Chapter

Clinical and Administrative Steps to the ECMO Program Development

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Abstract

Extra-corporeal membrane oxygenation (ECMO) is a rapidly evolving therapy for acute lung and/or heart failure. ECMO, from a technical standpoint, is conceptually simple—however, it can be very challenging to implement therapy at the individual patient level as well as at hospital (or healthcare system) level. ECMO program development involves engagement of key stake-holders including physicians, nursing, and administrative leadership. The goal of this chapter is to outline some of the crucial steps in developing a successful ECMO program including highlighting the necessary resources, team members and structure, and basic program structure and function.

Keywords: ECMO, administration, leadership, development, guidelines

1. Introduction

Extra-corporeal membrane oxygenation (ECMO) or extra-corporeal life support (ECLS) is quickly becoming a well-established form of therapy for patients presenting in severe respiratory failure and/or cardiogenic shock. The fundamentals of therapy, while technically challenging and involving a complex dynamic human-artificial circuit system, also requires a huge reliance on a multi-disciplinary team and an institutional infrastructure with robust administrative support at all levels to function effectively. While the medical and technical aspects of therapy are covered extensively in this text—and the others in this series [1, 2], a common fundamental question that is often asked is "how do we start and develop a program?" The development of an ECMO/ECLS program is far more complex than organizing a small group of interested providers and acquiring the hardware necessary for support—as such, the goal of this chapter is to outline those steps necessary to help establish a foundation for a successful institutional program.

2. Background

Acute respiratory failure—regardless of the etiology—remains a complex and difficult problem to treat. Management focuses on treating the primary problem and allowing lung healing via lung protective ventilation strategies, while maintaining adequate oxygenation and ventilation [3]. Unfortunately, morbidity and mortality remain high in patients with severe lung injury, despite implementing standard lung protective strategies. Even for those patients who survive, quality of life can be severely impacted for many years after their initial illness [4]. Acute cardiac failure, or cardiogenic shock, also presents a difficult clinical problem for which even contemporary outcomes are less than ideal. While the most common cause of cardiogenic shock remains pump failure after an acute myocardial infarction, other mechanical problems such as acute papillary rupture (with acute mitral regurgitation), ventricular septal rupture, and myocarditis [5] must be considered [6]. While the use of ECMO for either acute respiratory failure or cardiogenic shock (or often a combination of both) is well-described, in part due to more comprehensive reviews of these topics elsewhere in this text, their incidence and challenges—regardless of the circumstances—serve as a foundation for why there is a substantial interest in developing and growing ECMO programs.

There is growing evidence to support the role of ECMO in the management of these very difficult problems. ECMO has been shown to be an important tool in the armamentarium of any program that serves as a tertiary or referral center for complex cardio-pulmonary pathologies. In fact, excluding the survival benefit that has been demonstrated in patients who are supported with ECMO, there is also growing evidence to suggest that overall outcomes of patients with Adult Respiratory Distress Syndrome (ARDS) or cardiogenic shock treated at "ECMO Program Centers" are better regardless of whether they are treated with ECMO. In other words, the multi-disciplinary and administrative commitment to take care of patients (both adults and children) with complex and difficult cardiac and pulmonary problems can lead to improved outcomes independent of the actual use of ECMO [7–10].

Two randomized clinical trials in patients with severe ARDS support the implementation and increased utilization of ECMO therapy [11, 12]. These randomized trials—again, topics that will be discussed elsewhere in this text—despite their controversies, have demonstrated a clinical benefit of ECMO in the setting of ARDS. These well-conducted randomized trials, in addition to the extensive body of literature (case series, single center reports, and Extracorporeal Life Support Organization (ELSO) registry reviews—far too numerous to reference) combined with growing society guidelines and position papers, serve as a solid foundation of medical science to support the development of ECMO programs worldwide [13].

3. Implementation process

The clinicians and administrators first determine the need and support for an ECMO program. This multidisciplinary group then operationalizes the care team that needs to be assembled and trained. The team includes clinical, administrative, ancillary, and other stakeholders, which are required to care for the patient and support the infrastructure, while moving the program to implementation.

3.1 Physician members

Physicians from Cardiothoracic Surgery, Pulmonary/Critical Care, and Cardiology form the foundation of physician support for veno-veno and

veno-arterial ECMO patient identification, insertion, and management. In addition to the core physician team, there is a need to engage neurologists and infectious disease specialists to understand the therapy and the unique patient care challenges and complications associated with ECMO support. Vascular surgeons often will get involved with cannulation if others are not available or comfortable with placing large bore cannulas—likewise, there is a growing interest by general and trauma surgeons [14].

In addition, the Palliative Care team must be involved from the very beginning of program's development and some will advocate, especially in pediatric programs (while the focus of this chapter is on adult program development), Palliative Care providers are automatically involved and consulted on every ECMO case. As such, their understanding of the risks and benefits of ECMO are critical given the marginal outcomes associated with ECMO, even in the best of circumstances [15].

Inclusion of emergency physicians in the team can assist with early identification of patients on presentation to the emergency room, and implementation of protocols in the emergency room for cardiogenic shock and respiratory failure [16].

3.2 Administrative stakeholders

Administrators from the executive team should be engaged early to help support the creation of structures to accelerate implementation, project management, and assurance of adequate capital and personnel resources for a sustainable program. Financial models, which obviously vary from system (and country) to system, must be considered—and given the amount of resources required to establish and maintain an ECMO program, it is wise to have someone to monitor the financial implications.

3.3 Ancillary services

Respiratory therapists assist with identifying possible candidates and work closely with the team ensuring the implementation of lung protective strategies. The growth of electronic medical records can allow for daily (if not more frequent) reports of those patients who might be considered for ECMO based upon ventilator settings and arterial blood case results.

Perfusionists must be engaged to help with setup, oversight of the ongoing treatment and for their skill sets in understanding the complexities of the machines and testing required.

Finally, there are implications for laboratory department around testing and blood bank needs; as well as coordinating and consulting with case management, ethics, and chaplains in regard to complex shared decision-making to implement, care for, and remove therapy; and the rehabilitation needs for patients post-ECMO removal.

3.4 Nursing

In addition to leadership described previously, executive nursing leadership, departmental nursing leadership, nursing advanced practice providers (APP), and frontline nursing engagement are fundamental and are essential to assure the success of the program. This includes communication, input and collaboration with policy, procedures and evidence-based protocols, education and competency training of high performing clinical staff, and provision of surveillance and care of patients. Frontline nursing from outside the ICU are often engaged in patient flow and early identification of decompensating acute care patients, who may need to be

considered for ECLS. Since patients might require ECMO at any time, day or night, and given the amount of resources required to initiate and care for such patients, nursing administration must be involved to help develop protocols to organize "phone tree" lines of communication and specialized competent staff schedules to help recruit and arrange appropriate resources on very short notice.

3.5 Critical care transport

As the program grows beyond supporting the host hospital, it is necessary to engage Critical Care Transport to organize a system to transport patients from outside the facility with appropriate support and skill sets. This engagement is discussed more fully later in the chapter.

3.6 Nonclinical support

The IT department can help with order set development and the Medical Staff office will need to support the development of privileging requirements to assure consistent skill sets for new team members.

3.7 Establishing relationships with other tertiary centers

Especially in the situations with VA-ECMO use, long-term myocardial support may be needed. It is essential to build relationships with centers that can provide bridge to long-term LVAD support or transplant.

Additionally, the marketing and public relations departments engage to help in creating materials to help outlying hospitals and physicians have awareness of the program, with knowledge of how to identify patients and when to transport to higher levels of care for consideration of ECMO support.

4. Rapid change management

4.1 Triad leadership structure

A rapid pace for implementation is best served by a strong triad leadership: experienced physician leaders and champions who are experts in ECMO; nursing leadership; and hospital executives. All need experience in change management and are given support and authority to use project tools and cross-functional influence to fast track project goals across a wide span of departments. These members then must communicate progress within the executive team.

4.2 Change management approach

Following Kotter's change management theory, a small group of physicians, nursing leadership, and administrators gather to set a vision, determine the feasibility and challenges of the project, then create a shared project plan for the organization, structure, and timeline for implementation of the program [17]. The creation of a Gantt chart with key requirements and milestones is helpful in the early stages of program development—also useful in a sense of accomplishment and motivation of the team. Regular recurrent frequent meetings with agendas driven by a project management tool to assure progress is made on key deadlines, accountability to the individuals and team, and to create a shared message and plan for continued communication. Initial work should focus on best practice, research-based literature review,

professional organization review of standards and data, then develop a gap analysis of clinical guidelines, equipment, skill sets, and organizational readiness. This small group should include Cardiothoracic surgeon(s), Pulmonologists, a "C" level executive, the cardiovascular service line, and Intensive Care nursing leadership. A small tactical group allows for more rapid progress through the initial stages and supports creation of a shared vision to accelerate momentum when the inevitable resistance to change surfaces—as well as working through team dynamics, comfort level, and building relationships. This group must strive to produce early wins, however small, to enable the organization to "feel the progress" as more difficult hurdles are faced. These can include shared clinical guidelines, order sets, and eventually patients that lived thanks to the program—as a true connect to purpose for all involved.

Putting screening guidelines in place and educating the teams on the benefits of ECMO to patients who would otherwise be terminal are very compelling when used in a story format.

Finally, change in management requires vigilance to newly implemented care processes, or the tendency of the organization will slide back to previous status quo. Tools and strategies that assist in holding on to new skills are most effectively done through audits, constructive timely feedback, continuous process improvement discussions, and accountability to the process. While education can assist in reminding staff of the "why", it is not a sticky tool in terms of cementing new behaviors into a culture.

Once the ECMO program is up and running, collaboration with the quality abstractionist and review of registry data at regular intervals generates quality improvement projects to assure new practice and clinical referral patterns producing the optimal outcomes. It is also a way of preventing politics and rumors from gaining momentum as the facts are reviewed and discussed in larger quality forums. These forums are ideally multi-disciplinary and followed up with tangible action items that have due dates and closed-loop communication back to the CQI team, as the action items are completed.

5. Equipment

5.1 Hardware

The obvious hardware required for the program is the ECMO machine. The variables needed to make the correct choice for the program include need for portability of transport between facilities, as well as within the host organization, ease of use, skill sets of those responsible for managing the process, and the capital budget of the organization.

5.2 Disposables

In addition to the perfusion/ECMO machine, there is a need for a readily available stock of cannulas in various sizes, as well as for the variety of approaches that may need to be used. In addition, a well-stocked cart that allows the necessary equipment for sterile fields, cut-down, suturing, and possible complications of the cannulation procedures should be available to take to the patient's location, as often the patient is not stable to transport to the OR for the procedure. As these are tools routinely used by perfusionists and cardiothoracic surgeons, they need to be engaged in selecting the appropriate sizes, manufacturers, connectors, introducers, wires and par levels. Many programs, as a function of the need to initiate ECMO therapy on short notice and in many different clinical areas, will create an "ECMO cart" which consist of all the key disposable equipment and tools needed to cannulate anywhere at any time (**Table 1** and **Figure 1**).

Supplies	Size	Ref #	Qty
Cannulae:			
Medtronic bio-medicus single stage venous	23Fr	CB96605-023	×1
	21Fr	CB96605-021	×1
Medtronic bio-medicus multi-stage venous	25Fr	96880-025	×1
	21Fr	96880-021	×1
Maquet avalon	31Fr	10031	×1
	27Fr	10027	×1
Medtronic bio-medicus arterial	15Fr	96530-015	×1
Medtronic bio-medicus nexgen arterial	17Fr	96570-117	×1
	19Fr	96570-119	×1
	21Fr	96570-121	×1
Wires/dilators/introducer kits:			
Medtronic arterial introducer kit		96552	×1
Medtronic venous introducter kit		96551	×1
Lunderquist extra stiff		G31453	×1
Amplatz super stiff		M0066401080	×1
Sorrin dilator kit			×1
4Fr micro puncture			×4
4Fr introducer			×1
6Fr introducer			×2
8Fr Introducer			×1
Packs:			
Basic pack			×1
Angiography pack			×1
Suture:			
Pledgets			
2-0 Prolene SH			×4
2-0 Prolene MH			×4
3-0 Prolene SH			×4
3-0 Prolene RB-1			×4
4-0 Prolene SH			×12
4-0 Prolene RB-1			×12
4-0 Prolene large needle pledget			×12
4-0 Prolene small needle pledget			×12
5-0 Prolene C-1			×4
6-0 Prolene BV-1			×4
6-0 Prolene C-1			×4
7-0 Prolene BV-1			×4

Supplies	**Size**	**Ref #**	**Qty**
#1 Sofsilk			×6
0 Silk popoffs CT-1			×4
1 Vicryl CTX			×2
0 Vicryl CTX			×2
0 Vicryl CT-1			×2
2-0 Vicryl CT-1			×4
3-0 Vicryl SH			×2
4-0 Vicryl PS-1			×2
4-0 Monocryl PS-2			×2
3-0 Ethibond SH			×6
Heavy silk ties			×4
2-0 Silk ties			×4
3-0 Silk ties			×4
4-0 Vicryl ties			×4
2-0 Ethicon pacing wires			×2
Orange pacing wires			×4
Blue pacing wires			×2
#6 Sternal wires			×2
Double wires			×2
Prep:			
Chloraprep			×5
Duraprep			×1
Alcohol bottles			×2
PVP			×2
CHG surgical scrub brush			×5
Blades:			
#10			×10
#11			×10
#15			×10
Stryker sternal blade			×4
Hall redo blade			×2
Umbilical tapes			×8
Tourniquet 4 packs			×6
Red vessel loops			×2
White vessel loops			×4
Shods 10 pack			×2
Small yellow clip racks Qty 4			×5
Small red clip racks Qty 4			×5

Supplies	**Size**	**Ref #**	**Qty**
Small automatic clip applier			×1
Large automatic clip applier			×1
Asepto			×2
Suction tubing			×3
Cell Saver tubing			×2
Yankauer tip			×3
Poole tip			×2
Bovie pencil			×2
Bovie pad			×2
Long bovie tips			
Short bovie tips			
Eye cautery			×2
Snake clamp inserts			×1
86 mm inserts			×2
61 mm inserts			×2
33 mm inserts			×2
Hemostatics:			
Bone wax			×6
Felt 4×4			×1
Felt 6×6			×1
GelFoam			×1
Fibrillar			×5
Snow			×2
Nu-Knit			×1
Laps			×9
Baby laps			×5
Raytec			×5
Gowns			×7
Towel packs			×4
Gloves			
Drapes:			
Split sheets			×2
3/4 Sheets			×6
Bi-Lat split sheet			×1

Supplies	Size	Ref #	Qty
Cardiac drape			×1
Tegaderms			
4×4s			×5
Esmark			×1
Prineo			×1
Stapler			×1
Dermabond mini			×5
Hollister horizontal tube attachment device			×2
18 Ga Hypo			×4
Hep/blunt tip hypo			×4
60 cc syringe			×2
20 cc syringe			×2
10 cc syringe			×2
5 cc syringe			×2
Defib pads			×1
Pacing cables			×2
Decanters			×2
Plasmalyte 1 L			×2

Table 1. *ECMO cart supplies (sample).*

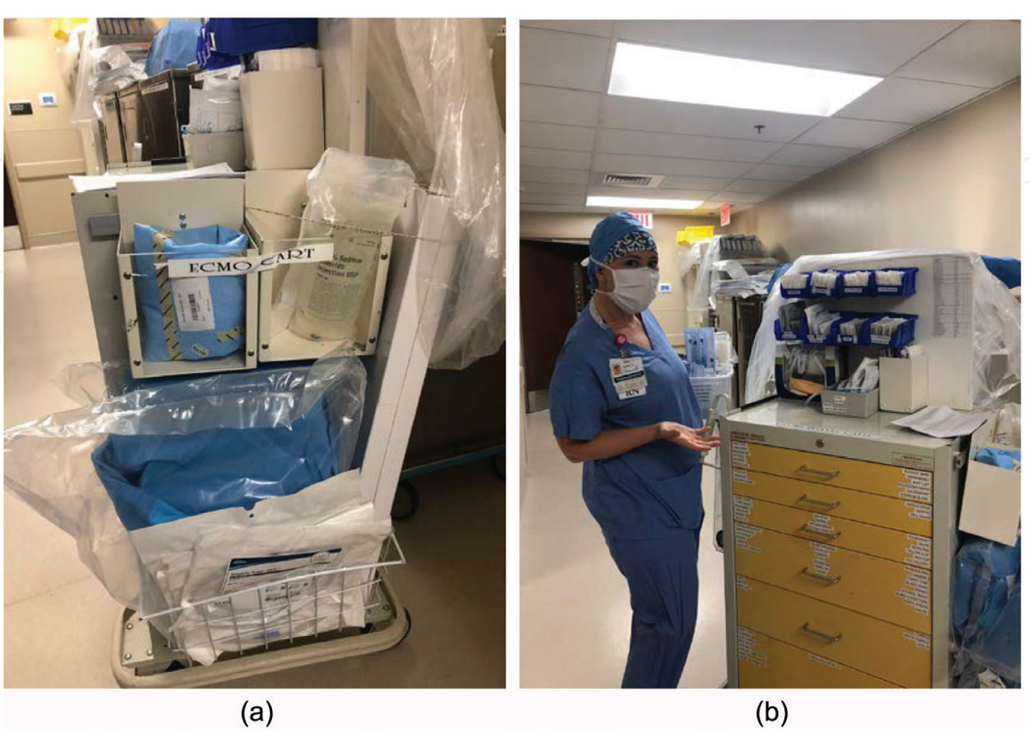

Figure 1.
(a and b): Portable ECMO cart that contains all the disposable tools needed for initiating therapy.

6. People

6.1 Structure and team building

The ECMO team skill set crosses a variety of normal reporting structures within the hospital, as well as contracted services used in hospitals, including surgical services, nursing, laboratory, perfusion, physicians—employed and independent. Hence, thought must be placed into creating a strong team-based culture among a group of individuals who may have primary team affiliation across multiple departments.

The use of multidisciplinary teams to develop project goals can serve as the first team building structure. Recognition of the team publicly can serve to bond the team more closely, and debriefings can prevent "silo formation" as individuals must often integrate in and out of the ECMO team due to patient volume and clinical needs. To cement this sense of team, the leaders of the departments that support the ECMO program should have regular meetings to discuss issues that arise, including productivity and interpersonal issues. Finally, the executive champion of the program should assure that there is accountability from all parties to the success of the program through goals and metrics, periodic meetings of the entire group of stakeholders, and shared public recognition of the successes of the program.

6.2 Who watches the patients?

Early in the development of any ECMO program, there must be a strategy for establishing "who watches what"—specifically, while nursing will always have bedside management of the patient, there must be consideration given as who has dedicated responsibility for the ECMO pump and circuit. As with any technology or "machine" that is directly connected to a patient—and provides critical life-saving support—there must be institutional guidelines and protocols regarding who monitors the functional status of the pump and circuit assuring safe and continuous functionality. In addition, the specific roles and responsibilities of this individual also need to be clearly defined. Various staffing models exist as described below.

6.2.1 Perfusionist based

Perfusionist is ideal bedside ECMO care providers, while initiating an ECMO program. Their advantages are considerable experiences in managing patients requiring extra-corporeal support as a function of their primary job responsibilities in the operating room supporting cardiac surgery procedures. Their training, credentialing, and licensure will often include formal experiences in managing patients requiring short-term mechanical circulatory support, including ECMO, outside of the operating room environment. A perfusionist-based model is appealing, however there are resource and financial limitations of this model. Perfusionists are usually limited in number (especially if they are also supporting an active clinical cardiothoracic surgical program) and their perspective is from a different care model which is focused around staffing limited time intervals in the operating room rather than 24/7 ICU-based ECMO care management. They are also an expensive resource for 24/7 daily ECMO use in the ICU. Given their availability and cost (and depending on how a program "employs" perfusionists—salary, per diem, hourly, contract employees, etc.), other care models are preferred for providing bedside ECMO support, particularly for veno-veno ECMO patients.

6.2.2 Nursing/respiratory therapy (RN/RT) based

RN/RT ECMO specialist staffing models are becoming widely accepted and utilized in programs nationally—these programs and the combination structure of RT and RN staffing pools are mainly volume dependent to maintain competence. RNs have many advantages with regards to their inherent familiarity with the complexities and challenges in managing sick patients who require various life-support therapies. For example, in many programs, nurses manage renal replacement therapy technologies, wean and manage ventilators directly, and even have ownership in the management of both short- and long-term cardiac/ventricular support therapies. An additional advantage is, as a function such nurses are often extremely experienced in the management and assessment of critically-ill patients, they can serve as a valuable resource in other areas of immediate patient care—and potentially with volume and competence that become a primary care model for the more stable ECMO patient. Although respiratory therapists (RT) often have extensive experience in the management—and independent assessment—of patients requiring mechanical ventilatory support, it has only been relatively recently that their experiences and training in pulmonary mechanics and respiratory physiology, have they as a profession, been engaged as ECMO specialists. In theory, since most busy intensive care units are often staffed with a high volume of RNs and RTs, who are clinically high performing and engaged, the addition of monitoring ECMO pumps and circuits might not require a substantial investment in human resources and expanding staffing models. As such, using RNs and RTs might be viewed as being potentially less expensive—it is important to recognize that prior to using this human resource to monitor ECMO patients, a substantial investment in extensive ongoing education and training to maintain competence is needed. There are many courses offered by large ECMO programs, professional societies, and ELSO (see below) that can assist in the training of bedside ECMO specialists. Significant advantages in the ECMO specialist staffing model, already described as financially fiscal, also include continuity of nursing-based care provided by hospital staff who have an investment in the organization and unit, as well as the patients they serve.

6.2.3 Hybrid models

Another attractive option is a combination of various specialists—often as a function of the acuity of the patient and the needs of the program at any given time. Such a model takes advantage of the strengths of each type of healthcare professional. Even though such models can be difficult to implement as protocols defining individual roles and when and how handoffs can occur, nevertheless, with a strong collaborative team, a hybrid model can be successful. For example, for "routine" (if such exists) veno-veno cases of isolated respiratory failure in an otherwise hemodynamically stable patient, a perfusionist might help initiate therapy, provide the first 24 hours of support, and once the patient is deemed stable on ECMO, care is handed off to a RT or RN ECMO specialist. On-call perfusion support for technical questions and issues can then be easily provided from home and might not require immediate bedside support. Veno-arterial cases, especially in post-cardiotomy patients, might be more complex, and therefore might require more direct involvement of perfusionists given their experiences of managing such patients in the operating room. The challenge in a hybrid model is to determine either objectively or subjectively—the clinical parameters that would allow for an appropriate hand-off between one type (or level) of provider to another (i.e. perfusionist to RN/RT ECMO Specialist).

Regardless of the care model provided, there must be collaboration between the team members to build evidence-based standardized protocols, as well as

strong physician buy-in in terms of supporting the individuals who manage the patient and pump at the bedside. Availability for immediate communication, using current technology, should be established between the ECMO specialist and/or perfusionist and the in-house physician. In addition, a strong and collaborative relationship between the ECMO specialist, perfusionist, and the bedside nurse must exist. Everyone must work together—inter-personality or professional conflicts cannot be tolerated and only get in the way of safe and effective patient care. Strong provider leadership, such as a perfusionist team leader, can be extremely effective in helping mentor other providers and serving as a resource for some of the day to day challenges in the management of an ECMO pump and circuit that might involve various disciplines, each of which have various levels of training and experiences.

In addition, while current ECMO pumps and circuits are much more reliable than previous technologies, they will often have more advanced monitoring options. Each specialist involved in the care of the patient must have extensive training and a sound understanding of the functionality and troubleshooting of the entire circuit. Simulation training, as discussed in other chapters, plays a critical role in education and maintaining proficiency and, therefore, should be a key component—when feasible—of every ECMO program.

7. Guidelines for therapy and patient selection

7.1 Access center/system

In a multiple hospital system of care, there is not generally a need for more than one ECMO center for the system to accommodate the needs for non-CT surgery-related ECMO support. A helpful resource to assure patients have rapid transfer to the ECMO program from other hospitals, it is useful to set up a access center process to assure a standardized approach to hand-offs, transport, and tracking of patient movement. Call system personnel trained in the indications for ECMO can assist critical access and other facilities in routing possible ECMO patients for evaluation at the Center of Excellence. Early coordination with the call center leadership will allow them time to develop protocols, education, and coordination with transport services to assure smooth operations when the first patient call is received (**Figure 2**).

7.2 Where is ECMO initiated

A question that is often asked early in the development of any ECMO program is "where the patients should be cannulated?" While each institution must identify the ideal location for ideal cases, it is critical to recognize the nature of ECMO often dictates therapy must be able to be initiated anywhere within the hospital, including, but not limited to the following locations:

- Emergency department
- Operating rooms (cardiac and non-cardiac)
- Catheterization labs
- Obstetric labor and delivery suites
- Intensive care units (medical, cardiac, surgical, neuro, etc.)

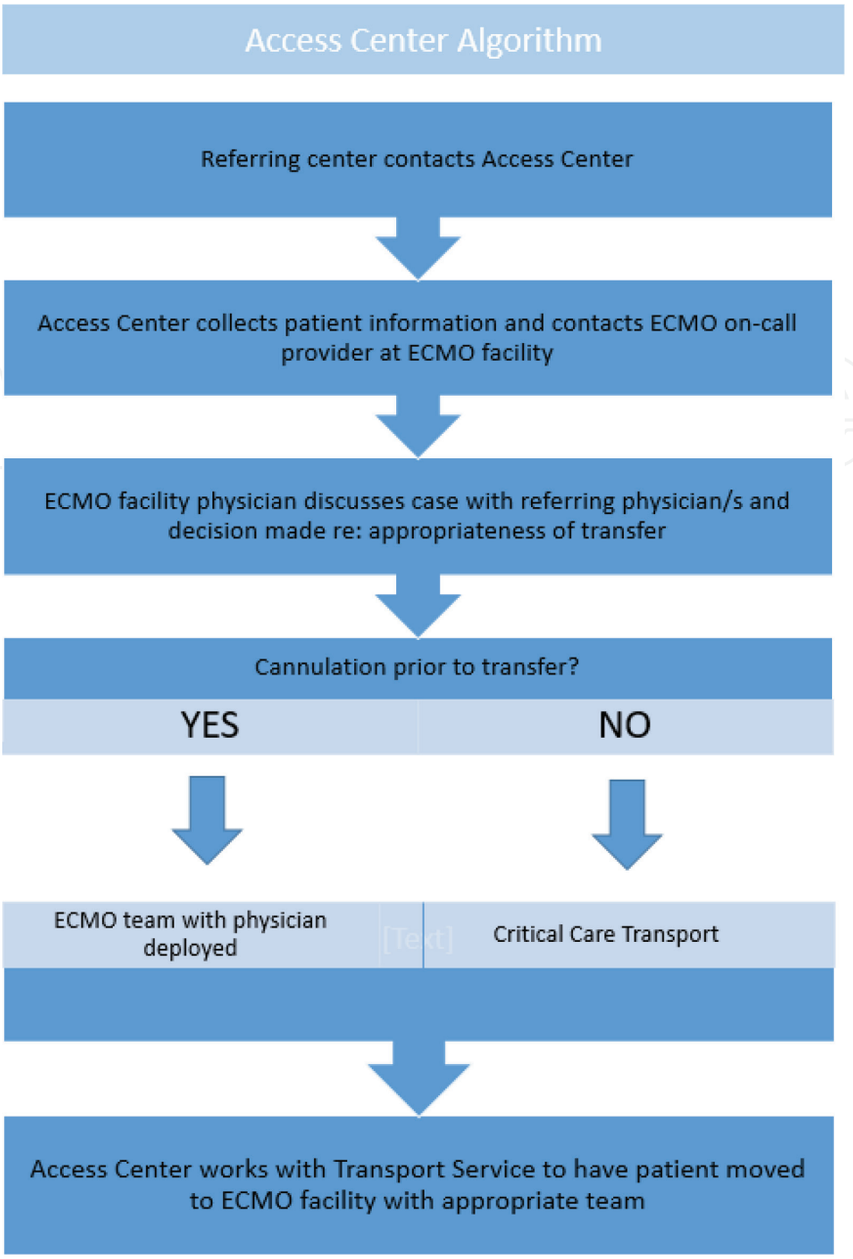

Figure 2.
Patient access/call center flow.

In fact, depending on the resources available and the resilience of the team, some centers will often consider initiating therapy in unusual out-of-hospital locations with the extreme example being the recent initiation of ECMO in the Louvre Museum in Paris, France [18].

Prior to considering the ideal location for initiating therapy, it is critical to outline those technologies that might be required. As discussed above, while it is important to have an "ECMO Cart" that contains, in a single location, all the key disposables that might be required, there might be a need for less portable equipment. For example, for cannulation, physicians might need immediate access to fluoroscopy and/or transesophageal echocardiography. Such technology might only be readily available in an operating room or catheterization lab. As many operating rooms, especially major trauma centers, and cardiac catheterization laboratories that support STEMI programs will often have access to advanced imaging, the exact ideal location often is dictated not only by physician preference, but also by potential administrative considerations. Such administrative considerations include the availability of a team to support cannulation, how disruptive emergency ECMO

cases would be to the scheduling and allocation of OR/Cath lab resources, and often "how comfortable" the team is with the procedures. For example, Cath lab teams who are more comfortable with the catheter and wire-base procedures than surgical team might be a better option for peripheral cannulation of ECMO (arterial and venous)—while operating room teams might be better skilled at assisting with central cannulation (especially if the chest is already open). Nevertheless, a core "ECMO team" of providers beyond physicians and perfusions must be identified and included in all communications so that therapy can be initiated efficiently and safely anywhere needed.

7.3 Order sets

Order sets provide a rapid, standardized, initiation for ECMO. The order set should include guidance for the perfusion team and nursing team to appropriately care for the patient in a variety of settings, as well as give parameters for physician notification to address changes in patient status quickly.

Order set elements should include:

- Instructions for ECMO machine priming
- ECMO circuit settings
- ECMO daily parameters
- Instructions for the perfusionist/nurse in charge of the machine
- Instructions to leave all catheters in if not functioning and notify physician
- Ventilatory settings
- Blood products and transfusion parameters
- Massive transfusion protocol parameters
- Post-cannulation radiology studies
  - AP abdomen post-cannulation
  - AP chest post-cannulation
- Radiology ◦studies
  - Echocardiogram for symptoms
  - Daily and routine laboratory studies
- Anticoagulation and associated laboratory monitoring and adjustments
- Triggers for notification of the ECMO physician/nurse practitioner
- Other
  - Nursing care
  - Sedation medications

- Physical therapy
  - Occupational therapy
  - Case management
  - Routine ICU parameters

8. ECMO transports

Critically ill patients requiring ECMO can be transported by ground, helicopter, and fixed wing aircraft. Considerations in choice of transport include distance, number of team members required, equipment, electrical and oxygen needs, and cost. Ideally, patients can be identified and transported prior to initiation of ECMO therapy, however there are models of care with good results in which the team goes to the patient and initiates ECMO, and then the patient is transported to the ECMO center.

8.1 Team members for transport

Per the 2015 ELSO guidelines, team members will vary depending on the need to cannulate the patient [19]. An ECMO specialist physician is required in either case, as is an ECMO specialist and a transport RN/RT. If cannulation is required, and the ECMO specialist physician is unable to perform this, there may be the need to add a cannulating physician and a surgical assistant to the team. Each team member has specific roles that should be delineated and understood prior to deployment to the outlying facility.

A checklist, should include all the needed equipment for the return trip with the patient, and should be verified prior to departure.

The equipment recommended by ELSO includes [20]:

1. Suitable blood pump, centrifugal, or roller
2. Membrane oxygenator, appropriate for the patient size
3. Device(s) for heating and regulating circuit blood temperature (less critical for adult transports)
4. Medical gas tanks, regulators, hoses, connectors, flow meters, and blenders for provision and adjustment of blended sweep gas to the oxygenator
5. Venous and arterial pressure monitoring device(s), according to center-specific practices
6. Point-of-care anticoagulation monitoring equipment (e.g., activated clotting time)
7. Emergency pump or manual control mechanism in the event of primary pump failure or power failure
8. Uninterruptible power source(s) capable of meeting the electrical power needs of all equipment during transfer between vehicles and in the event of vehicle power source failure.
9. Portable ultrasound machine, if not provided by the referring facility

Method of transport	Advantages	Disadvantages	Distance for transport
Ground	1. Lowest cost 2. Least noise 3. Number of team embers 4. Ease of loading equipment 5. Unlimited weight	1. Shortest ideal distance for transport	Up to 300 miles
Helicopter	1. Speed 2. Ease of loading equipment 3. Limited weight	1. Least number of team members 2. Noise 3. Higher cost	Up to 450 miles
Fixed wing	1. Speed 2. Number of team members 3. Limited weight	1. Costly 2. Can be difficult to load equipment 3. Noise	Unlimited

Table 2.
Decision-making for ECMO transport options.

Additional equipment recommended by 2015 ELSO to improve safety includes:

1. System for servo-regulation of flow to balance venous drainage rate from the patient and blood return to the patient

2. Blood flow rate monitor (may be internal or external to the blood circuit)

3. Monitor(s) for circuit blood temperature, blood gas, oxygen saturation, and hemoglobin (may be internal or external to the blood circuit)

4. Capacitance "bladder" incorporated into the circuit

5. Bubble detector with or without automatic pump regulation function

Of note, the requirements for voltage, current, and power for all equipment should be verified for the transport vehicle prior to departure and monitored throughout transport. An adequate oxygen source must also be available with sufficient reserve to support high-flow 100% oxygen delivery for the duration of the transport. Provisions must be made to adequately secure the equipment during transport—brackets, holders, straps, etc. should be tested prior to first-time transport and should be compliance with appropriate regulatory guidelines (i.e., Federal Aviation Administration for the United States) (**Table 2**).

No patient should be transported without a means of manually providing circuit flow in the event of an electrical pump failure or malfunction.

9. Quality and outcomes

As with all areas of medicine, the optimization of patient outcomes must be a priority. This concept is especially important in the context of developing and maintaining an ECMO/ECLS program. Many other disease therapies have an infrastructure for monitoring clinical outcomes and benchmarking them against peer groups, national, and even international programs. These infrastructures typically are in the form of voluntary registries and databases (although some might argue that participation is becoming less and less voluntary and more and more a

requirement—especially are payor sources are starting link payments to participation and eventually outcomes in such programs). Examples of these types of programs include the Society for Thoracic Surgeons (STS) Outcomes database (https://www.sts.org/registries-research-center/sts-national-database) and the American College of Cardiology National Cardiovascular Data Registry (ACC NCDR: https://cvquality.acc.org/NCDR-Home). Both organizations also for submission of patient characteristic data, comorbidities, therapies performed, and outcomes with the goal of providing program (and sometimes provider) specific outcome data—often risk adjusted, therapy specific, and benchmarked against other programs with provided summaries that can allow for continuous quality improvement initiatives.

9.1 Role of ELSO

Currently, the Extracorporeal Life Support Organization (ELSO) provides a mechanism for tracking and benchmarking outcomes for ECMO programs (https://www.elso.org/Home.aspx). The organization was founded in 1989 and is headquartered in Ann Arbor, Michigan, USA. While the organization serves many roles to assist ECMO providers and programs—voluntary membership allows for the submission of clinical program outcome data and in return, summary data are provided. The organization also provides access to clinical guidelines, discussion forums, announcements for relevant meetings, links to key publications and references, and overall serves as a hub for ECMO/ECLS-related activities. Membership is strongly encouraged and the organization claims international membership and helps coordinate worldwide activities.

9.2 Interval reviews

In addition to submitting clinical patient and outcome data for benchmarking to ELSO, programs should also establish a formal case presentation and review process. Much like traditional surgical "morbidity and mortality" reviews, given the high-acuity and resource intensive nature of ECMO, similar periodic reviews of institutional ECMO outcomes should also be reviewed. While the focus should not be in individual practices or decision-making, ideally, each case should be reviewed by the team in a non-judgmental fashion to explore for potential areas of opportunity. Likewise, while good outcomes should be discussion in the context of "what went right"—such cases should also serve as team learning opportunity for growth and improvement. Depending on the number of cases performed, such meetings should be held in a timely manner (monthly, quarterly, etc.) so that real-time assessments can be performed and the nuances of each case might still be relatively fresh in the minds of the providers. While the structure of such meetings can be variable, many "quality" meetings typically will only involve key stakeholders—both providers (i.e. physicians, ECMO specialists, perfusionists, etc.) and appropriate administrators. The benefit of having meetings limited is that there is then the opportunity for open, honest, and transparent conversations—either on a case-by-case basis or from a programmatic standpoint—in a manner that can and should be protected from legal disclosure under the umbrella of a formal peer-review or quality improvement initiative. Appropriate protections of patient data and provider involvement must be maintained and established from the onset.

Likewise, summary data of program outcomes—such as the number of cases, types of cases, and overall outcomes should be actively tracked in real-time and made available to institutional leadership as a gauge of program growth and success. Institutional leadership/administration should also be able to provide financial data

as profit/loss margins must be tracked in the context of program growth and success. Additional benchmarking information should also be considered and tracked in real-time to help monitor the evolution of a program—and should include, but not necessarily be limited to:

(1) Patient demographics (i.e., age, gender, and major comorbidities)

(2) Primary indications for support and etiologies of respiratory failure and/or cardiogenic shock

(3) Type of support (VV, VA, eCPR, and cannulation)
(4) Duration of support

(5) Blood and blood product utilization

(6) Outcomes

- Successful weaning from support
- Death on support
- Death despite successful weaning
- Major factors contributing to patient death (i.e., multi-organ failure, neurologic, etc.)

Such summary data should be in addition to the extensive amount of clinical and circuit data that is collected and tracked in the ELSO registry (see above).

9.3 Continuous quality improvement (CQI)

As discussed above, the tracking of outcome data should be a key component to helping measure program growth and success. Such initiatives must be established from the onset and involve the program champions—both clinical and administrative leaders to be successful. While it is important to review cases in the context of

Topics for review	Potential desired outcome
Anticoagulation protocol	Reduction in bleeding and bleeding related complication. Reduction in blood product utilization
Antibiotic utilization	Integration in an antibiotic stewardship program Reduction in multi-drug resistant infections Reduction in opportunistic infections
Time from admission/intubation to initiation of ECMO support	Potential impact on improving weaning and survival outcomes
Mortality despite successful weaning from ECMO	Improving overall outcomes and survival to discharge.
Medication utilization	Opportunities for potential cost savings
Family/patient satisfaction scores	Opportunities to improve communication with families, Improved satisfaction metrics

Table 3.
Suggested topics for continuous quality initiatives

tracking outcomes—both good and bad—from a programmatic standpoint, it is also important to examine outcome summary data with the focus of exploring potential opportunity for improvement. It should be a primary objective of the ECMO team to consider periodic continuous quality improvement (CQI) activities. The activities should be viewed as opportunities to review best practices, current literature on various topics, and metrics with the focused goal of improving outcome metrics—while the primary focus should always be on improving patient survival, other metrics, program practices, and guidelines should also be considered as topics for review. Key topics can be identified, champions identified, and a timeline established for review and the development of potential action plans. While the specific details of how to develop and implement CQI is out of the scope of this topic—it does emphasize the importance of engaged administrative leadership individuals and team who have established experiences with these programmatic and institutional activities. By no means, comprehensive, various CQI topics are listed in **Table 3**.

10. Miscellaneous topics

10.1 Referral sources engagement

Once the complex set of internal processes, personnel, and patient care skills are established, the ECMO program has the potential to serve patients in a wide area around the ECMO center. To assure that other hospitals and emergency facilities have the information to know of the resources available, and when to engage them, the primary facility should engage a multi-pronged approach to raise awareness and clinical decision-making skills of potential patient care partners. As with all endeavors, this should be done in the WIIFM (What's In It For Me) with the patient and practitioner at the outlying facilities interests' in mind. A good place to begin this is to address the benefits to the patient, the current science that supports the need for ECMO, the parameters for consideration of ECMO support, the process to easily move the patient, and the resources to enhance education of the topic. This is accomplished by marketing informational materials, individual outreach to create awareness, an education program that includes lectures, publication of successes, a plan for follow-up communication to the referring institution to help them understand the results of their referrals, and finally, by creating branding that helps the referral sources easily retain a connection to the program.

10.2 Marketing

Marketing materials should ideally be created to reflect the ECMO program as a larger system of care around ARDS and shock. In addition to the organization housing the ECMO program, clear guidance on referral processes (see Call Center Section), there should also be some succinct explanation of the use of VV and VA ECMO, parameters for initiation of referral, as well as references to studies supporting the decision. Consideration should be given to having two sets of guidance; one for critical access lower acuity facilities/ER's and one geared toward facilities with ICU care directed by intensivists, as the threshold for referral will be different.

10.3 Outreach

The personal touch of a visit cannot be underestimated when establishing trusted referral center status for complex procedures such as ECMO. It affords a chance to create personal trust, as well as allowing answers to questions are procedures and

processes for transfer, and expectations for communication regarding patient status from the ECMO center. The outreach should be well versed on all of these processes, as well as having the ability to provide physician to physician conversations to answer any outstanding issues.

10.4 Education

Education is a valued commodity for referring physicians and clinicians when learning a new resource for their patients. The education can include multiple formats to meet the needs of the audience including lectures, educational brochures, webcasts, publications regarding outcomes and patient stories, and conferences at the ECMO center on topics related to ECMO such as current ARDS and shock therapies.

10.5 Follow-up communication

While clearly an avenue to enhance education, follow-up communication is also an important tool to create the interpersonal relationship that develops trust between the organizations. It is very important for referring provider to learn the "end of the story" regarding patients that were sent for therapy. In addition, this provides a transition of care so that appropriate ongoing care can be provided to the patient in their home medical community. This also establishes that trust of the referring providers that patients sent for a specific therapy will be sent back to the home community for the care that can be provided in that setting.

10.6 Branding

As the use of ECMO increases, the need to create a memorable brand for the program becomes a key component to establishing the reputation of the ECMO center that is distinguishable from other future programs. The program should ideally be branded as a part of the larger cardiothoracic-vascular/pulmonary/critical care program of the institution. This allows the halo of the organization's programs to create synergistic enhancement quality outcomes and growth opportunities.

11. Conclusions

The initiation of an ECMO program is a comprehensive multidisciplinary project, which must be based on the clinical needs of the patients served. It requires advanced clinical capabilities and decision-making, and clear pathways for patient care to make it high quality and financially sustainable. As such, strong leadership is needed from physician leaders, nursing leaders, and administrative leaders working in a triad professional leadership model.

Once the clinical case for implementation is made, a multidisciplinary team should be identified, and given the ability to work across multiple departments and stakeholders to assure all quality and operational details are aligned and accomplished. The team is encouraged to work using change management format and techniques supported with strong project guidelines to assure that the internal and external resources needed to support ECMO care are identified, captured as project goals, and systematically completed prior to initiation of ECMO patient care. Use of tools such as order sets, access center protocols, and education tools support clinical standardization across the team, and provides a consistency of clinical care.

Quality metrics are identified at project initiation and can be supported by ELSO tools allowing comparisons across programs internationally. The commitment to high quality and a relentless curiosity to find improvements that can be made, are critical to provide best practices to this high acuity population. The data and outcomes collected can help educate and encourage referrals from other programs that do not have ECMO capabilities, thus providing added advanced patient care options on regional basis.

The literature has previously benchmarked an 18 month ramp up to program initiation as rapid deployment. Using the tools provided by others in the literature, a strong triad leadership process, and a dedicated multidisciplinary team with strong project management support, it is possible to accomplish program initiation in a six-month period in a hospital with an established CV Surgical program. We believe this process is replicable, and provides tools and implementation models that can be used by other hospitals to add needed ECMO support to meet their community needs [8–10].

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References

[1] Firstenberg MS. Extracorporeal Membrane Oxygenation–Advances in Therapy. Rijeka, Croatia: InTech; 2016, 2016. p. 392. ISBN: 978-953-51-2553-2. Print ISBN: 978-953-51-2552-5. Under CC BY 3.0 license. DOI 10.5772/61536. http://www.intechopen.com/books/how-to-link/extracorporeal-membrane-oxygenation-advances-in-therapy

[2] Firstenberg MS, editor. Advances in Extra-corporeal Perfusion Therapies. London, UK: InTech Publishing Limited; 2019. ISBN: 978-1-78984-914-1. Print ISBN: 978-1-78984-913-4. https://www.intechopen.com/books/advances-in-extra-corporeal-perfusion-therapies

[3] Putensen C, Theuerkauf N, Zinserling J, Wrigge H, Pelosi P. Meta-analysis: Ventilation strategies and outcomes of the acute respiratory distress syndrome and acute lung injury. Annals of Internal Medicine. 2009;**151**(8):566-576

[4] Bernard G. Acute lung failure—Our evolving understanding of ARDS. The New England Journal of Medicine. 2017;**377**(6):507-509

[5] Van Diepen S, Katz JN, Albert NM, Henry TD, Jacobs AK, Kapur NK, et al. Contemporary management of cardiogenic shock: A scientific statement from the American Heart Association. Circulation. 17 Oct 2017;**136**(16):e232-e268

[6] Thiele H, Ohman EM, Desch S, Eitel I, de Waha S. Management of cardiogenic shock. European Heart Journal. 2015;**36**(20):1223-1230

[7] Combes A, Brodie D, Bartlett R, Brochard L, Brower R, Conrad S, et al. Position paper for the organization of extracorporeal membrane oxygenation programs for acute respiratory failure in adult patients. American Journal of Respiratory and Critical Care Medicine 2014;**190**(5):488-496

[8] Kattan J, Godoy L, Zavala A, Faunes M, Becker P, Estay A, et al. Improvement of survival in infants with congenital diaphragmatic hernia in recent years: Effect of ECMO availability and associated factors. Pediatric Surgery International. 2010;**26**(7):671-676

[9] Unai S, Tanaka D, Ruggiero N, Hirose H, Cavarocchi NC. Acute myocardial infarction complicated by cardiogenic shock: An algorithm-based extracorporeal membrane oxygenation program can improve clinical outcomes. Artificial Organs. Mar 2016;**40**(3):261-269

[10] Dalia AA, Ortoleva J, Fiedler A, Villavicencio M, Shelton K, Cudemus GD. ECMO is a team sport: Institutional survival benefits of a formalized ECMO Team. Journal of Cardiothoracic and Vascular Anesthesia. 2018

[11] Peek GJ, Mugford M, Tiruvoipati R, Wilson A, Allen E, Thalanany MM, et al. Efficacy and economic assessment of conventional ventilatory support versus extracorporeal membrane oxygenation for severe adult respiratory failure (CESAR): A multicentre randomised controlled trial. Lancet. 2009;**374**(9698):1351-1363

[12] Combes A, Hajage D, Capellier G, Demoule A, Lavoué S, Guervilly C, et al. Extracorporeal membrane oxygenation for severe acute respiratory distress syndrome. The New England Journal of Medicine 2018;**378**(21):1965-1975

[13] Extracorporeal Life Support Organization (ELSO). Guidelines for Adult Respiratory Failure. Ann Arbor Michigan, USA: Extracorporeal

Life Support Organization; August, 2017. https://www.elso.org/Portals/0/ELSO%20Guidelines%20For%20Adult%20Respiratory%20Failure%201_4.pdf. [Accessed on 05.05.2019]

[14] Bosarge PL, Raff LA, McGwin G Jr, Carroll SL, Bellot SC, Diaz-Guzman E, et al. Early initiation of extracorporeal membrane oxygenation improves survival in adult trauma patients with severe adult respiratory distress syndrome. Journal of Trauma and Acute Care Surgery. 2016;**81**(2): 236-243

[15] Doorenbos AZ, Starks H, Bourget E, DM MM, Lewis-Newby M, Rue TC, et al. Examining palliative care team involvement in automatic consultations for children on extracorporeal life support in the pediatric intensive care unit. Journal of Palliative Medicine. 2013;**16**(5):492-495

[16] Joseph T, Selzman Craig H, Malin Michael P, Smith Brigham R, Youngquist Scott T, Antigoni K, et al. Development and implementation of a comprehensive, multidisciplinary emergency department extracorporeal membrane oxygenation program. Annals of Emergency Medicine. 2017;**70**(1):32-40

[17] Kotter J. Leading Change, Harvard Business School Press, © September 1, 1996

[18] Lamhaut L, Hutin A, Deutsch J, Raphalen JH, Jouffroy R, Orsini JP, et al. Extracorporeal cardiopulmonary resuscitation (ECPR) in the prehospital setting: An illustrative case of ECPR performed in the louvre museum. Prehospital Emergency Care. 2017;**21**(3):386-389

[19] Broman LM, Frenckner B. Transportation of critically Ill patients on extracorporeal membrane oxygenation. Frontiers in Pediatrics. 2016;**4**:63

[20] Dan D, Richard F, Chris H, Dirk L, Matthew B, Steve C, et al. Extracorporeal Life Support Organization (ELSO) Guidelines for ECMO Transport. Ann Arbor Michigan, USA: Extracorporeal Life Support Organization. 2015. https://www.elso.org/Portals/0/Files/ELSO%20GUIDELINES%20FOR%20ECMO%20TRANSPORT_May2015.pdf. [Accessed on 05.05.2019]