Intensive Care Med
https://doi.org/10.1007/s00134-018-5064-5

CONFERENCE REPORTS AND EXPERT PANEL

Position paper for the organization of ECMO programs for cardiac failure in adults

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Abstract

Extracorporeal membrane oxygenation (ECMO) has been used increasingly for both respiratory and cardiac failure in adult patients. Indications for ECMO use in cardiac failure include severe refractory cardiogenic shock, refractory ventricular arrhythmia, active cardiopulmonary resuscitation for cardiac arrest, and acute or decompensated right heart failure. Evidence is emerging to guide the use of this therapy for some of these indications, but there remains a need for additional evidence to guide best practices. As a result, the use of ECMO may vary widely across centers. The purpose of this document is to highlight key aspects of care delivery, with the goal of codifying the current use of this rapidly growing technology. A major challenge in this field is the need to emergently deploy ECMO for cardiac failure, often with limited time to assess the appropriateness of patients for the intervention. For this reason, we advocate for a multidisciplinary team of experts to guide institutional use of this therapy and the care of patients receiving it. Rigorous patient selection and careful attention to potential complications are key factors in optimizing patient outcomes. Seamless patient transport and clearly defined pathways for transition of care to centers capable of providing heart replacement therapies (e.g., durable ventricular assist device or heart transplantation) are essential to providing the highest level of care for those patients stabilized by ECMO but unable to be weaned from the device. Ultimately, concentration of the most complex care at high-volume centers with advanced cardiac capabilities may be a way to significantly improve the care of this patient population.

Keywords: Extracorporeal membrane oxygenation, Extracorporeal life support, Mechanical circulatory support, Cardiac failure, Cardiac arrest, Hospital organization, Critical care networks, Position article

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Introduction

Extracorporeal membrane oxygenation (ECMO) is a high-risk, complex, and resource-intensive therapy. Its use for adult patients with cardiac failure and cardiac arrest has grown rapidly over the last decade in the setting of advances in extracorporeal technology [1, 2]. ECMO plays a pivotal role in providing life-saving mechanical circulatory support in selected patients. However, rigorous data supporting its use are limited [3], ECMO practices vary widely across hospitals and countries [4], and there may be room to improve outcomes in certain populations [5].

ECMO for cardiac failure should be implemented with a clear understanding of its indications, limitations, and risks, and be performed at centers that are prepared to both initiate and subsequently manage these patients, whether it be internally or by partnering closely with institutions capable of such management. There are numerous current potential uses of ECMO for cardiac failure, and additional evidence as well as standardized practices are needed to better define the optimal patient populations for this invasive and expensive therapy [6].

Purpose of this position paper

This position paper represents the expert opinion of an international group of physicians, ECMO specialists, and allied healthcare workers, spanning six continents, who have expertise relevant to mechanical circulatory support (MCS) used to treat patients with severe cardiac failure. Many practices in the care of patients with cardiogenic shock are not supported by randomized, controlled data and for this reason we seek to offer expert opinion to provide some guidance for the use of ECMO as circulatory support. A companion position paper was previously published addressing organizational issues for centers utilizing ECMO for acute respiratory failure [7]. The aim of this paper is to provide clinicians, ECMO center directors and coordinators, hospital administrators, healthcare organizations, and regional, national, and international policy makers a consensus approach to the organization of ECMO programs for cardiac failure and cardiac arrest in adults. Our goal is that this will help ensure ECMO is delivered appropriately, safely, and proficiently. Given that ECMO is being widely used across centers of varying case volume and experience, a key message of this paper is that ECMO should be performed within a framework of cooperating hospitals (Table 1). Centers with limited resources should have collaborative relationships with high-volume centers capable of providing long-term cardiac support therapies, such as durable ventricular assist devices (VAD) and heart transplantation.

ECMO in the spectrum of mechanical circulatory support devices

Venoarterial ECMO is one of several short-term, or temporary, MCS options, i.e., catheter- or cannula-based vascular access with mechanical pumps that are used as first-line rescue therapy in patients with refractory cardiogenic shock [8, 9]. Other short-term MCS devices used in this setting include intra-aortic balloon pumps (IABP), percutaneous VADs, and surgical VADs [10–12]. The differences between the various short-term MCS devices are outlined in Table 2 [10]. The use of different MCS devices is not necessarily exclusive, as IABP or percutaneous VADs, for instance, may be used to manage left ventricular over-distention in patients receiving venoarterial

Table 1 Summary of key recommendations

Extracorporeal membrane oxygenation (ECMO) needs to be understood and implemented in the greater context of mechanical circulatory support options and reserved for the appropriate clinical scenarios
The use of pre-specified inclusion and exclusion criteria for consideration of ECMO should be used to facilitate a standardized approach that can be implemented expeditiously
ECMO for cardiac failure should ideally be performed at experienced, high-volume centers (i.e., comprehensive care centers) capable of providing other forms of advanced cardiac support, including percutaneous coronary interventions (PCI) and long-term heart replacement therapies (e.g., ventricular assist devices (VADs) and heart transplantation). Such centers should have multidisciplinary teams readily available and should ideally be equipped with mobile ECMO teams capable of cannulation and retrieval of patients from other facilities with limited ability to provide ECMO
Regional referral centers capable of performing ECMO, including ECMO transport, but without access to long-term heart replacement therapies, should have collaborative relationships with comprehensive care centers
Both local centers that may or may not have PCI capabilities and referral centers with access to both PCI and percutaneous VADs, but without the capabilities of ECMO management, are encouraged to have affiliations with regional referral centers or comprehensive care centers in order to have appropriate access to ECMO
In order to optimize outcomes, we recommend that, whenever possible, centers performing ECMO for cardiac failure achieve a minimum ECMO case volume of 30 cases per year, with a substantial proportion being for cardiac failure
ECMO centers should have continual access to the facilities, equipment, and staffing necessary for both routine ECMO management and management of unanticipated emergencies of ECMO complications
ECMO centers should adhere to best practices and routinely perform quality assurance assessments to ensure they are meeting acceptable clinical standards. Participation in national or international databases provides a standard against which programs can benchmark their performance
Given the relative lack of high-level evidence for ECMO in cardiac failure, ECMO centers are encouraged to participate in large, multicenter registries, such as with the Extracorporeal Life Support Organization (ELSO), as well as research consortia, such as the International ECMO Network (ECMONet), whose missions are to better study and elucidate the role of ECMO, including in cardiac failure and cardiac arrest in adults

ECMO [13]. Similarly, ECMO may be initiated for a patient inadequately supported by a percutaneous VAD. It is important to note that, although the terminology we use throughout the paper is in common usage in the field, there is currently no universally accepted nomenclature for mechanical circulatory support devices.

Indications and contraindications for venoarterial ECMO

There are several etiologies of cardiac failure that are supportable with ECMO. These can be broadly classified into severe, refractory forms of cardiogenic shock, i.e., cardiogenic shock despite the use of multiple vasoactive medications or an MCS device (i.e., Interagency Registry for Mechanically Assisted Circulatory Support (INTERMACS) level 1); cardiac arrest; refractory ventricular arrhythmias; and acute or decompensated right heart failure in the context of pulmonary vascular disease (e.g., pulmonary hypertension or pulmonary embolism) [14–31]. Table 3 provides a list of indications (with the corresponding level of evidence) and contraindications to venoarterial ECMO [32, 33].

Proposed nomenclature for cardiac centers

Access to and experience with ECMO and other MCS devices, inter-hospital ECMO transport, long-term heart replacement therapies, and other cardiac procedures help inform the appropriate strategy for ECMO use. Among centers with potential access to ECMO, we define *local centers* as those that may or may not have interventional cardiology facilities available on-site. *Referral centers* are centers with access to cardiac catheterization and percutaneous left ventricular assist devices. *Regional referral centers* have access to short-term MCS devices with the ability to perform inter-hospital transport on MCS. *Comprehensive care centers* have all of the resources of regional referral centers with the additional capability of performing long-term MCS and heart transplantation. Proposed relationships between centers are shown in Fig. 1.

Organization of ECMO centers for cardiac failure

The implementation of ECMO for cardiac failure differs from that for respiratory failure because of the more frequent need for emergent ECMO support. Furthermore, some etiologies of cardiac failure require prompt

Table 2 Mechanical circulatory support options for cardiogenic shock (Adapted from Table 3 in [10] by Garan AR and Rabbani LE)

	IABP	TandemHeart	Impella (2.5, CP, 5.0, RP)	VA ECMO	Central surgical VAD
Mechanism	Pneumatic	Centrifugal, paracorporeal	Axial, transvalvular	Centrifugal, extracorporeal	Centrifugal, extracorporeal
Device configuration	Descending aorta via femoral artery	Inflow: LA via transseptal (or RA) Outflow: femoral artery (or pulmonary artery)	Inflow: LV (or IVC) Outflow: ascending aorta (or pulmonary artery)	Inflow: femoral vein/IVC or internal jugular vein/SVC Outflow: femoral, axillary/subclavian, or innominate artery	R Inflow: IJ, femoral, RA, or RV R Outflow: PA L Inflow: LV or LA L Outflow: aorta or subclavian artery
Type of ventricular support	LV	LV or RV	LV or RV	LV and RV	LV and RV
Maximum cardiac output support (L/min)	0.5–1	4	2.5–5	> 5	> 5
Magnitude of LV unloading	+	+++	++/+++	Variable[a]	+++
Afterload effect	–	+++	None	+++	None
Complexity of implantation	+	+++	++/+++	+	+++
Complexity of management	+	+++	++	+++	+++
Risk of limb ischemia	+	+++	++	+++[b]	Variable
Risk of hemorrhage	+	+++	+++	+++	++
Gas exchange support	None	None[c]	None	+++	None[c]

IABP intra-aortic balloon pump, *VA ECMO* venoarterial extracorporeal membrane oxygenation, *VAD* ventricular assist device, *L* left, *LV* left ventricle, *LA* left atrium, *IVC* inferior vena cava, *SVC* superior vena cava, *R* right, *RA* right atrium, *RV* right ventricle, *PA* pulmonary artery, *IJ* internal jugular; (+) low, (++) moderate, (+++) high, (–) reduced

[a] Preload is reduced while afterload is increased

[b] Can be mitigated by use of distal reperfusion cannula

[c] May be used with an oxygenator to provide gas exchange

Table 3 Indications for venoarterial ECMO and quality of evidence

	Highest level of evidence
Indications	
Myocardial infarction-associated cardiogenic shock	Cohort studies
Fulminant myocarditis	Cohort studies
Sepsis-associated cardiomyopathy	Cohort studies
Adult congenital heart disease with acute decompensated heart failure	Case series
Post-cardiotomy cardiogenic shock	Cohort studies
RV support during LVAD implantation	Cohort studies
Bridge to VAD or heart transplantation	Cohort studies
Post-transplantation graft failure	Cohort studies
ECPR	Cohort studies with matched propensity analyses
Cardiogenic shock post-cardiac arrest	Cohort studies with matched propensity analyses
Refractory ventricular arrhythmia	Cohort studies
Pulmonary hypertension with RV failure	Case series
Massive pulmonary embolism	Cohort studies
Contraindications	
Absolute	
Severe irreversible non-cardiac organ failure limiting survival (e.g., severe anoxic brain injury)	
Irreversible cardiac failure if transplantation or long-term VAD will not be considered	
Severe aortic insufficiency	
Aortic dissection	
Relative	
Severe coagulopathy or contraindication to anticoagulation	
Limited vascular access	
Severe peripheral arterial disease	

ECPR extracorporeal cardiopulmonary resuscitation, *LVAD* left ventricular assist device, *RV* right ventricular, *ECMO* extracorporeal membrane oxygenation, *VAD* ventricular assist device

intervention to reverse the underlying pathology (e.g., percutaneous coronary intervention in an acute coronary syndrome), which, in turn, may substantially shorten the duration of circulatory support necessary for survival. For both of these reasons, the decision to initiate ECMO or other MCS must be made expeditiously. ECMO for cardiac failure would ideally be performed at regional referral or comprehensive care centers, where ECMO is part of a broader management strategy for advanced cardiovascular disease that may incorporate percutaneous coronary interventions, long-term MCS, and heart transplantation [32]. Such centers should have algorithms in place to assist with rapid decision-making, and ideally be able to quickly convene a multidisciplinary "heart team" or "shock team," which may consist of cardiothoracic surgeons, interventional cardiologists, heart failure specialists, critical care physicians, and any other team members deemed essential who can pursue the most appropriate management strategy [34–37]. However, this does not preclude the use of ECMO at less experienced or less well-resourced centers, especially in cooperation with a more experienced center.

The use of ECMO to restore circulation during cardiac arrest, referred to as extracorporeal cardiopulmonary resuscitation (ECPR), presents its own unique set of challenges. Unlike progressive, severe cardiogenic shock, which most often will occur in the cardiac catheterization laboratory, intensive care unit, or operating room, cardiac arrest may occur unpredictably in any location throughout the hospital, including emergency departments, where ECPR programs have been increasingly under development. ECPR may also take place in the pre-hospital setting, which is a venue under active investigation [38–41]. Although the specific needs of ECPR programs are beyond the scope of this paper, we strongly recommend that these programs be linked to inpatient intensive care unit programs that are capable of managing the cases wherever they are initiated, or that rapid transfer to a partner center for further management can be guaranteed. Regardless of the location, both the decision to initiate (or not initiate) ECMO, and the cannulation itself, must be executed as quickly as possible, ideally with the use of pre-specified criteria to identify patients most (or least) likely to benefit from ECPR (Table 4) [42, 43]. A rapid response team, similar to the aforementioned multidisciplinary team for cardiogenic shock, helps facilitate the successful implementation of ECPR [22, 23, 44, 45]. An approach utilizing smaller arterial

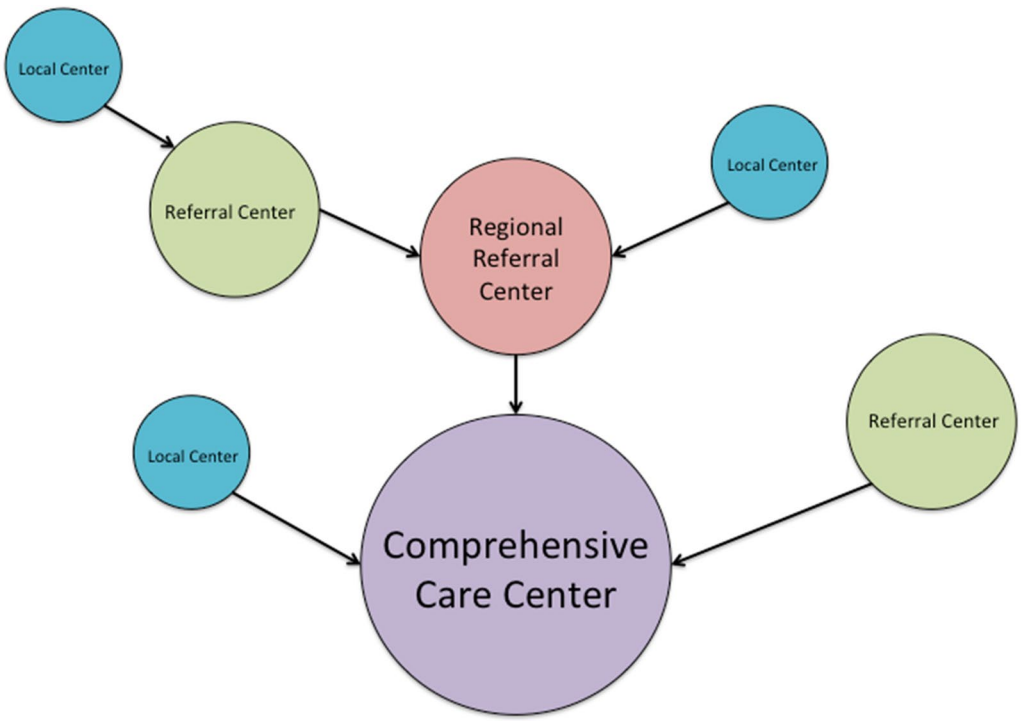

Fig. 1 Referral model for ECMO for cardiac failure in adults. Local center: may or may not have interventional cardiology facilities available on-site. Referral center: access to cardiac catheterization and percutaneous LV assistance devices ± ECMO. Regional referral center: access to short-term MCS devices including ECMO with ability to perform inter-hospital transport on MCS. Comprehensive care center: regional referral center + long-term MCS and heart transplantation

cannulas inserted percutaneously under ultrasound guidance, or under fluoroscopic guidance in the catheterization laboratory, should be encouraged to reduce hemorrhagic, infectious, and vascular complications [46].

It should be emphasized that ECMO is a short-term means of supporting the patient's circulation but does not treat the underlying pathology. As soon as feasible (and in some cases emergently), this underlying pathology must be aggressively managed to optimize the chance of recovery and expedite safe weaning from ECMO. This includes but is not limited to revascularization (percutaneously or surgically) for patients with ischemic heart disease as the etiology [47, 48], valvular surgery for patients with a valvular etiology, medical or ablative therapy for those with refractory arrhythmia [49], and thrombolysis (systemic or catheter-directed), pulmonary embolectomy,

Table 4 Suggested criteria for ECPR

Indications
Failure to achieve ROSC despite 15 min of conventional CPR
Cardiac arrest presumed to be of cardiac origin (including pulmonary embolism)
Contraindications
Relative
Advanced age
Prolonged or unknown time from onset of cardiac arrest to initiation of CPR
Absolute
Acute aortic dissection or severe aortic insufficiency
Underlying end-stage heart failure if long-term heart replacement therapies will not be considered
Any non-cardiac condition or organ dysfunction that would limit the likelihood of overall benefit from ECPR, such as severe, irreversible brain injury or untreatable metastatic cancer
Inconsistent with patient's previously expressed goals of care

CPR cardiopulmonary resuscitation, *ECPR* extracorporeal cardiopulmonary resuscitation, *ROSC* return of spontaneous circulation

and pulmonary endarterectomy for patients with acute or chronic thromboembolic disease [50]. For those with little chance of ventricular recovery or safe weaning from support, early evaluation for heart replacement therapies should be initiated. In addition to having advanced cardiac therapies available, centers performing ECMO to support patients with severe pulmonary vascular disease should have access to clinicians with expertise in pulmonary hypertension management and, ideally, the ability to perform lung transplantation [28].

Higher ECMO case volume at a given hospital has been associated with lower in-hospital mortality [51], suggesting that referral to high-volume ECMO centers may lead to improved outcomes [52–54]. Cannulation may be performed by either the originating hospital or the receiving hospital at the time of transport, depending on the capabilities of each center and the agreement between them [55]. Centers initiating ECMO should have surgical services immediately available that can manage the potentially life- or limb-threatening vascular complications of cannulation.

For local and referral centers without the ability to initiate ECMO, we recommend the creation of networks around regional referral or comprehensive care centers capable of deploying mobile ECMO teams to initiate this therapy and transfer these patients. If ECMO is initiated by local or referral centers for resuscitation of a patient with severe cardiogenic shock or cardiac arrest, including as back-up to high-risk cardiac interventions, the patient may be exposed to substantial risk and suboptimal outcomes. For these centers, we recommend a formal partnership with regional referral or comprehensive care centers willing to accept these patients for transfer (with mutual agreement of indications, contraindications, criteria for initiation, and technique for cannulation) [56]. These approaches have been successfully adopted for respiratory ECMO centers with favorable results [53, 57, 58].

The minimum acceptable case volume for an ECMO center remains controversial. Recent data from an analysis of 290 centers within the Extracorporeal Life Support Organization (ELSO) registry suggest an inverse linear relationship between case volume and mortality, with centers performing more than 30 adult ECMO cases per year (from 2008 to 2013) having a significantly lower mortality than centers performing fewer than 6 cases per year (adjusted OR 0.61, 95% CI 0.46–0.80), a relationship that held true when the analysis was limited to ECMO for cardiac failure [51]. However, it is important to note that this threshold was determined on the basis of retrospective registry data from centers whose levels of expertise were not specified.

As with any therapy, familiarity with ECMO will improve outcomes as the potential complications can be recognized and addressed quickly at centers where volumes are high. Therefore, to optimize outcomes for this therapy we recommend that a reasonable goal should be a minimum case volume of 30 adult ECMO cases per year, with a substantial proportion being for cardiac failure [51]. This case volume goal should be achieved through evidence-based practices and protocols where available, and otherwise through expert consensus. However, centers should resist the temptation to perform ECMO only to increase center volume as a way of meeting this or any other volume goal. Adult cardiac ECMO centers should work in close coordination with their pediatric and adult respiratory ECMO colleagues. In particular, because some patients with severe refractory cardiac failure may develop concomitant severe respiratory failure, cardiac ECMO programs should have access to clinicians or to a center with expertise in the use of ECMO for respiratory failure, ideally within their own center. Clinical competence should be developed and maintained through local, national, and international educational programs with an emphasis on both user-specific and multidisciplinary aspects of such training. Multiple medical societies and other organizations, including ELSO, offer training and education in the provision of ECMO.

Patient selection criteria

To guide decision-making and optimize outcomes, standardized pre-specified ECMO criteria should be created whenever possible. These criteria may differ from one disease process to another, and often depend on the anticipated duration of support and likelihood of weaning from mechanical circulatory support. For some indications, there are not enough data to create definitive criteria. This is particularly important for programs performing both ECPR as well as ECMO for cardiogenic shock, where decisions often have to be made with limited clinical information. For centers initiating ECMO with the intention of referral to a tertiary care center, preestablished inclusion and exclusion criteria as well as the approach to cannulation should be agreed on between referring and receiving hospitals to ensure acceptance of the patient by the receiving hospital. Standardization of equipment, where feasible, is also advised. The recent development of prognostic scoring systems, such as the Survival After Venoarterial ECMO (SAVE) score, may help guide clinicians in selecting appropriate candidates for ECMO [47, 59]. More research is needed to help establish disease-specific criteria to provide the best estimation of favorable clinical outcomes and to externally validate predictive survival models.

Mobile ECMO teams

High-volume ECMO centers, particularly those serving as the regional referral or comprehensive care centers within hospital referral networks, should ideally establish and coordinate mobile ECMO teams to retrieve patients with severe cardiac failure refractory to conventional therapy. These mobile teams should be available 24 h a day, 7 days a week, and employ experienced personnel trained in transporting critically ill patients, insertion of cannulae (if performed by the mobile team), as well as circuit and patient management. The team should include some combination of physicians, surgeons, transport specialists, nurses, perfusionists, or other ECMO specialists. Imaging requirements at the referring hospital should be considered, including echocardiography or fluoroscopy. Portable ultrasound equipment is essential to aid in vascular access. Checklists should be considered to ensure availability of all necessary equipment and consistency of provider roles and actions before and during transport. After-action reviews are recommended. Successful transportation of patients on cardiopulmonary support by ambulance, helicopter, and fixed-wing aircraft has been described [60–62]. Centers performing ECMO should develop specific guidelines and ensure adequate staff training to provide uninterrupted availability to intrahospital transport of patients receiving ECMO. The equipment used for transport should meet the relevant standards for ground or air transport, with an emphasis on safety and durability.

Recommendations for physical facilities and equipment

The equipment that should be readily available is listed in Table 5. Importantly, a primed circuit should be available at all times in case of emergency, which should be possible in centers with sufficient ECMO volume. Some evidence suggests that primed circuits may be able to be stored for up to 4 weeks without increased risk of infection [63, 64]. Availability of both staff and equipment should allow for rapid circuit exchange in case of sudden circuit malfunction. For programs performing ECPR, the same staff and equipment availability should allow for the possibility of initiating cannulation within 15 min of conventional CPR onset in any location within the hospital (Table 4). Rapid initiation of extracorporeal support may require pre-primed circuits and other essential equipment to be stored in multiple locations throughout the facility. An organized approach to ECPR should be undertaken with a clearly delineated team, ideally available 24 h per day, that can respond immediately to in-hospital cardiac arrests.

Staffing

All staff involved in ECMO should meet the requirements of their subspecialty training as set forth by their specific governing body [65]. The director of the cardiac ECMO program should be a board-certified cardiovascular specialist with expertise in critical care; a thoracic, vascular, or trauma surgeon; or other board-certified specialist with specific training and experience in ECMO. Every member of the team should receive specific ECMO

Table 5 Equipment and facilities needed within the intensive care unit providing ECMO

Equipment and facilities needed in the ECMO unit
Backup components of the ECMO system and supplies for all circuit components
Uninterrupted power system for all equipment, monitors and pumps for at least 45 min
Clamps
Surgical instruments for revision of cannulae or exploration for bleeding complications
Adequate lighting to support surgical interventions
ECMO water heater
Equipment for intrahospital transport
Mobile ECMO cart
Uninterrupted power system for all equipment, including mobile equipment
Mobile ECMO monitoring device
Emergency transport backpack with clamps and emergency drugs
Wet-primed circuit available for immediate use recommended
Ultrasonography machine with Doppler-echocardiography capabilities
Monitoring device to assess distal perfusion of cannulated limbs (e.g., vascular Doppler ultrasound, near-infrared spectroscopy (NIRS))
Fiberoptic bronchoscope
Device(s) capable of venting the left ventricle, e.g., intra-aortic balloon pump or percutaneous LVAD

ECMO extracorporeal membrane oxygenation, *LVAD* left ventricular assist device

training and demonstrate competencies on an ongoing basis. There should be 24-h availability of an on-call physician comfortable with managing patients receiving ECMO both to assist with urgent or emergent management of patients and to evaluate patients from referring hospitals. Selected members of the ECMO team should be trained in vascular and cardiac ultrasonography for insertion, maintenance, and surveillance of the ECMO device. Fully trained ECMO specialists should be immediately available for circuit-related concerns, including ECMO circuit exchange.

ECMO specialists should be trained to prime and set up the circuit. Depending on the center-specific caregiver model, the ECMO specialist may also be responsible for managing equipment and supplies, daily rounds, troubleshooting, education, and performing administrative duties. An ECMO coordinator (often one of the lead ECMO specialists) is essential to assist the medical director with various aspects of the ECMO program, including but not limited to training, staffing, quality improvement, and patient data entry into the ELSO registry or other relevant databases.

ECMO staff should receive regular training and education on theoretical and practical aspects of ECMO, including simulation training whenever available [66]. Participation of staff in this education program should be recorded and their proficiency evaluated, with retraining of team members as needed, on the basis of criteria set forth by the ECMO program [65]. Standardization of assessing proficiency should be a goal for the ECMO community. Roles and responsibilities for staff who manage specific aspects of patient care, including circuit setting adjustments, ventilator changes, anticoagulation, and cannula care and adjustments, should be clearly outlined, with role-specific training organized by the ECMO program. Training and education materials as well as practical courses in ECMO are available through ELSO and other major medical organizations [67]. For institutions starting new ECMO programs, adequate planning and training by qualified personnel is necessary prior to performing ECMO. Consultation from experienced personnel at other centers is advisable.

Non-ECMO services

Various personnel from medical, surgical, and laboratory services should be available 24 h per day to assist with management of patients receiving ECMO support (Table 6). Ideally services needed for ECPR would be available in-house at all times. An ECMO center should be able to provide cardiothoracic surgery, percutaneous coronary intervention, vascular and abdominal surgery, and interventional radiology services on an emergent basis. The hospital's biomedical engineering department should maintain ECMO equipment on a regular basis. Physical and occupational therapy should be available on a non-urgent basis, with specific training in optimizing patient mobility on ECMO [68]. Pastoral and palliative care, along with other patient and family support services, should be available, at least on a non-urgent basis, in regions where such services exist. Pre-emptive palliative care consultation prior to ECMO initiation may be appropriate for patients in whom outcomes are especially uncertain, such as those in patients where ECMO is used as a "bridge to decision" [69]. Access to ethics consultation, similarly, may be of particular importance for situations in which patients are dependent on ECMO for survival but without an option for destination therapy, a so-called bridge to nowhere scenario [70, 71]. In order to help prepare patients' families and manage expectations, access to written materials about ECMO may be useful.

Program evaluation and quality assurance

The ECMO program should have procedures in place to perform quality assurance for internal ECMO program evaluation [65, 67]. Each ECMO center should hold routine multidisciplinary meetings to analyze its activity and review its equipment needs. Regularly scheduled meetings should be organized among ECMO centers and other referring hospitals within a given ECMO network to report activities and review cases. Any major complication or death should undergo prompt review by the appropriate ECMO team members and the hospital committee responsible for oversight of such adverse outcomes, adherent to the relevant quality assurance laws. Formal clinical-pathological case reviews with a multidisciplinary approach should also be conducted regularly.

Documentation of the maintenance of equipment and supplies should be performed. Data reports summarizing the indications for and results of ECMO should be available for quality assurance review. ECMO centers are strongly encouraged to submit their data to large national or international databases for clinical audit and benchmarking, to allow for comparison of outcomes and to highlight variation with other national and international institutions. Regional and national accreditation organizations should be created to establish guidelines for best practices, thereby allowing ECMO programs to be evaluated regularly for adherence to accepted standards. Centers with poorer than expected results should be encouraged to engage in extensive practice evaluation and improvement strategies. This review should be constructed to identify strengths and weaknesses within the program to help ensure its sustainability. We recommend that new programs create an advisory committee consisting of experts from outside the institution to assist with program development and quality review, which could

Table 6 Non-intensive care unit support services at regional referral and comprehensive care centers

Clinical staff and services available on an emergent basis
Cardiothoracic, vascular, and general surgery with operating capabilities
ECMO specialist
Interventional cardiology
Interventional radiology
Esophagogastroduodenal endoscopy
Clinical staff available on an urgent basis
Cardiology with the ability to perform transthoracic and transesophageal Doppler-echocardiography
Anesthesiology
Pulmonology
Hematology
Neurology and neurological surgery
Nephrology
Gastroenterology
Otolaryngology
Obstetrics
Diagnostic radiology for emergency imaging, including cardiac computed tomography
Pharmacy, with critical care expertise
Clinical staff available on non-urgent basis (where available)
Physical and occupational therapy
Palliative care
Ethics consultation
Pastoral care
Psychiatry
Laboratory capabilities
Blood gas analysis
Blood chemistry and hematologic testing
Coagulation testing
Blood bank with capability of rapid blood product delivery
Microbiology

ECMO extracorporeal membrane oxygenation

allow for an appropriate period of oversight for new programs to ensure the new center is meeting acceptable standards. Cost considerations vary across centers and countries, and should be evaluated on the basis of local needs.

Patient follow-up

Each ECMO center should ensure appropriate short- and long-term follow-up for patients who survive having received ECMO, with specialty-specific consultation as needed, particularly for those with ongoing heart failure and those at risk for delayed mortality. Physical rehabilitation programs may be of particular importance given the potential for ICU-acquired weakness in patients requiring prolonged MCS. Psychological and cognitive rehabilitation may also be important with survivors, as well as screening for psychological distress post-discharge.

Research

There is an ongoing need for controlled clinical trials and other high-level evidence to clarify the appropriate use of ECMO in severe refractory cardiogenic shock and other cardiac indications. These data will help to guide clinicians with respect to disease-specific indications and contraindications. Given the relatively small number of ECMO cases at any individual center, and the large numbers of patients needed to study meaningful clinical outcomes, national and international organizations of ECMO centers are useful; two such organizations are ELSO (https://www.elso.org) and the International ECMO Network (ECMONet, https://www.internationalecmonetwork.org). ELSO maintains the largest registry of ECMO patients, which has proven to be a valuable tool for researchers. Similarly, ECMONet is a research consortium that includes ECMO-specific expertise dedicated to conducting and supporting high-quality, high-impact research in the field. Both randomized controlled

trials and matched pairs trials may be suitable for studying these patients with severe cardiac failure, several of which are either being conducted or in the planning phases [41, 53, 72–76].

Conclusions

ECMO for cardiac failure is a high-risk and complex therapy. ECMO will very likely continue to play a vital role in the management of cardiovascular failure, and it should be performed responsibly within a given center or within a network of centers, by clinicians with the appropriate expertise. More precisely defining the role of ECMO in cardiac failure, and the optimal techniques that should be used, will require further evidence. Ongoing technological developments and future research will no doubt spur continued evolution in the field.

Funding

CH is supported by a Future Leader Fellowship from the National Heart Foundation of Australia (Award ID: 101168); funding source had no role in the writing of the manuscript or the decision to submit for publication. PKP receives funding support from the National Heart, Lung, and Blood Institute (NHLBI), National Institute of Allergy and Infectious Diseases (NIAID), Food and Drug Administration/Biomedical Advanced Research and Development Authority (FDA/BARDA), Bristol-Myers Squibb, and AtoxBio; funding sources had no role in the writing of the manuscript or the decision to submit for publication.

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Compliance with ethical standards

Conflicts of interest

DB is currently on the medical advisory boards of ALung Technologies and Kadence. All compensation for these activities is paid to Columbia University. All other authors have no conflicts of interest to report.

Received: 2 December 2017 Accepted: 12 January 2018
Published online: 15 February 2018

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