

Rapid Development and Implementation of an ECMO Program

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Extracorporeal membrane oxygenation (ECMO) is an established therapy in the management of patients with refractory cardiogenic shock or acute respiratory failure. In this report, we describe the rapid development and implementation of an organized ECMO program at a facility that previously provided *ad hoc* support. The program provides care for patients within the Emory Healthcare system and throughout the Southeastern United States. From September 2014 to February 2015, 16 patients were treated with either venovenous or venoarterial ECMO with a survival to decannulation of 53.3% and survival to intensive care unit discharge of 40%. Of the 16 patients, 10 were transfers from outside facilities of which 2 were remotely cannulated and initiated on ECMO support by our ECMO transport team. Complications included intracerebral hemorrhage, bleeding from other sites, and limb ischemia. The results suggest that a rapidly developed ECMO program can provide safe transport services and provide outcomes similar to those in the existing literature. Key components appear to be an institutional commitment, a physician champion, multidisciplinary leadership, and organized training. Further study is required to determine whether outcomes will continue to improve. ASAIO Journal 2016; 62:354–358.

Key Words: extracorporeal membrane oxygenation, implementation, outcome, adult

In recent years, the number of cases and centers offering adult extracorporeal membrane oxygenation (ECMO) has risen.¹

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Patients with refractory cardiogenic shock (CS) or acute respiratory failure (ARF) can be stabilized with venoarterial (VA) or venovenous (VV) ECMO, respectively, until definitive therapy can be offered. Experienced centers have demonstrated that patients can safely be transported on ECMO to specialized centers for further care.^{2,3} Recent publications demonstrate that ECMO outcomes correlate with the case load at respective centers.^{4–6}

For years, Emory University Hospital (EUH) provided emergent ECMO support on an *ad hoc* (as needed) basis. Outcomes during this time were not tracked, but perception was that survival was below that observed at large volume centers with established ECMO programs and protocols. This was likely because of multiple factors: 1) no formal mechanism to evaluate patients that may require ECMO therapy, 2) inadequate formal ECMO training for nursing support, and 3) general inexperience in the care of patients, particularly those with respiratory failure. In addition, perfusionists operated the ECMO circuit and were required to be present at the patient bedside 24 hours/day, resulting in system stress.

Given the limitations of the previous ECMO support services and the growing recognition that ECMO support may improve outcomes, EUH and the Emory Critical Care Center (ECCC) decided to develop a formal ECMO program. It was hypothesized that the advantage of shared knowledge, improved skill sets, specialized/knowledgeable personnel with specialized facilities, and easily transportable equipment would improve patient outcomes. This article details the rapid development of the ECMO program and discusses the outcomes for the first 6 months of its operation.

Methods

We attribute the success of an ECMO program to the synergy of multiple components: 1) institutional commitment, 2) key personnel with continuous involvement in ECMO management, 3) a physician leader with hospital supported time to develop the program, and 4) a formal consultative service to evaluate ECMO candidates.

A timeline for the development of the program is shown in **Figure 1**.

Institutional Commitment

The first step in the development of the program was an institutional commitment on the part of EUH and ECCC to develop a comprehensive ECMO program. One-time financial support in excess of \$700,000 was supplied by EUH for equipment and training. Ongoing support is provided for program staff and consumables. It was understood that starting such a program would show dividends in patient care and hospital revenue over years, but there were no mandated performance expectations from EUH. A workgroup was formed under the direction of ECCC to develop ECMO protocols and standard of care.

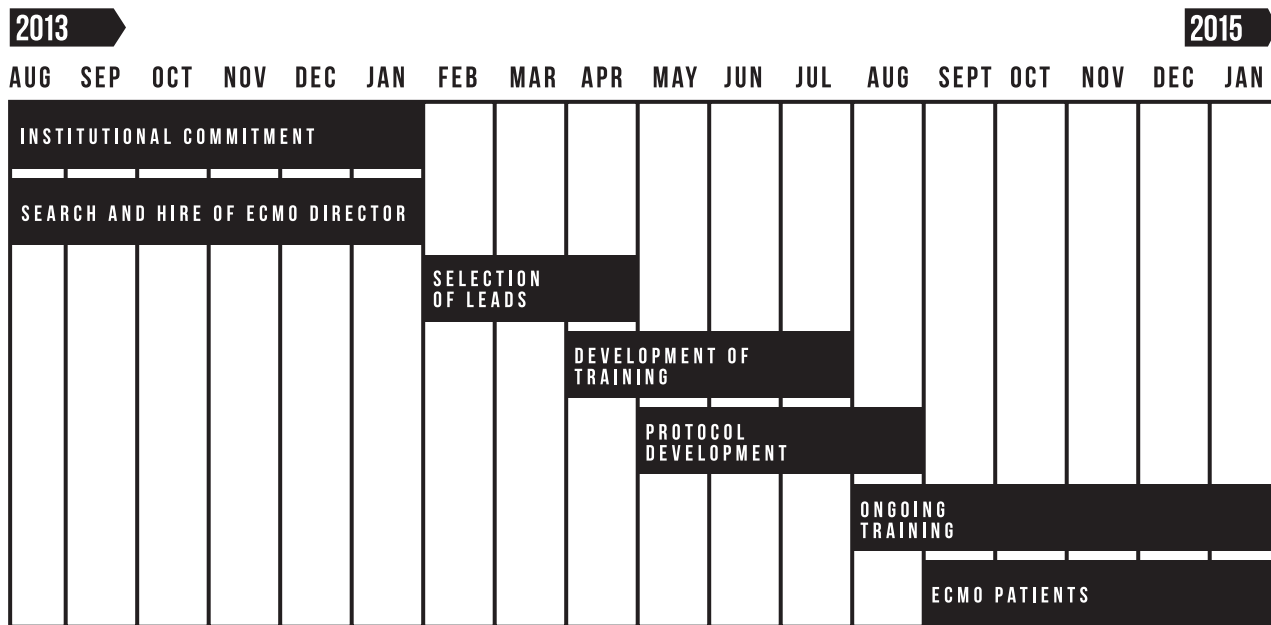


Figure 1. Timeline for extracorporeal membrane oxygenation (ECMO) program development.

Key Personnel

Early in the process of program development, it became clear that programmatic success would be best achieved with a physician champion who would serve as a director of the ECMO service. This individual would be accountable for the development of protocols and processes to efficiently provide ECMO therapy. He/she would also be responsible for being the liaison between different services and responsible for monitoring program quality.

Furthermore, leads were selected from all the services to be involved with the care of patients (see Figure 2). As the Emory Healthcare system involves four hospitals, it was determined that providing care at all centers was inefficient and potentially dangerous. Hence, providing ECMO transportation services would be a priority with careful attention to develop guidelines and standards to provide safe remote cannulation and transportation of ECMO patients from Emory and other facilities. Once key personnel were selected, equipment procured, and standards of care developed, training modules were initiated centered on EHC ECMO standards and ECMO-specific equipment with acute trouble shooting a priority.

Staffing Design

Extracorporeal membrane oxygenation support at Emory was historically provided by perfusionists. Because of the infrequent use of the therapy, when ECMO therapy was instituted, significant demands were placed on the existing system. This resulted in the frequent cancellation of cardiac operating room cases because of the lack of available perfusion support and significant dissatisfaction among the cardiac surgeons, patients, hospital administration, and perfusionists.

After consideration of multiple models for care, a hybrid respiratory therapist (RT)/perfusionist model of ECMO care was selected. This model was selected because of the preexisting skill-set of RT, the lack of flexible nurse staffing, and the reimbursement and flexibility of respiratory therapy full-time equivalents.

Training of Staff

The educational program for key personnel was created using internally developed materials detailed in Table 1. Therapists undergo formal training every 6 months to remain current on protocols and use of the technology. This includes training to rapidly prime a new circuit and perform circuit exchange in the event a perfusionist is not physically available. In the event,

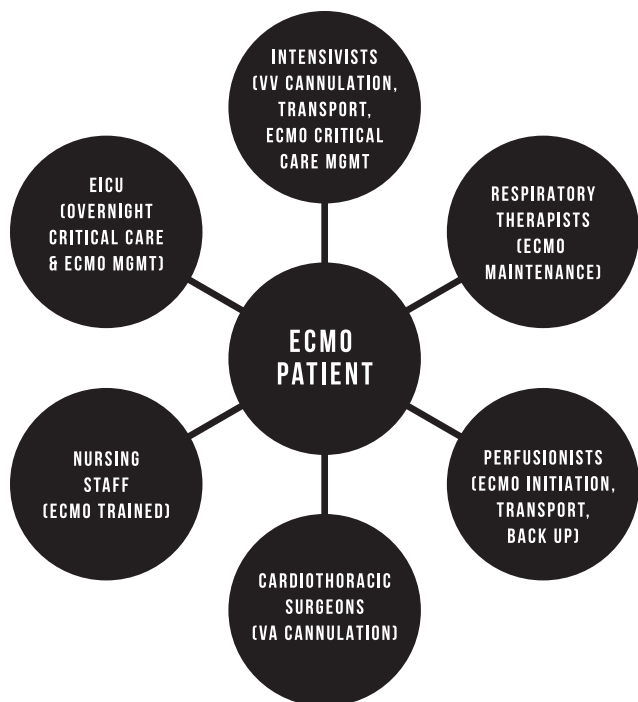


Figure 2. Displays the extracorporeal membrane oxygenation (ECMO) team's key personnel.

Table 1. Educational Program for Key Personnel

Staff	Training
Nurses	6 hours of didactic teaching sessions with annual refreshers.
Respiratory therapists	15 hours of didactics and wet laboratories with competency demonstrated by satisfactory completion of a written and hands-on examination. This is followed by 24 total hours of proctored direct management of an ECMO circuit and patient under the direct supervision of a perfusionist at the bedside before being allowed to manage one patient independently. Upon completion of 60 hours of independent ECMO circuit management in the care of a single patient, an RT is permitted to independently manage more than one patient. Ongoing competency for RTs consists of additional training and completion of written and wet laboratory examination every 6 months.
Physician extenders	Comprehensive lecture series amounting up to 5 hours of training.
Physicians	Ongoing education, monthly conferences, education on ECMO protocols, didactic courses, and continued mentoring by the medical director.

a therapist has questions; an on-call perfusionist is always available by phone.

Protocol Development

The ECMO working group established criteria for ECMO therapy. A comprehensive review of the literature was conducted in conjunction with examination of the Extracorporeal Life Support Organization (ELSO)⁷ guidelines, and the workgroup developed a set of criteria based on a consensus process.

The criteria offer a series of strong and relative contraindications to help screen for ECMO therapy based on the best existing evidence. Strong and relative contraindications were chosen for ARF with consideration of the criteria for the Conventional ventilatory support vs extracorporeal membrane oxygenation for severe adult respiratory failure (CESAR) and Extracorporeal Membrane Oxygenation for Severe Acute Respiratory Distress Syndrome (EOLIA) trials^{4,8} for CS criteria mostly surround the likelihood of recovery or bridge to transplant or VAD. Hence, contraindications included age > 70 years, preexisting renal failure, or multiorgan system dysfunction with preexisting significant cardiac failure. The contraindications were not absolute but designed to guide the selection of candidates that had the potential for survival after decannulation either through organ recovery or implantation of mechanical circulatory support.

Leveraging published and other available resources and prior experiences of the medical director and working group members, ECMO-specific protocols were drafted and reviewed by members of the ECMO workgroup, then circulated to additional nursing, physician, RT, perfusion therapy, and pharmacy support for commentary before being finalized.

Equipment

While the protocols were being developed, the medical director in cooperation with the lead perfusionist for the ECMO program selected program equipment. The Cardiohelp system by Maquet (Maquet Cardiovascular, Wayne, NJ) best fit the needs of the proposed service especially to facilitate local and airborne transportation, although this device does not have a Food and Drug Administration indication for support greater than 6 hours. Contracts were negotiated with critical care transport companies to facilitate ground and airborne ECMO transport including time for training.

ECMO Transport and Referral System

An ECMO transport and referral system was developed. Extracorporeal membrane oxygenation pager numbers

and on-call schedules were established. The ECMO transport and remote cannulation team consists of cannulator or intensivist or fellow, a perfusionist, and a nurse or paramedic.

Any ECMO referral is channeled to a knowledgeable intensivist. The case is then evaluated by the intensivist, medical director, and other invested parties (cardiology, pulmonology, cardiothoracic surgery, etc.) depending on patient's prognosis. Three care options are offered:

1. Critical care transport with or without physician support to EUH for advanced management and ECMO evaluation.
2. Cannulation by outside hospital and transport to Emory on ECMO.
3. Remote evaluation and cannulation and transport to Emory by the ECMO transport team.

Once the patient is cannulated, the ECMO team's perfusionist initiates ECMO and assures appropriate support. Once stabilized on ECMO, the patient is transported to EUH for further care. Transport modality depends on estimated travel time and weather. Once the patient has arrived in the ICU and is stable, RTs assume care of the ECMO circuit.

Standard anticoagulation, transfusion, and weaning protocols are used based on the ELSO guidelines. A lead critical care pharmacist reviewed the guidelines and the literature to finalize anticoagulation protocols and order sets. Decannulation is typically performed at the bedside, unless bleeding complications are anticipated.

Program Evaluation

The program is continuously monitored quarterly by the medical director and multidisciplinary ECMO clinical management team. Each case is discussed in detail with a goal to improve the value of care.

Statistical Methods

Survival was defined as time from initiation of ECMO to decannulation, death, or last chart review through March 2015. Survival estimates and descriptive statistics were calculated using R (R project for statistical computing).

Results

From September 2014 to February 2015, 16 patients were treated with ECMO at EUH. Details of support are listed in **Table 2**.

Table 2. Characteristics of Initial ECMO Cases

Patient	Age (years)	Gender	Etiology	Indication for Support	Type of Support	Length of Support (hours)	Transfer	Survival to decannulation	Survival to Hospital Discharge
1	66	M	Pancreatitis, ARDS	RDS	VV	164	Y	Y	N
2	25	F	Sp pulmonary artery stent, hypoxia	CS, RDS	VAV	24	N	N	N
3	33	M	CS	CS	VA	110	Y	Y	Y
4	42	F	Respiratory failure	RDS	VV	307	N	N	N
5	71	F	CS post-thoracic aortic aneurysm repair	CS	VA	6	N	N	N
6	26	M	ARDS post-trauma	RDS	VV	54	Y	Y	Y
7	51	M	CS	CS	VA	216	Y	Y	Y
8	45	F	ARDS	RDS	VA converted to VV	48	Y	N	N
9	23	M	ARDS	RDS	VV	111	N	Y	Y
10	67	F	Pulmonary embolism	RDS	VV	252	N	N	N
11	37	F	CS	CS	VA	141	Y	Y	Y
12	63	M	Failed CABG	CS	VA	80	Y	Y	N
13	62	M	Acute myocardial infarction, CS	CS	VA	37	Y	N	N
14	74	F	Respiratory failure	RDS	VA	156	Y	N	N
15	30	F	Respiratory failure	RDS	VV	12	Y	Y	Y
Mean ± SD	47.6 ± 17.6					114.5 ± 88.3		53.30%	40%

ARDS, acute respiratory distress syndrome; CABG, coronary artery bypass graft surgery; CS, cardiogenic shock; F, female; M, male; RDS, respiratory distress syndrome; VA, venoarterial ECMO; VAV, venoarterial-venous; VV, venovenous ECMO.
 *Reflects only ECMO time at Emory University Hospital, ECMO times at outside hospital were not available.

One patient died during cannulation because of already persistent severe hypoxia pre-ECMO and was not included in the survival results. Three patients had intra-aortic balloon pumps in place. Overall, patients had a survival to decannulation of 53% and survival to discharge of 40%. Seven patients received VV-ECMO, of these four survived to decannulation (57%) and three to discharge (43%). Eight patients were placed on VA-ECMO, of these 50% survived to decannulation and 38% to discharge. One of the survivors had a left ventricular assist device inserted.

One patient in CS from an outside hospital developed dilated and nonreactive pupils. was cannulated and placed on ECMO at our facility. Twelve hours later, a brain death examination was positive, and the patient was subsequently referred for organ donation but not accepted.

Median support time on ECMO was 114 ± 93.5 hours (VA-ECMO median time was 89 ± 7 4.3 hours; VV-ECMO median time was 135 ± 102.8 hours).

Complications included intracerebral hemorrhage, bleeding from other sites, and limb ischemia for which diverting cannulas were placed. One case of heparin-induced thrombocytopenia was confirmed. No complications during ECMO transport were noted (no ECMO circuit failure including malfunctions of centrifugal pump, tubing, cannula, and oxygenator) although there were failures of three pieces of unrelated transport equipment.

Discussion

The implementation of an RT-driven ECMO program can be completed rapidly with results consistent with published outcomes. After 6 months, the overall survival to discharge was 40%. This is comparable with outcomes at other ECMO programs at early stages.⁵ Our VV survival rate to decannulation was 57%, which is lower than that in published VV trials from

Table 3. Available Pre-ECMO Arterial Blood Gases

Patient	2	3	4	5	9	10	11	13	15
Fio ₂	1	1	0.8	1	1	1	0.8	1	1
pH	6.82	7.31	7.24	7.28	7.18	7.06	7.4	7.19	7.18
CO ₂	102	32	84	40	68	53	12.4	35	54
O ₂	45	59	92	354	43	69	238	84	39
HCO ₃	16.1	15.9	36	19.2	24.9	14.4	7.5	12.9	19.6
BE	-19.4	-9.2	6.4	-7.4	-4.3	-15.9	-14.9	-14.2	-9.3
HB	12.3	13.3	11.4	96.7	10.9	13.3	10.5	11.1	17.5
% O ₂ HB	48.8	89	94.2	20	66.9	87.8	98.8	93.2	62.3
% O ₂ saturation	45.2		96	8.7	66	84.9	99.4	93.9	60.8
% COHB	0.4	0.3	0.7	1.4	1	1.3	0.4	0.2	0.3
% Methemoglobin	0.3	0.4	1.4	1.6	0.4	0.2	0.2	0.5	0.2
[a-A] DO ₂	541.5		364		584.8	568.5		574.2	600.3
Lactate (mmol/L)	9.29	6.21	2.63	>15.0		3.19	9.59	8.72	3.98

Patients not listed were cannulated at outside hospitals not within the Emory system, and no pre-ECMO data were available. BE, base excess; HB, hemoglobin; COHB, carboxyhemoglobin.

the H1N1 epidemic,^{4,6} which may be related to patient selection or delayed referral for ECMO therapy.

No patient complications occurred during transport, demonstrating that training and protocols can result in safe transport from a new program. Overall results are similar to those from the Columbia group⁹ and improved from earlier results¹⁰ likely because of advances in ECMO technology. Future goals for the program include increased academic study of ECMO for ARF and an examination of the technology's application in refractory septic shock.

Conclusions

The rapid development of an adult ECMO program can be achieved, and it offer results similar to the survival published in several series. Key components to success appear to be institutional commitment, a physician champion, multidisciplinary leadership, and organized training. Using consistent training, a combined RT/perfusionist model, and organized transport, complications can be minimized. Further study is required to determine whether outcomes will improve with increased experience.

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