regard to whether or not the current status of the patient is reversible, there are instances in which a patient may be an ECMO candidate when their organ failure is considered irreversible. For example, ECMO may be used in patients with irreversible heart failure as a bridge to transplant (Allen, 2011).

Indications for V-V ECMO in respiratory failure include adult respiratory distress syndrome, primary graft/organ failure after lung transplantation, and trauma. Historically V-V ECMO as a bridge to lung transplantation was considered controversial due to poor outcomes (Allen, 2011), however many centers are using ECMO as a bridge to lung transplant. The duration for treatment with ECMO is typically 2 weeks with most centers discontinuing if patient condition does not improve. Oftentimes limits are pushed, with the hopes of patient recovery. There have been case reports of patients surviving on ECMO for up to 8 weeks in cases where infection was the indication for the intervention, but that is the exception (Tanaka, 2017). The primary reason for the change in thought and acceptability is continued research in the area of ECMO and improvements in technology. Over the past 20 years, outcomes in patients who are bridged to transplant have improved. Hayanga et al showed that in 2000-2003, the 1-year survival rate after ECMO bridging to lung transplantation was 25% with survival increasing to 74% from 2009-2011 (Loor, 2017). Decisions to initiate ECMO as a bridge to lung transplantation should involve a multidisciplinary team in order to consider realistic endpoints, management goals and expected outcomes (Loor, 2017).

V-V ECMO for respiratory failure has also found utility in the treatment of COVID-19. COVID-19 can lead to acute respiratory failure necessitating ICU admission and mechanical ventilation; it can further decompensate into acute respiratory distress syndrome (ARDS) causing very low blood oxygen levels and death (Schmidt, 2020). Although experts initially recommended ECMO for critically ill patients after the initial outbreak in China, survival rates were low in the initial Chinese case series of ECMO treated COVID-19 patients and many questioned the utility of ECMO in this patient population (Schmidt, 2020). Schmidt et al performed a retrospective cohort study to assess outcomes in patients who were placed on ECMO as part of their COVID-19 treatment. Unlike previous studies, Schmidt and his colleagues found that the estimated 60-day survival of patients placed on ECMO with COVID-19 was similar to the data published for the last 2 years on ECMO use in patients with severe ARDS; they concluded that ECMO should be considered in patients developing refractory respiratory failure despite optimized care (Schmidt, 2020).

ECMO alternatives

There are no alternatives to ECMO. At the point in which a patient is being considered for initiation of ECMO, all other treatment modalities have usually been explored. In instances in which a patient is being considered for V-A ECMO due to cardiac failure, maximum medical or surgical management has already been explored. Treatments prior to consideration of ECMO range from inhaled, oral, and intravenous medication optimization to surgical considerations regarding ventricular assist devices (VADs). VADs are mechanical devices that may be implanted surgically or inserted percutaneously to assist the heart with perfusion of the rest of the body. In patients that become candidates from V-V ECMO as a result of respiratory failure,

the patient has also been optimized medically. This usually involves supplemental oxygen, inhaled and intravenous medications, mechanical ventilation with optimized ventilator settings, and patient positioning to improve gas exchange. ECMO is the last resort, rather than a first line therapy. The one alternative that does exist though is not to initiate ECMO.

Complications

There are a large number of complications that can occur as a result of initiating ECMO in patients. Complications can be related specifically to the type of ECMO that is being used (V-A ECMO vs V-V ECMO), ECMO itself, or the patient's underlying condition (Makdisi, 2015). The most common complication related to ECMO is hemorrhage. Aubron et al reported an incidence of hemorrhage of 34% and 17% in patients on V-A ECMO and V-V ECMO, respectively (Makdisi, 2015). Thrombus is another devastating complication that can occur. Although ECMO has the ability to act as the heart and or lungs, the circuit does introduce a foreign object into the body which puts the patient at risk for infection and sepsis. Due to the many risks and complications that can occur as a result of managing patients on ECMO, it is paramount that they all are explored with the patient and/or family prior to instituting therapy.

ECMO is a relatively new and extraordinary technology that can be used to prolong life. Patients can be kept alive for almost a month on this support, hoping that the body recovers. One consideration that should be closely evaluated is whether or not constraining the use of ECMO by limiting its uses to only patients with a high probability of recovery stifles medical advancement. It is possible that this extraordinary technology will one day be considered the standard of care. This is compelling because at one point in time most treatments were considered extraordinary or experimental. Some of the most profound medical discoveries

involve biotechnology, and pharmaceuticals. Unlike many of these advancements mortality rates in ECMO patients have not drastically decreased over the last 45 years, and the widespread use of ECMO should be questioned. All technological and pharmaceuticals go through a growth period in which unexpected complications may occur, but the expectation is that the majority of patients will receive therapeutic benefits from the treatment. The argument can easily be made that this device is simply delaying the inevitable in critically ill patients, which calls into question prevalent use of the technology and further highlights many ethical dilemmas that arise.

CHAPTER II: ETHICAL DILEMMAS- MORAL DISTRESS

Case: A 41-year-old man with a history of non-ischemic cardiomyopathy presents to the hospital in cardiogenic shock that is refractory to medical management. A decision is made to initiate V-A ECMO. The patient was listed for a heart transplant. While awaiting transplantation, the patient experienced multiple complications including multiple strokes and pneumonia. During his ICU stay his conditioned waxed and waned. At times he was extubated, and ate and experienced lucidity while at other times he was being taken to the operating room for multiple procedures. The patient was on ECMO for 92 days and ultimately the decision was made by the family to withdraw care and the patient died.

Analysis: Instances in which patients are on ECMO for a protracted period of time and with a constantly changing prognosis stresses patients and their families, the hospital system and the healthcare team. The toll that caring for ECMO patients places on healthcare workers is often overlooked.

Ethical dilemmas often lead to moral distress for healthcare workers and new technologies such as ECMO can exacerbate this problem. The perspective and impact that caring for patients on ECMO may present to medical providers is not always considered. Andrew Jameton defined moral distress as occurring in situations in which one recognizes a moral problem, but is constrained from acting on it or resolving it (Jameton,2017). This term is used when distress occurs as a result of experiencing intimate pain during care of the dying, constraints from proximate and background challenges of health care organizations, and changing perspectives on therapeutic technologies derived from global environmental perspectives (Jameton, 2017). Most of the literature that has addressed moral distress in healthcare workers has come from nursing studies, and those that look at moral distress in

physicians is somewhat scarce (Dzeng, 2016). Also, there have been a few recent studies that have examined moral distress in physician trainees. With a few exceptions the outcomes from nursing and physician trainee studies can be extrapolated to other members of the healthcare team.

Medical Futility

Asayesh et al studied the relationship between futile care perception and moral distress among intensive care unit nurses (Asayesh, 2018). In this case, futile care was defined as an instance in which therapeutic care goals are not attainable and certain medical actions are considered ineffectual. This study used a futile perception questionnaire that included 17 statements that assessed the nurses' perceptions of futile care based on frequency and severity. Asayesh found that there was a positive correlation between nurses experiencing a high level of moral distress and perceived delivery of futile care (Asayesh, 2018). Another quantitative review of the nursing literature found that many nurses experience moral distress associated with difficult care situations and feel burnout, which can have an impact on their professional position (Oh, 2015). Williams (Williams, 2016) cites a review of nursing studies in which Browning asserts that perceived medical futility is the most common phenomenon causing moral distress in critical care nurses; although her review focused on ventilator support as the form of futile treatment, one might hypothesize that this can be extended to ECMO as well. Williams argues that many patients on ventilators at the end of life and many ECMO patients have in common the perceived qualities of failure to thrive, lack of benefit from treatment and enduring suffering which allows for application of Browning's results in ECMO patients (Williams, 2016).

Dzeng et al (Dzeng, 2015) performed a qualitative study that examined moral distress amongst American physician trainees in end of life settings. The results of this study showed

that trainees experienced significant moral distress when they were obligated to provide treatments that they believed to be futile or harmful (Dzeng, 2015). In a commentary, Dzeng further addresses moral distress amongst physicians and uncertainty regarding new life sustaining technologies. She acknowledges that there is much uncertainty around ECMO, particularly in regard to the futility of care and the definition of death. An intensivist that she interviewed described a clinical situation involving the care of an ECMO patient:

> "So, I'm sure that I have a dead patient on ECMO, but the pump still flows. They may be asystolic…so you have a patient on ECMO…who you are almost certain has an anoxic injury with cerebral edema, but you can't do a brain exam on them because you can't do an apnea test, because they're on an ECMO circuit. So, declaring brain death on a patient on ECMO is one of the hardest things…Ultimately what it took was, we consulted ethics, and basically we had to…write notes that we believed the patient was clinically dead, which was the weirdest thing to write. Based on what? It probably went on for 48 hours longer than it should have because we were like, 'this is such a weird situation, what do we do with this?'" (Dzeng, 22)

The concerns around defining brain death on ECMO patients is well documented. The intensivist further stated:

> "I think what probably bothered everybody most …is that final 48 hours where we took it too far, that we didn't call it sooner. I think that's probably a failure to diagnose death…the distress and what makes people walk away not feeling good about what we do. It's that we put people through for all of this, for LVADs, for

> ECMO, that we push it too far. I think that's what weighs our nursing staff…we lose nurses from this ICU unlike any other area…" (Dzeng, 23)

Wirspa et al examined the use of ethics consultations to mitigate ethical conflict and moral distress in ECMO patients. In this study they found that care teams experienced distress over possible harm being caused in patients on ECMO. They found that members of the care team, including nurses, advanced practice providers (APPs), and fellows, all referenced the effects of ECMO as a source of distress. These effects included amputations, dyspnea, and anxiety for awake and alert patients on ECMO. One nurse in the study stated

> "everything we did just caused more complications…like losing your limbs or having a stroke or coding. I question, what are we actually doing? Are we treating this person like a human being or is (the patient) becoming a lab experiment?" (Wirspa, 4).

Carolina Jaramillo and Nicholas Braus, a medical student and critical physician respectively, acknowledge that caring for patients on ECMO is morally distressing and challenging and sited an observational study in a neonatal ICU to support the claim. The study describes a phenomenon known as the "residue effect" in which any stress or negative feelings experienced by a provider caring for a critically ill patient can be transmitted to the care of other patients and their colleagues (Jaramillo, 2019).

Physicians often have their own perceptions about when they are providing futile treatment, but it is often difficult to deescalate care once it has been initiated. For many physicians, concerns about futile care arise when the treatments that are being provided are not therapeutic and may even be harmful to the patient. One may ask why physicians offer such treatment if they believe they are futile, and the reasons vary. The most common reasons include patient's/family members' request, provider beliefs, and fear of litigation (Aghabarary, 2016).

One study found that the best predictor of prolonged and expensive ICU care in patients from whom survival was unlikely was medical record documentation of unrealistic family expectations (Swetz, 2014).

One retrospective study reviewed the medical records of patients for whom surrogates and medical team requested that the patient be withdrawn from ECMO; 53% of patients died within 24 hours of separation from ECMO (DeMartino, 2019). The median ECMO duration in this study was 6 days and the longest duration was 138 days. These results confirm that over half of the patients were being kept alive solely because of the use of ECMO, in other words these patients were dependent on ECMO support to sustain life . Although some patients have a positive outcome after being supported with ECMO, those that do not improve or worsen often require withdrawal of care. Most medical providers would define futile treatment as a treatment that has a low likelihood of providing a meaningful quality of life. A treatment may be deemed futile as a result of the treatment itself or the current status of the patient.

Although medical providers may have a general sense of when a treatment may be considered futile, there is not a clear definition of futility, which becomes challenging when counseling families and patients. In cases of disagreement regarding treatment plans, the fact that there is no clear definition of medical futility increases the complexity of decision making for physicians and families and further contributes to moral distress. There is currently no agreement by the major medical associations as to how to define futility. The terms "reasonable," "meaningful", and "certain" have all been used by various organizations to describe the expected recovery in cases where futility is a concern (McCabe,2008). These attempts to define futility are very vague and can increase confusion in regards to medical decision making.

One bioethicist, Lawrence Schneiderman, divides futility into 2 categories, qualitative and quantitative. He defines quantitative futility as treatment capable of producing a desired result, but unlikely to do so in a particular instance; and qualitative futility is defined as a treatment that may achieve a certain result, but it is a result that lacks value in that situation (Schneiderman, 2011). These definitions are helpful because they actually put the idea of futility in context. Although there is not a consensus on a definition, the literature has found that most of the definitions are based on the probability of achieving a physiological effect or goal, the amount of benefit and utility an intended treatment has for a specific patient, survival rate of intended treatment, post treatment quality of life, and cost effectiveness of treatment (Aghabarary, 2016). Although it is important that physicians are clear with patients and their families regarding individual treatment plans and the goals of ECMO, it can be a challenge considering the difficulty with predicting outcomes in this patient population. Aghabarary argues that these goals are in fact the most fundamental component of the definition of futility because treatments must be balanced against the intended goals for the individual patient.

The lack of clear definition is not the only problem with futility. Futility takes its toll on all parties involved, not only the patient. The pressure that can be placed on healthcare providers by families can be overwhelming. Medicine has become complex and many interventions like ECMO can be difficult to explain to patients and families especially when concerns for futility arise. Aghabarary asserts that medical futility causes suffering for patients and families, contributes to physician burnout and low morale, puts other patients at risk by diverting resources, and presents a financial burden to patients and families, healthcare systems, and society in general (Aghabarary, 2016).

The American Medical Association (AMA) recommends that all institutions regardless of size, adopt a policy on medical futility and define steps to consider regarding futile intervention and fair decision-making. The AMA also states that evaluation of medical futility includes joint decision-making, negotiation of disagreements, potential to escalate a consultation within institutional ethics committees for resolution, support for potential to transfer care to a different physician or transfer to an alternative institution to resolve conflicts regarding defining futile intervention with medical technology (AMA code of ethics). A joint policy statement with The American Association of Critical Care Nurses, American Thoracic Society, the American College of Chest Physicians, the European Society for Intensive Care Medicine, and the Society for Critical Care Medicine are in agreement with the AMA's evaluation of medical futility policy and have similar recommendations (Williams, 2016). The problem is that without a clear definition of medical futility, providers will continue to experience moral distress. Most cases involving ECMO are considered on a case by case basis, but the uncertainty of medical outcomes in these patients often complicate treatment plans, cloud family expectations and lead to ethical dilemmas.

Balancing Principles

Healthcare providers are constantly balancing the ethical principles which is another source of moral distress. In addition to respecting a patient's autonomy, physicians must balance the principles of beneficence and non-maleficence. As defined by Beauchamp and Childress, beneficence means a physician should do what is best for the patient; while non-maleficence describes the act of doing no harm. Although the concept and importance of autonomy has evolved and is often the primary influence in decision making, the interpretation of the definitions of beneficence and non-maleficence have remained relatively unchanged. A patient

on ECMO may have frequent changes in their overall status and the perceptions of beneficence and non-maleficence in regard to a patient often change as one's hospital course progresses which leads to further uncertainty regarding decisions being made. One study assessed the perception of critical care physicians caring for the critically ill, and it reported that 80% of physicians sometimes felt that they were trying to save those that could not be saved; while only 8% thought they were giving up too soon (Carter, 2017). Although survival rates for those who are placed on ECMO are roughly 53%, other concerns include decreased function, and overall quality of life outcomes after hospital discharge (Carter, 2017). What may be perceived as beneficence initially, often develops into maleficence albeit unintentionally. The harm that may occur may not only be physical for the patient, but also mental, psychological, and familial. Even if the patient's condition may change over time, the two principles must be considered together with the overarching goal being to produce net benefit over harm (Gillon,1994). In order to ensure that patients are being offered maximum net benefit, care must be individualized to each patient, risk and benefits must be assessed and interventions only offered to those with the best chance of recovery (Gillon, 1994). There is always the question of what net benefit to a patient is, because it is relative. Continued research in the area of extracorporeal membrane oxygenation will allow for better assessment of possible candidates and both their short and long-term prognosis.

The literature points to multiple other causes of moral distress including delayed end of life discussions and delayed or poor decision making, medically inappropriate care, poor communication during notification of neurologic death, health disparity cases, and grieving family members; all of which can contribute to medical futility (Rosenthal, 2017).

CHAPTER III: ETHICAL DILEMMAS: RESOURCE ALLOCATION

Case: A 38 y/o woman with cardiomyopathy presented with acute exacerbation of heart failure and hypotension refractory to medical treatment. She underwent VA ECMO cannulation and was listed for a heart transplant. Her hospital course was complicated by multiple hemorrhagic episodes. She underwent 15 operative procedures. After over 4 months of support she had an acute deterioration in neurologic status and the decision was made to withdraw care because she was no longer considered a transplant candidate. She was supported on ECMO for 138 days (DeMartino, 2019).

Analysis: This patient had a prolonged trial of ECMO. Although the primary decision to initiate ECMO was justified and an appropriate treatment, her hospital course dictated a change in her care goals. The question remains whether or not care should have been withdrawn sooner considering her complications. This case highlights questions resource allocation and costs.

Resource allocation.

Another trigger of moral distress is poor allocation of resources and perceived justice or lack thereof in the care of ECMO patients. There is always the concern that if scarce technology is being used in an ineffective manner that resources are being directed away from others that may benefit. This is a concern in patients being treated with ECMO. These patients are required to be in the ICU. If in fact they are receiving futile care they are using an ICU bed and other resources that could be used by another patient. Poor allocation of resources refers to not only medical technology and hospital beds, but also personnel and time. ECMO centers and teams that are qualified to care for patients on ECMO are limited. If patient selection and ongoing care is inappropriate and futile, these resources are likely best diverted to other patients. Kirsch,

a neonatal intensivist and bioethicist endorses the following considerations for just resource allocation including fairness in apportionment and access, potential for undue benefit or harm, and protection of vulnerable persons from exploitation or exclusion from benefit (Kirsch, 2018). Lack of consideration of appropriate resource allocation may intensify the moral distress discussed in the previous chapter.

Justice must be considered in the care of ECMO patients. Ethicist Raanan Gillon often divides justice into three categories; distributive justice which is the fair distribution of scarce resources, rights-based justice or respect for other's rights, and legal justice which is respect for morally acceptable laws (Gillon, 1994). Although ECMO was first used in the 1970s, it is still a relatively new technology and a scarce resource. There are only a few hundred ECMO centers in the United states, and each has a limited number of ECMO equipment and personnel (Kukora, 2016). The lack of readily available access to ECMO and mediocre outcomes often leads to a debate about how this resource should be allocated. Healthcare systems must develop policies that take resource allocation into consideration. One determinant in appropriate allocation requires assessment of cost-effectiveness; calculation of quality adjusted life years (QALY) saved has been used in some assessments of ECMO cost effectiveness, but it should be noted that quality adjusted life years requires some subjective reasoning. Kirsch admits that studies done comparing outcomes with utilization and hospital costs have produced mixed results and may not necessarily clarify cost effectiveness; and that results are likely to vary dependent on geography, resource availability, local institutional styles and institutional commitment to pushing the envelope of care. Kirsch suggests that expensive and scarce resources are best allocated by creation of national health policy, which would create a better balance of resource

utilization and ensure fair allocation principles with protection for vulnerable populations (Kirsch, 2018).

ECMO Costs

Mishra, an economist, performed a prospective study that evaluated the costs of ECMO in 14 ECMO patients in Norway. Cost estimates included all costs, which included personnel, diagnostic procedures and lab tests, operating room procedures, and medications and blood products. The mean cost of the procedure alone at $73,122, and total hospital costs which includes pre- and post-ECMO procedures was found to be $213,246. They found that the mean duration of ECMO support was 9.5 days and the average length of hospital stay was 51.5 days. In caring for these patients, there is always the concern that resources will be diverted to these patients from those that may have a higher likelihood of survival. This was amplified during the COVID-19 pandemic, in which many institutions created policies regarding the use of ECMO; resource allocation was the primary focus and strict contingency plans were developed in regard to patient criteria for use of this life sustaining therapy (Khan, 2020, Ehman 2021). Also, as a result of the costs, ECMO cannot be provided to all patients. It could be argued that a device should not be used to medicalize death if it cannot reasonably be provided to the majority of patients (Mishra, 2010).

Harvey et al, performed a systematic review that evaluated US and International in-hospital costs of ECMO. The review ultimately included a total of 18 studies, 10 from the United States and 8 were from international sites. That review noted that costs were higher in the United States than internationally. They noted total costs were about $100,000 in all of the studies in the U.S., while half of the international costs were under $100,000. Although the

excessive cost of the procedure is clear, the authors acknowledge that it can be difficult to make cost comparisons between countries (Harvey, 2015).

Hayanga, et al studied the cost of ECMO based on indication for the procedure. This national study evaluated over 15,000 patients requiring ECMO with a mean age of 52.8 years. They separated costs for ECMO on the basis of indication including post-cardiotomy, cardiogenic shock, acute respiratory failure and heart/lung transplantation. The mean duration of ECMO support was found to be 5.3 days, while length of hospital stay was 23.4 days. They found that mean charges for the entire cohort was $731, 914 per patient. Transplant patients assumed the highest costs, with heart transplant costs noted to be $1,448,931 while lung transplant costs were $1,574,378(See Figure 3). Charges for other indications were observed to be lower. The costs for the other cohorts were found to be: post-cardiotomy patients $798,909, cardiogenic shock 644,099, and acute respiratory failure 824,852 (See Figure 3). Mortality for those enrolled in the study was 55% (Hayanga, 2020).

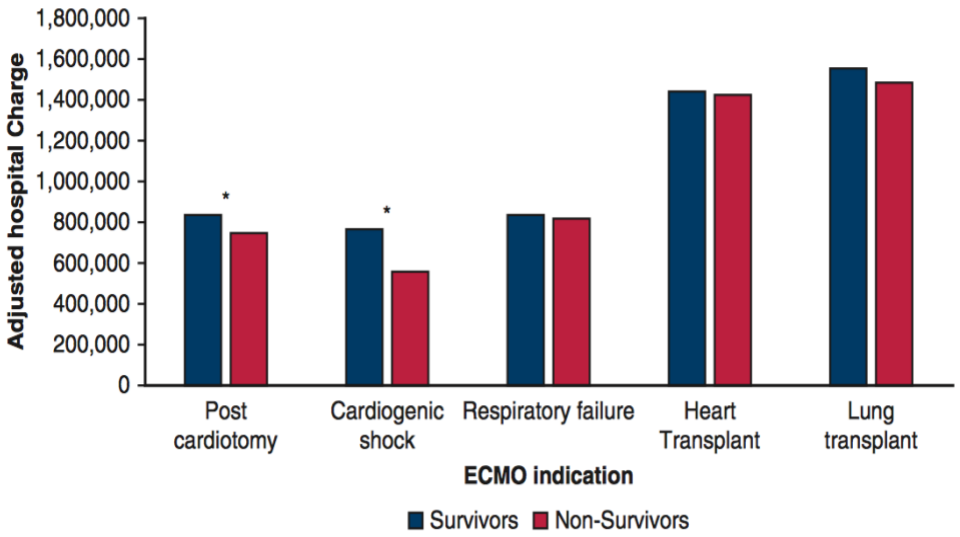

Figure 3: Costs of ECMO for survivors and non-survivors based on indication for ECMO (Hayanga et al, 2020)

Several ECMO centers in the United states have made recommendations for scarce resource allocation, specifically the use of ECMO, during the COVID-19 pandemic. Five health systems in Maryland formed a consortium to address and develop a scarce resource allocation process during a public health care crisis, specifically COVID 19 (Ehmann, 2020). The goal of the partnership was to develop a process that could create community trust by ensuring that allocation decisions were fair, consistent, legally permissible and nondiscriminatory across all participating hospitals. The group used ethical principles that include duty to provide care, duty to steward resources, distributive and procedural justice, equitable and standardized practices and transparency. One of the group's goals was to enhance objectivity and limit the moral distress of treating clinicians. The structure requires that a multidisciplinary triage team make resource allocation decisions, this team is separate from those caring for the patient. The group created an ECMO allocation algorithm, as well as an ECMO capacity management team that defined ECMO capacity based on equipment and staff availability. Patients were given a 7-day trial of ECMO before reallocation was considered; a secondary review can be requested or reallocation decisions would remove patients from support. Although this system only was activated once ECMO resources were scant, when only 2 additional patients could be accommodated, a systematic state-wide plan was enacted to care for patients (Ehmann, 2020). A systematic approach to appropriate ECMO resource allocation should be systematically created at all ECMO centers. COVID-19 has highlighted the limitations of the US medical system and lessons learned from the pandemic should be applied long after cases have subsided. COVID-19 strained the US medical system and increased the use of ECMO, it has allowed for some regions to give strong consideration to strategies that may be helpful in mitigating moral distress to providers; other regions in the country would likely benefit from similar policies.

As medicine and technology continue to progress resource allocation must be more strongly considered and means to mitigate scarce resources should be implemented. The Maryland consortium's approach to ECMO use during the pandemic reiterates Kirsch's considerations for a just resource allocation system in ECMO patients. Her recommendations include fairness in apportionment and access, potential for undue benefit or harm, protection of vulnerable persons from exploitation or exclusion, and specific allocation strategies that prioritize specific ideals. These ideals include societal benefit, helping those worst off, overall population health, undifferentiated access or a lottery and social worth (Kirch, 2018).

CHAPTER IV: ETHICAL DILEMMA-INFORMED CONSENT

Case: A 82 y/o man is diagnosed with a type A dissection and is brought to the operating room for an emergent repair of his aorta. He has a past medical history of hypertension, hyperlipidemia, type 2 diabetes, and gout. His operation is uneventful until there are attempts to wean the patient from cardiopulmonary bypass. After 3 failed attempts, the decision is made to initiate ECMO. The surgeon asked the nurse to alert the family that the case was more difficult than he expected, but he would come meet with the family shortly. The patient was taken to the ICU postoperatively. On POD# 3, he was started on dialysis and on POD #7 he suffered a large hemorrhagic stroke and imaging confirmed concern for herniation. The wife opted to withdraw care because she did not think that her husband would want to live like this, she was also under the impression that he would only require ECMO support for 2-3 days.

Analysis: Extracorporeal membrane oxygenation presents many challenges for informed consent. The previously mentioned case highlights just a few of the problems associated with traditional informed consent in cases involving ECMO: the urgent nature of being in the operating room as well as the decision to initiate ECMO with the expectation that it would be short lived, but also the uncertainty of ECMO and the complications associated with this form of support make such predictions difficult.

Informed consent requires several elements in order to be valid. These elements include competence, voluntariness, disclosure, recommendation, understanding, decision making and authorization (Beauchamp, 2017). Although the requirements for informed consent appear to be straight-forward, they are more complex than the elements previously mentioned. In emergent situations, such as those involving ECMO, it is highly unlikely that all of the elements informed

consent will be met. While autonomy is the ethical foundation of informed consent, there are some limitations. Kantian philosopher Onora O'Neill (O'Neill, 2003) has pointed out several of these drawbacks. She first acknowledged that only a patient with decision making capacity could give informed consent. She acknowledges that medical illness may render a patient unable to make decisions, while emotional duress may compromise a family member's ability to make appropriate decisions. It was also noted in the same paper that there is sometimes a lack of transparency and transitivity in the informed consent process, meaning that a patient may not be informed of every detail of a procedure while acknowledging that doing so could be counterproductive and confusing to patents (Boyd, 2015).

Several factors must be taken into consideration when communicating with patients, and barriers must be recognized and addressed. Oftentimes the focus is placed on obtaining a signature in order to proceed with a procedure or intervention. However, informed consent is more than a legal document. Non-specific to ECMO but still relevant barriers to informed consent include those that are patient specific and those that are process specific (Taylor, 1999). Patient specific factors that present as barriers include age, education, and illness; and process specific factors are timing of discussion, readability and content of consent form, amount of time allotted for the traditional informed consent process (Taylor, 1999). As previously mentioned, competence and understanding are two of the seven elements of informed consent. Effective communication is essential to the process of informed consent. One systematic review found that lack of comprehension was a large impediment in the process of informed consent and found that various interventions did improve overall patient comprehension during the process (Schenker, 2011). The review examined 44 studies, some of the cases involved intrathoracic interventions, that assessed different interventions and found that additional written information,

audiovisual/multimedia programs, extended discussion and feedback techniques all improved overall patient comprehension in informed consent (Schenker, 2011). Another ethicist, Levy, argued that as a result of the imperfections in human reasoning cited in psychological studies, human beings are poor reasoners which affects the judgments that are made in regards to informed consent. He makes the claim that this ultimately undermines autonomy such that informed consent should be reconfigured even if it decreases the level of an individual's decision making in regard to undergoing a procedure (Boyd, 2015). All of this becomes more problematic when interventions are technologically advanced, as in the case of ECMO or when care is futile.

Peetz et al (Peetz, 2015), raise the question as to whether or not informed consent is even possible in ECMO patients and ultimately concludes that it is not realistic for these patients. They highlight general barriers and those that are more likely to be encountered with ECMO patients. They describe misunderstanding, emotional distortion, and patients' beliefs about expertise as problems that may be encountered in most medical decisions. He cites one study which found that many patients often do not view themselves as necessarily making an informed decision but rather they believe that they are accepting a recommendation from an expert (Peetz, 2015).

In instances of patients being considered for ECMO there are many factors, primarily situational, that make communication more difficult. Time is usually a factor in cases involving ECMO; patients usually require this intervention urgently or emergently. This added pressure when caring for a critically ill patient does not lend itself to in depth conversations with patients and families regarding the treatment. The emergent nature of ECMO will almost always lead a

physician to proceed with ECMO and address consent later. This means that when physicians are faced with the decision to preserve life versus communicating effectively, albeit unintentionally, many will err on the side of preservation (Peetz, 2015). The complex nature of ECMO which has been previously discussed creates another barrier to effective communication and problems with consent. The authors cite the classic case of Haskell Karp and Dr. Denton Cooley. This case involved the use of an artificial heart, a new and complicated medical intervention, and ultimately a heart transplant. The case of Mr. Karp ended with his death, but there was much controversy surrounding whether or not his wife understood the complex nature of what was being proposed. In the end, the legal battle ended favorably for Dr. Cooley, but the case is often referenced in regard to informed consent and full understanding of an intervention being offered. Lastly, Peetz, a critical care physician, also recognizes that uncertainty which is common in the case of ECMO is another barrier to communication with ECMO patients. Hospital course and outcome can be difficult to predict, making presenting information to patients and families difficult. Physician care goals and patient expectations must be aligned in order for patients to be provided with optimal care.

The literature highlights a need for improved communication during the informed consent process and that additional resources should be made available to patients in order to ensure that patients have a full understanding of what interventions they are consenting to. This need may be even more pronounced when consenting for ECMO. A recommendation regarding how to mitigate problems with informed consent and a possible change to the current consent process will be discussed in the last chapter. A proposed ECMO-POLST will be introduced as a possible resolution to the current issue.

Chapter V: ETHICAL DILEMMAS- DECISION MAKING QUANDARIES

Case: A 38 y/o woman with a past medical history of pulmonary hypertension is intubated for respiratory failure and right ventricular heart failure. She is a transplant candidate and the decision is made to place her on veno-arterial ECMO in order to preserve her candidacy. After 2 weeks on ECMO, she develops renal failure that necessitates hemodialysis and is removed from the transplant list. The patient is neurologically intact and comfortable. Multiple attempts to wean her from ECMO are unsuccessful. The healthcare team recommends removal from ECMO, but the patient refuses. (Abrams, 2014)

Analysis: The previously described case is what is known as a "bridge to nowhere" scenario (Abrams, 2014) . This simply means there is no viable endpoint regarding the use of ECMO in this patient. As previously stated ECMO is a type of supportive therapy and not a long-term treatment plan, yet at this point in her care there is disagreement between the clinical care team and the patient as to how to proceed.

The problems highlighted previously with informed consent and ongoing questions about whether autonomy or paternalism should be the overriding principle in medical decision making has caused some medical centers to create policies that address anticipated problems with more complicated interventions or treatments. Medical technology is advancing at a rate that far exceeds the medical literacy of most patients and their families. Even with the best education imparted to patients and their families by healthcare providers, it is reasonable to explore whether patients and families are capable of making decisions in the cases of complex care. That in addition to the fact that patient and familial decisions may be in opposition to recommendations of healthcare providers complicate decision making in this patient population.

The concept of shared decision making indicates that physicians present recommendations to a patient based on a patient's condition and in turn patients, families, and physicians make a decision regarding treatment options; based on the patients and goals and values. The American Thoracic Society in conjunction with the American College of Critical Care Medicine endorses the shared decision-making model and supports the following (Kon, 2016):

- Shared decision making is a collaborative process that allows patients, or their surrogates, and clinicians to make healthcare decisions together, taking into account the best scientific evidence available, as well as the patient's values goals, and preferences

-Clinicians should engage in a shared decision-making process to define overall goals of care (including decisions regarding limiting or withdrawing life-prolonging interventions) and when making major treatment decisions that may be affected by personal values, goals and preferences.

- Clinicians should use as their default approach a shared decision-making process that includes three main elements: information exchange, deliberation and making a treatment decision

- A wide range of decision-making approaches are ethically supportable, including patient or surrogate directed and clinician directed models. Clinicians should tailor the decision-making process based on the preferences of the patient or surrogate

-Clinicians should be trained in communication skills

- Research is needed to evaluate decision making strategies

Although the shared decision-making approach is what has been endorsed by various medical societies and is taught in medical schools; ethical issues arise based on differing interpretations of conversations by family and physicians, as well as understanding of ECMO technology and value systems. Madiski and Madiski (Madiski, 2017) describe and recognize the ethical dilemmas that are associated with ECMO. They acknowledge the review by Courtwright et al that found that the most common ethical issue that arises in ECMO patients is disagreement

about the ongoing use of ECMO; and that this disagreement may occur between health care providers, between surrogates, or health care providers and surrogates. They further state that when there is a disagreement between health care providers and surrogates that (Madiski, 4)

> "It is important not to force the family into making decisions that are against their beliefs and to provide them with adequate psychological support through and after the process, it is also important to understand their emotional needs, and understand the problem from their prospective."

Abrams, a critical care pulmonologist, advocates for discontinuation of ECMO against the wishes of a surrogate when the goals of ECMO are not being met and states:

> "in a situation in which a resource intensive technology is merely prolonging dying rather than accomplishing any therapeutic goal for the patient, a strong case can be made to discontinue the intervention, with appropriate concessions of timing to the surrogates" (Abrams,879).

These examples demonstrate differing viewpoints regarding decision making among physicians in cases involving ECMO.

Arthur Caplan, an ethicist, has advocated that more emphasis be placed on physician expertise in decision making. He references a number of studies that show that large percentages of people who give informed consent do not truly understand what they are authorizing and that within autonomy lies a level of hope that may or may not be warranted (Caplan, 2014). Caplan ultimately concludes that there is nothing wrong or unethical about healthcare providers recommending interventions based on their expertise and experience and that the principle of

autonomy should be able to be challenged by a provider's evidence-based suggestions (Caplan, 2014).

Abrams et al (Abrams, 2019) performed an international survey of physician attitudes in regard to initiation, maintenance and discontinuation of ECMO therapy. They surveyed 539 physicians in 39 countries. Abrams found that most of those that responded make decisions in collaboration with other physicians, and only half make decisions in conjunction with the patient or their surrogate. The survey further revealed that 15% of respondents rarely or never discussed the possibility of ECMO withdrawal with the patient or surrogate at the time of ECMO initiation. It was deduced that perhaps the respondents thought that the complexity of ECMO may be too difficult to understand and that is why families and patients were not always involved in decisions (Abrams, 2019). This study and the practice style that respondents display reveal important opinions towards the use of ECMO and decision making.

Another study that looked at provider attitudes regarding discontinuation of therapy in patients on extracorporeal membrane oxygenation (ECMO), showed that seventy-one percent of physicians familiar with this therapy reported that physicians ought to retain decisional authority and should have the right to discontinue ECMO treatment over surrogate objection (Meltzer, 2016). Meltzer et al recognized that further studies are needed to determine the reasoning for physician attitudes. They speculated that reasons could be physicians have increased knowledge and experience with ECMO compared to patients and families, the desire to avoid providing futile care, and wanting to avoid conflict with families (Meltzer, 2016). These study results may illustrate a problem with the shared decision-making model in medicine, at least in cases in which complicated interventions are involved.

Some institutions have created policies for complicated new treatments. The left ventricular assist device (VAD) was first developed and implanted in the 1960s; therefore, it has a similar timeline as a medical intervention to ECMO. There are many other parallels between VADs and ECMO, both devices are expensive, complex, and patient outcomes can be unpredictable. Both devices can act as a cardiopulmonary bypass machine and prolong the inevitable, death. The ethics committee at Columbia Presbyterian Center of the New York Presbyterian Hospital has been proactive about establishing goals of treatment in the instance of ventricular assist devices (VAD). They have drafted a statement that must be reviewed by physicians with patients and families prior to institution of the device. The statement says that:

> "[E]very effort will be made to help our patients on ventricular assist devices to improve to the point where they meet the criteria to receive a heart transplant or stabilize enough to be discharged from the hospital on a VAD. However, if despite all our efforts, a patient has not a reasonable chance of achieving either of these goals, we will discontinue the VAD, as it will, under these circumstances, no longer be serving the purpose for which it was originally used. When this occurs, the VAD will be discontinued only after the physicians caring for the patient are in agreement that the goals for VAD use cannot be met, and have consulted with the patient, or when the patient is too ill, with the family or friends of the patient" (Prager, 1688).

This statement is useful for several reasons. First and foremost, it is standardized, and every time this therapy is initiated on a patient, the patient and or family is aware of the goal of the treatment. Secondly, the document explicitly states what will happen if the goal of treatment is not reached. Lastly, the document acknowledges that the patient and or family will be consulted

prior to discontinuing therapy which reinforces trust between the physician and patient. In the event of a disagreement between the medical team and the family regarding discontinuation of the VAD, the ethics committee is consulted for resolution. The state of New York requires that one of the following criteria be met in order for a patient who lacks decisional making capacity to be removed from life support (Prager, 1688):

> "The patient's written advance directives request removal in such a situation
>
> The patient has a duly appointed health care proxy who requests removal of life support.
>
> In the absence of a health care agent or written advance directives, the patient has left verbal "clear and convincing' evidence that this would be his/her wishes."

The ethics committee at Columbia ultimately believes that the usual criteria for withdrawal of care set forth by the state of New York does not apply to VAD patients because they present a different set of circumstances compared to other ethical dilemmas in medicine. This is primarily because once the VAD is placed, the goal is to stabilize the patient so that they can go home and/or receive a heart transplant. If the VAD is unable to provide these therapeutic goals, then the care becomes futile. The same could be said about ECMO patients. Both devices function on some level similarly to a cardiopulmonary bypass machine (CPB), and in the operating room setting a surgeon does have the authority to turn the CPB machine off in instances where care is futile. This is unlike other clinical situations. That is a unique authority that surgeons have in those instances and is often warranted. This type of decision is justified in the operating room because patients have often experienced an injury or complication that may be impossible to repair. In these instances, continuation of cardiopulmonary bypass would simply delay the

inevitable and may further harm the patient. The same concerns arise when patients are on ECMO and not improving. This document could serve as a blueprint for hospitals in instances where a patient's baseline condition or the actual treatment being provided has a high likelihood of becoming less predictable and futile (Prager, 2002).

Meltzer et al, describes a case report in which shared decision making was practiced prior to initiation of ECMO, yet there was still disagreement between providers and family. She describes the case of a 40-year-old Hasidic Jewish woman with lymphoma with heart failure as a result of encasement of her left and right ventricles. The medical team proposed use of V-A ECMO as a means for supportive therapy to allow the patient to receive chemotherapy. As a result of her religious practice that usually does not allow for discontinuation of life sustaining treatment and concerns about ECMO being viewed as such, the medical team asked for an ethics consult prior to recommending a treatment plan. Multiple meetings were held which included the patient, family, and religious leaders. The team was able to explain and frame the use of ECMO as a bridge to treatment and not a life-saving treatment (Meltzer, 2014). However, when the family was approached about discontinuation of ECMO, they refused. More meetings were called, and the family finally agreed to discontinue use of ECMO. The patient survived, although she passed away a year later from her cancer (Meltzer, 2014). Meltzer acknowledges that several centers require consent for discontinuation of ECMO prior to initiating ECMO to avoid conflict; her institution believes that that practice could be viewed as coercive if patients or surrogates need to agree to termination prior to receiving it and they note that no other life-sustaining treatment has that stipulation (Meltzer, 2014) This case illustrates that disagreements still arise when providers are forthcoming with the plan with families and even when ethics committees are involved.

Although Meltzer et al, cites ethical grounds for her institution's refusal to require agreement to discontinuation of ECMO prior to initiation of treatment, there is both ethical and legal support for this practice. The state of Texas has made progress by creating legislation that addresses decision making at the end of life when conflict arises between families and healthcare providers. The Texas Medical Directives Act was enacted in 1999 and allows a health care facility to discontinue life sustaining treatment against the wishes of a surrogate when it is considered futile, but it requires that the family receive ten days written notice (Texas Advance Directives Act, 1999). This law is supported on the grounds that:

> "respect for the moral value of physician and institutional integrity in discerning the limits of medical interventions which complements the right of patient determination that must be given both voice and effect in any forum for medical decision making; and is rooted in a combination of concerns such as avoiding harm to patients, avoiding provision of unseemly care, and just allocation and good stewardship of medical resources." (Abrams, 879)

An author of the guidelines notes that there has not been a case in which support has been removed from a patient with decision making capacity (Abrams, 2014). Although most states do not have directives as explicit as the one in Texas, they do recognize a physician's right to refuse to provide futile care; nevertheless, futility in not well defined.

As previously stated the survival rate for patients undergoing ECMO is only approximately 50% with little increase in survival since it has been in use. Patients on ECMO are confined to the ICU for days or weeks which is expensive. The combination of poor outcomes and cost lead many in healthcare to be more critical of the therapy when initiated

improperly. Frequently when the time presents for the intervention to be discontinued, conflict arises between medical teams and surrogates. The American Medical Association (AMA), does provide conflict-resolution recommendations in instances of disagreement particularly when care may be futile. This first step in the process involves communication. The AMA recommends that physicians attempt to relay to patients and their families which treatments are futile and which are not, which encourages joint decision making (McCabe, 2008), but this can be very difficult in ECMO patients because of the lack of predictability of hospital course. In the event that this does not resolve the conflict, the AMA then recommends that the physician consult their ethics committee (McCabe, 2008). The AMA recommendations are helpful for when families and providers do not agree, but they do not address many of the problems and questions that come with the decision-making process in most ECMO cases.

Chapter VI: ETHICAL DILEMMAS- APPROPRIATENESS OF ECPR

Case: A 48 y/o man is brought to the operating room for a right video assisted thoracoscopy with decortication and irrigation of the chest. He was originally admitted to the hospital for a pneumonia and bacteremia. His hospital course was complicated by a respiratory arrest at the time of intubation 3 weeks prior to his surgical procedure. Prior to his arrival to the operating room the patient was awake and consented to his procedure. The procedure went well, and the surgical team opted to perform a bronchoscopy prior to waking the patient up. As they began the bronchoscopy the patient arrested and was noted to be ventricular tachycardia and ultimately with pulseless electrical activity (PEA). Chest compressions commenced and the patient was defibrillated. The patient received cardiopulmonary resuscitation for 50 minutes prior to being placed on VA ECMO. He was not consented for ECMO prior to the procedure and 35 minutes into the code, his wife was notified that there was a plan to place him on ECMO. On POD #3 the patient was stable and removed from ECMO.

Analysis: This case reiterates the problems with informed consent in ECMO, which have already been discussed in a previous chapter, but it also includes time pressure due to the emergent nature of the situation and emotional distress on the part of the wife. It also introduces the concept of ECPR, extracorporeal cardiopulmonary resuscitation. It should also be noted that although the patient had a good outcome, this case illustrates problems with the use of ECPR such as informed consent, cost, patient selection, and risk benefit stratification.

ECPR involves use of ECMO in conjunction with conventional cardiopulmonary resuscitation (CCPR). The major clinical concern in regard to ECPR is the lack of retrospective controlled trials, the gold standard, comparing ECPR to CCPR; most of the data regarding

outcomes consists of cohort studies, case-controlled studies and case series reports (Henry, 2019). This alone causes many clinicians to question its use. Although a joint literature review and meta-analysis found that ECPR produced more survivors at 30-day discharge and of those survivors more were neurologically intact, the authors recognized that there is a potential for bias in the studies (Twohig, 2019). The first two ethical concerns that ECPR presents, informed consent and cost, have been discussed elsewhere in this paper, and therefore will only briefly be highlighted. Informed consent is impossible to obtain in a patient in cardiac arrest, the only caveat would be if the patient has an advanced directive. There is also not a way to realistically know a patient's wishes in these situations, particularly if the cardiac arrest occurs outside of the hospital. In instances, in which the cardiac arrest occurs in a hospital setting, the care team may have some insight into the patient's wishes and treatment goals, but not always. Although there may be an opportunity to get information from family if they are present, that is not guaranteed. The other ethical concern with ECPR that has been discussed is cost. Dennis et al performed a cost analysis using data from all ECPR cases at two ECMO centers in Australia and found that ECMO support for refractory cardiac arrests is cost effective and compares favorably to accepted cost effectiveness thresholds (Dennis, 2019). The group came to this conclusion by comparing their cost per QALY gained to those thresholds mandated by the Spanish National Health service, the National Institute for Health and Care excellence, the United Kingdom, the American Heart Association and the American Cardiology Association (Dennis, 2019). This study used a Markov model which was developed by combining the cost analysis results with patient outcomes to examine ECPR effectiveness over a 10- year period (Dennis, 2019). The group then integrated costing figures with patient survival rates and estimated patient QALYs based on cerebral performance category scores. Other studies have come to similar conclusions

and studied cost effectiveness of ECPR for in and out of hospital cardiac arrest individually. A group in Japan performed a multi-centre prospective cohort study that evaluated the cost-effectiveness of ECPR for out-of-hospital cardiac arrest (Matsuoka, 2020). The decision model used estimated lifetime costs and outcomes for out-of-hospital cardiac arrest and compared those receiving ECPR and CCPR; QALY was used as the main outcome measure. This study concluded that ECPR was an economically acceptable strategy for resuscitation (Matsuoka, 2020). Another group from the Netherlands studied the cost-effectiveness of extracorporeal cardiopulmonary resuscitation after in-hospital cardiac arrest (Gravesteijn, 2019). Similarly, to the previously mentioned out of hospital study, cost effectiveness was evaluated by using costs per QALY. A model was created that was comprised of a decision tree and Markov model; the model was dependent on age, sex, and the Charlson Comorbidity Index. This study concluded that ECPR can be considered a cost-effective treatment after in-hospital cardiac arrest from healthcare perspective since conventional willingness to pay thresholds in Europe and North-America is between 50,000-100,000 euro or US dollars (Gravesteijn, 2019). Although all of these studies validate the use of ECPR from a cost-effectiveness standpoint, they all acknowledge the shortcomings of these results considering the lack of evidence regarding the efficacy of ECPR and its long-term complications (Dennis 2019, Matsuoka 2020, Gravesteijn 2019).

However, without retrospective controlled trials studying the improved survival and good neurological outcomes of ECPR, cost-effectiveness data is somewhat premature. Ultimately an expensive intervention, such as ECPR, should be offered only to patients if they have been shown to increase survival and decrease morbidity. The only way to access these parameters is

by using ECPR and studying results; if outcomes are not equal or better than traditional CPR then use of ECPR should be discontinued.

The other issue with ECPR is patient selection. The case described above was a witnessed arrest in the operating room, a situation in which the patient's entire medical history was documented and the physicians caring for the patient had access to his history. This differs from most cardiac arrests. The leading cause of mortality is out of hospital arrest. Over 400,000 cardiac arrests occur each year outside of a hospital in North America (Henry, 2019). The question then becomes how does the setting of a cardiac arrest affect treatment options and likelihood of survival. For example, what happens to patients who arrive in the emergency department (ED) via ambulance in cardiac arrest. Because it is an emergency it could be argued that all efforts should be made to preserve life, while at the same time a patient who arrives in the ED may or may not have an advance directive and may or may not be a good candidate for ECMO based on their medical history. The question remains whether or not ECPR should be treated as any other life saving measure, such as intubation and medical ventilation, and be covered under the emergency presumption (Meltzer, 2019). Meltzer et al, recommends that the care team follow the suggestion of ELSO guidelines and apply proportionality as an ethical value when considering the potential benefits of ECPR versus its risks in conjunction with the patient's overall clinical status. In theory that is a reasonable goal, but applying proportionality in an emergency setting when there may be little known about a patient is challenging. Currently decisions to proceed with ECPR are made on a case by case basis, with the focus being on the probability of survival. Riggs et al (Riggs, 2015) points out that this could lead to bias; but also concedes that there may difficulty creating a reasonable criterion for ECPR. They acknowledge that part of the challenge in establishing a protocol is that the data and studies do not show

consistency in outcomes based on time to ECPR. There have been cases in which ECPR was not offered to patients that arrive 45 minutes after their cardiac arrest, while survival was reported in patients who received ECPR more than 150 minutes after the start CCPR (Riggs, 2015).

Lastly, as with all modes of intervention the risks and benefits of ECPR must be evaluated. ECPR is associated with coma, stroke, and bridge to nowhere scenarios. Another point that should be noted is that CCPR does not require family or surrogate consultation, whereas withdrawing or stopping ECMO requires a discussion with families; this point reiterates several of the concerns that have been discussed in previous chapters. Although ECPR may show a glimpse of promise in very specific situations, it has the ability to create multiple ethical dilemmas for families and healthcare teams.

CHAPTER VII: DISCUSSION AND FUTURE RECOMMENDATIONS

Health care providers must remember that their ethical duty is to offer and provide care which is of benefit and not harmful, while allowing patients to retain their autonomy. These principles must be balanced while health care providers remain mindful of their societal responsibility to maintain a level of care which can be accessible for all. In instances in which patients are critically ill and extraordinary measures are required to keep patients alive, healthcare providers should have serious conversations with patients in an effort to avoid futile treatments and provide patients with the best care possible. Much of this can be accomplished through discussions with patients regarding their goals of care and desires for end of life treatments and interventions. Although each of the ethical dilemmas presented can be approached individually, creation of a document similar to a Physician Orders for Life Sustaining Treatment (POLST) and aggressive involvement of the hospital ethics committee is a more comprehensive approach to mitigating the ethical dilemmas that arise in ECMO patients.

ECMO POLST

Seventeen states have implemented POLST statewide or are considering implementation and another twenty-eight states are in the process of developing a POLST program. (Moore, 2016). Advanced care planning has evolved over the last few decades, and many tools are available to ensure that patient's wishes are respected in the end of life. Advanced Care planning is an invaluable tool that all individuals, regardless of their age or health care status, should take advantage of. The goals of advanced care planning are to provide a guide for families and health care providers as to the wishes of the patient in the event that the patient is unable to express them at the time. This is becoming increasingly important as medicine continues to

advance. To a much greater extent than in the past, the capability of modern medicine and technology to keep patients alive has pressed heath care providers into an era where the very goals of medicine must be reviewed with patients. Discussions prior to the need for various interventions; particularly advanced treatments, are paramount in providing optimized care, setting expectations and providing an opportunity for well informed decision making. Advance directives may be helpful in discussions about ECMO, but the creation of a vehicle similar to POLST may be more advantageous in regard to tailored decision making in ECMO patients (Bomba, 2012).

Providing ideal care in the critically ill is constantly evolving. Patients and families still often face obstacles when confronted with certain situations and decisions. In times of crisis, patients may be unable to make decisions about their care and families may be emotionally unable to make those decisions for multiple reasons. One study that was performed in parents of pediatric ECMO patients illustrates this. This study involved sending questionnaires to families 4 weeks after completion of ECMO support and assessed their experiences about overall communication, emotional experiences and if they would consent again to ECMO (Curley, 2003). 60% of families felt that they did not have a choice in regard to consenting to ECMO because of the severity of the child's illness and 22% recalled hearing about the possibility of death for the first time after the child failed to improve with the intervention. All parents admitted to feeling fear and anxiety throughout the process (Curley, 2003). These results suggest that one of the problems with traditional informed consent in instances in which ECMO is a possible intervention is that stress and emotions affect decision making. Advanced care planning is helpful in decision making especially when the patient's wishes are not congruent with those of their family. Use of advanced care planning may help prevent families and health care teams

from being presented with decisions that may be not be beneficial to patients.

POLST is not meant to replace an advanced directive, but should be used as another instrument that can be used in advanced care planning for those that qualify for POLST. Similarly, the creation of an ECMO document would not replace an advance directive or traditional POLST, but would serve as a compliment to other advanced care planning documents. Utilization of POLST may mitigate some of the problems with decision making and consent. POLST requires an in-depth discussion between the treating health care practitioner and the patient, or the patient's authorized surrogate, about key end-of-life care treatment options (Sabatino, 2011). In instances in which a patient may require ECMO at some point of their life, application of a POLST may be more useful than traditional informed consent. The overall goal is to determine the wishes of the patient in light of his or her current condition and discuss the available care options as explained by the treating health care provider; an existing advance directive may aid and inform the discussion. (Sabatino, 2011). In patients that may become ECMO candidates, it is important that physicians discuss with patients what their goals are at a time in which these patients are in a better overall state of health mentally, physically, and emotionally compared to a time in which they may necessitate ECMO. This is particularly important for patients that may have chronic diseases that may necessitate ECMO. It also would allow for benefits and complications to be discussed in detail, as well as the concept of ECMO possibly being a "bridge to nowhere" (Abrams, 2014). Bridge to nowhere is a term which means that the patient is dependent on ECMO for survival, which is not its intended use. The goals of ECMO are to bridge patients to transplantation or VAD placement or to allow time for the patient's organ function to return to a state that is compatible with life, but that often is not possible. Another discussion that should be discussed is length of time the patient would be

willing to be treated with ECMO, as well as the length of time most care teams are willing to initiate a trial of ECMO. Most of the disagreements that occur once a patient is placed on ECMO surround the issue of discontinuation of the therapy (Abrams, 2014). Therefore, if a patient opts for ECMO after being presented with all of the information, they should also have the opportunity to discuss how long they consent to therapy. These conversations can be difficult for patients, families and practitioners. A POLST eight step protocol was developed as a guide for practitioners in the discussion. This generic protocol includes (Bomba, 2012):

- Advises how to prepare for the discussion
- Advises that providers begin the conversation with discussing what the patient already knows
- Provide new information about the patient's condition and values from the medical team's perspective
- Advises providers on how to reconcile differences in regards to prognosis
- Discusses how to respond empathetically,
- Use POLST to guide choices and finalize patient wishes
- Fill out and sign POLST
- Review and revise periodically

This protocol serves as a guide to ensure that the conversation is truly shared and informed. A similar process should be created for patients in regard to ECMO and the wishes of a patient if they were to become severely ill. Currently there are not any centers documenting use of POLST forms for patients that may become candidates for ECMO.

POLST is a portable document. There are advantages and disadvantages to the portability of the document. The fact that the form is portable and recognized by all medical professionals across all settings requires that providers ensure that the POLST form actually travels with the patient whenever he or she moves from one setting to another, thereby promoting the continuity of ethical decision making (Sabatino,2011). Although the portability of the form has positive attributes, it does call into question the likelihood that the patient will have access to the form in the event of severe illness which rendered them unconscious, or in the event that the

patient did not have the form with them on arrival to the hospital and their condition rapidly deteriorated. Even though there is always the possibility that a family member may be available to present the form to the healthcare team, there are still no guarantees that they are immediately available in an emergency situation. This would also be a disadvantageous in the event that a similar model was created for an ECMO. One option would be to encourage a national POLST electronic database that all practitioners have access to. Regardless of patient location and availability of a physical form, the patient's wishes can then be respected.

Extracorporeal Life Support Organization (ELSO) could facilitate the process of a national database for ECMO POLST forms. Creation of a national database by this organization that includes an ECMO form would help alleviate the drawback to the portability of the form. All hospitals and ECMO centers would have access to the database, and the ability to quickly assess whether the patient has a form and what their choices are if they are unable to communicate at the time of admission. The one drawback to having ELSO as a participant in the creation of a national database to store the ECMO POLST is that the organization does have a vested interest in the use of ECMO and therefore they are not a neutral party; their involvement could be seen as a conflict of interest. This document should be used in addition to a traditional POLST, as the ECMO POLST is not intended to replace a traditional POLST but be an adjunct. Documentation for ECMO should be completed by the patient's primary care physician in conjunction with an intensivist and updated at least annually with an option for more frequent updates based on any changes to the patient's overall health status. The primary care physician has a well-established relationship with the patient and is most likely to be able to identify and understand any barriers to informed consent for the patient. The intensivist's role is to explain ECMO technology, including the difference between VA and VV ECMO and the indications for

each, to the patient in a way a primary care physician may be unable to and also explain common additional treatments that are required for patient on ECMO. The intensivist would also be able to discuss the usual hospital course of those on ECMO including the usual length of a trial of ECMO and survival over time. In addition to the primary care physician's relationship with the patient, they also interact with their patients regularly and would have the ability to alter the form as a patient's health status and wishes changed. Patients should have the opportunity to listen and ask questions without being under pressure due to illness or emotional duress. If these conversations occur before a patient is in a situation in which they may require ECMO, there will be ample time to ensure that patients comprehend the technology, and complications. In the event that a surrogate is completing the form on behalf of the patient, they should be familiar with the patient's healthcare goals, in the event that they are unfamiliar they likely should not complete the form until they are able to obtain that information.

Most of the literature points out the ethical dilemma associated with consent in ECMO patients, but no studies or proposals have been made to change the way in which patients are consented for ECMO. Most of the protocols and changes that have been suggested in the literature are related to withdrawal of ECMO. This form will not prevent all problems associated with informed consent, but it is a start, similarly to how other forms of advanced care planning helps guide the care of patients (See Figure 4).

Physician Orders for Life-Sustaining Treatment (POLST) for Extracorporeal Membrane Oxygenation (ECMO)

Patient First Name:_____ Preferred Name:_____
Middle Name/Initial:_____ Last Name:_____ Suffix_____
DOB (mm/dd/yyyy):____/_____/_____ State where form was completed:_____
Gender: M ☐ F ☐ X ☐

A. Extracorporeal Membrane Oxygenation (ECMO): Follow these orders if a patient requires supportive cardiac, pulmonary or cardiopulmonary support

☐ YES ECMO: including inserting cannulas, mechanical ventilation, defibrillation, cardioversion	☐ NO ECMO

B. Length of ECMO trial (average length of time on VA ECMO 5-10 days, average length of time of VV ECMO 10-14 days)

☐ 1-7 days ☐ 7-14 days ☐ > 14 days

C. Administration of blood products is common in patients placed on ECMO (critically ill patients often required blood and other blood products, blood/product consent still required prior to administration)

☐ Yes blood/blood products	☐ No blood/blood products

D. Tracheostomy (prolonged mechanical ventilation is often required in ECMO patients)

☐ Yes, tracheostomy	☐ No, tracheostomy

E. Active Comfort Care (in the event that the care team declares that my condition will not improve)

☐ I agree to comfort care	☐ I do not agree to comfort care

F. Additional orders: (dialysis, enteric feeds, quality of life)

G. Signature: Patient or Patient Representative. This form is voluntary. I have discussed ECMO with my primary care physician and a critical care physician and understand my treatment options. If I am signing as a surrogate, the treatment plan is aligned with the wishes of the patient.
Sign:_____ Date:_____
Print:_____
If other than patient, legal authority:_____
This form supersedes any previously signed POLST forms.

Physician Signatures: I have discussed the orders with the patient/surrogate including treatment alternatives and the orders reflect the patient's wishes.
Primary Care Physician
Signature:_____Date:_____
____
Print:_____ Contact Phone #_____
State/License #_____
Critical Care Physician
Signature:_____Date:_____
____
Print:_____ Contact Phone #_____
State/License #_____

Figure 4: ECMO POLST Form

Ethics Committee Involvement

Creation of an ECMO form through the Extracorporeal life support organization is one alternative and recommendation to the current state of the decision-making process. The ultimate goal of decision making should be that patients and families are able to take time after being presented with risks, benefits, and prognosis to choose what is ultimately best for them. The current process does not ensure that these goals are met. Patients and providers would also benefit from official guidelines created by the international organization that includes how to address ongoing ethical issues that may arise after ECMO has been initiated. The European Association for Cardio-Thoracic Surgery (EACTS)/ ELSO/Society of Thoracic Surgeons (STS)/ American Association for Thoracic Surgery (AATS) have released a 43-page consensus statement that simply endorses a shared decision-making model of care and that an advanced/palliative care team consult be obtained for all patients on ECMO (Lorusso, 2020). ELSO also has separate guidelines that dedicates just a half of a page to ethical issues, and the only ethical issues mentioned are medical futility and resource allocation (ELSO general guidelines, 2017, ELSO COVID-19 guidelines, 2019). Although all of these recommendations are an excellent start, they do not go far enough in recognizing and addressing the ethical dilemmas that arise in ECMO patients.

ELSO should mandate that ethics committees at hospitals be consulted and engaged in all cases in which patients are considered and placed on ECMO, regardless of the planned time period of treatment. Many of the ethical dilemmas present prior to initiation of ECMO. Ideally hospitals would have an ECMO consult team on call that consisted of a cardiac surgeon, intensivist and ethics committee member that were briefly consulted prior to initiation of ECMO. The cardiac surgeon and intensivist both have the experience of caring for patients on ECMO

and understanding the complications that may arise, as well as the usual medical course of patients on this life sustaining therapy. This consult team, particularly the surgeon and intensivist, would not be a part of the primary team caring for the patient. The reason for this is to allow for objectivity in assessing the realistic goals and outcomes in the patient being considered for ECMO. Once the decision is made to proceed with initiating ECMO, an ethics committee member would be required to round on the patient daily and complete the ethics committee ECMO daily rounding from, (see Figure 5). One study found that at their institution there was an increase in the number of ethics committee consults for patients on ECMO over a 2-year period (from 21% to 93%) which is positive. However, consults were found mostly to occur after ECMO had already been initiated and there was some disagreement either among health care workers, surrogates, or both about discontinuation of ECMO (Courtwright, 2016). Ethics committee involvement prior to initiating ECMO and continued daily involvement during the patient's trial of ECMO would likely help alleviate many of the ethical dilemmas that arise. Daily involvement is important in ensuring that families and surrogates have a clear understanding of the patient's status, care goals, treatment options, and current prognosis. One case that illustrates that multiple ethical issues can arise in cases involving ECMO is a case of an 84-year old female with a history of severe aortic stenosis with a low ejection fraction of 25% (normal is 55%), hypertension, diabetes, hyperlipidemia, and new-onset dementia who presented for a transcatheter aortic valve replacement or a minimally invasive aortic valve replacement. There are multiple approaches to this procedure, but they all avoid a sternotomy or opening of the chest through the sternum or breastbone. During the minimally invasive procedure a complication occurred: it was discovered that there was a hole in her heart, and she coded. Her chest was then opened via sternotomy emergently, she received open cardiac massage to the

heart for approximately 45 minutes and she was transported to the operating room. The patient was placed on cardiopulmonary bypass (CPB) and the hole in her heart was repaired. The patient is unable to be weaned from CPB and she is placed on ECMO and transported to the ICU. The family informs the medical team that they want "everything done". The patient's hospital course was complicated. On post-operative day (POD) #1 she was brought back to the operating room for bleeding, on POD #4 her right arm was amputated as a result of ischemia or lack of blood flow to her arm, and on POD #6 the family decided to withdraw care. This case presented many ethical dilemmas, the primary question is what were the clinical goals in this patient when ECMO was initiated. Based on her age, the medical complication, and the length of time she received open cardiac massage or CPR, the probability of her surviving was very low. This patient most likely never should have been placed on ECMO, if the ethics committee and surgeon that had not been caring for her had immediately been consulted initiation of ECMO and her subsequent complications probably could have been avoided. This case also highlights why it is important that a surgeon that is not involved in the care of the patient be selected as a member of the ECMO consult team. In this case the complication was iatrogenic and it is natural that the surgeon operating on this patient would want to correct the problem, which underscores the importance of objectivity when promoting ethical decision making. This is an example of ECMO being used as a "bridge to nowhere." The ethicist has the ability to facilitate discussions prior to the initiation of ECMO and during the patient's hospital course in order to optimize communication, particularly as one's hospital course changes. As ECMO indications and the number of patients being place on ECMO increases, clear communication between patients, and or families, and providers in regard to ethical clinical decision making must be closely evaluated, challenged and improved.

This thesis examined the multitude of ethical dilemmas that can arise during the use of ECMO. New technologies often present novel challenges that may not be an issue with traditional treatments. ECMO, unlike many other treatments, does not treat the underlying cause of a patient's condition but is a supportive in-hospital therapy. Its goal is to sustain life until the patient's heart and/or lungs recover. This creates many problems for physicians including moral distress, inadequate informed consent, decision making conflicts, and resource allocation. These quandaries must be considered whenever ECMO is being considered for patients. The literature identifies these challenges but offers very little guidance in how to clearly address them. As ECMO use continues to rise world-wide, thoughtful solutions to address the issues must be explored. Early use of ethics committees, ideally prior to initiation of ECMO, can help mitigate some of the issues that have been discussed. Adoption of an ECMO-POLST can act as an informative tool for patients and a means to solicit their wishes prior to them or their surrogates being presented with ECMO as a treatment option. Future ECMO use should be guided by a proactive approach to addressing the many well-documented ethical challenges that often occur with this life-sustaining technology.

ECMO Ethics Committee Rounding/Consultation Form

ECMO DAY #_____

Reason for Initiation of ECMO:

Treatment Goals (bridge to transplant, recovery, etc.):

Current Condition of Patient (progress/setbacks):

Procedures performed (in addition to ECMO):

Family meeting (if not, why):

Family/Surrogate understanding or perception of patient status:

Family/Surrogate goals:

Has Palliative Care been consulted:

Other services consulted/involved with care:

Changes in treatment plan after meeting (DNR, comfort care, ECMO wean, etc.):

Figure 5: Ethics Committee ECMO Daily Rounding Form

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