Extracorporeal Life Support Organization (ELSO)

ECLS Center Certification Program Level 1 Designation Blueprint

June 2025

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About the ECLS Center Certification

ELSO's ECLS Center Certification program designates scope of care for ECLS programs. It is designed to be informative for programs everywhere, while also providing structure and purpose for organizational help on a global scale. The program addresses key components that ELSO views essential: ECLS team education and training, policies and procedures, governance, financial management, and research for all institutions aiming to provide safe and accessible ECLS care. Quality of care continues to be assessed by ELSO's Center of Excellence program, which has a separate application and award process.

ECLS care includes Extracorporeal Membrane Oxygenation (ECMO), Extracorporeal Carbon Dioxide Removal (ECCO2R), Extracorporeal Cardiopulmonary Resuscitation (ECPR), Extracorporeal Interval Support for Organ Retrieval (EISOR), and other forms of life support that utilize an artificial organ to support the patient. While the ELSO Center Certification program will evaluate all forms of ECLS, the focus of this program is ECMO – the predominant form of ECLS currently provided.

The ECLS Center Certification will recognize ECLS centers by *Patient Population*, *ECLS Support Type*, and *ECLS Certification Level*. Applicant centers will designate their desired Patient Population and ECLS Support Type. The Center's Level will be designated by ELSO.

Patient Population

The patient population designations are as follows:

- ***ELSO Adult ECLS Center Certification*** designates ECLS programs who treat patients aged 18 years and older.
- ***ELSO Pediatric ECLS Center Certification*** designates ECLS programs who treat patients aged 29 days through 17 years. Some Pediatric programs will treat patients up to 21 years old.
- ***ELSO Neonatal ELCS Center Certification*** designates ECLS programs who treat patients from birth through 28 days.

ECLS Support Type

- ***Cardiac ECLS*** designates centers that provide ECLS for cardiac indications, including – but not limited to – cardiogenic shock, post-cardiac arrest recovery, post-cardiotomy recovery, cardiac failure, and infection-related cardiac conditions.
- ***Pulmonary ECLS*** designates centers that provide ECLS for pulmonary indications, including – but not limited to – acute respiratory distress syndrome (ARDS), bacterial or viral infection, drowning, embolism, and hypoxic respiratory failure.
- ***Extracorporeal Cardiopulmonary Resuscitation (ECPR)*** designates centers that provide ECLS for the resuscitation of in-hospital cardiac arrest (IHCA) patients. Out-of-hospital cardiac arrest (OHCA) is not presently evaluated as part of the ECLS Center Certification program.

ECLS Certification Level

Centers who achieve ECLS Center Certification will be awarded one of three (3) designations by ELSO. Level designation is a scope of services award designed to objectively demonstrate the ECLS services provided by an ECLS Certified Center.

- ***Level 1*** designates centers that provide all locally available modes of cardiopulmonary support, including but not exclusively ECLS. Level 1 Centers must provide full ECLS transport capabilities*; be able to perform ECLS cannulations at external medical facilities**; provide access to heart and lung transplant services[T]; and be open to internal and external ECLS consults at all times.
- ***Level 2*** designates centers that are capable of initiating and managing long-term ECLS management. Level 2 Centers will accept outside hospital transfers but may also transfer some patients to a Level 1 (or equivalent) facility for advanced treatment. Level 2 centers may have ECLS transport and/or heart & lung transplant services – but these are not required.
- ***Level 3*** designates cannulation-only facilities and/or those that manage ECLS patients for a brief period. Level 3 Centers are primarily transferring their patients to a Level 1 or 2 Certified Center (or equivalent facility) for extended management.

	LEVEL 1	LEVEL 2	LEVEL 3
Full-Service ECLS Center	**R**	**-**	**-**
Always Open to ECLS Consults	**R**	**-**	**-**
Initiate and Mange Long-Term ECLS	**R**	**R**	**-**
ECLS Cannulation and Short-Term Care Only	**-**	**-**	**R**
Services			
ECLS Transport*	**R**	**O**	**-**
Cannulate Patients at an External Facility**	**R**	**O**	**-**
Heart Transplant Services[T]	**R**	**O**	**-**
Lung Transplant Services[T]	**R**	**O**	**-**
All Modes of Locally Available Cardiopulmonary Support	**R**	**-**	**-**

R = Required Service; O = Optional Service

**Access to ECLS Transport: Key features are responsiveness, competence, and ability to perform all types of ECLS transport.*

***Cannulation at an external facility: send a team from the Level 1 Center to an external facility, perform an ECLS cannulation at the external facility, and transport the patient to the Level 1 Center.*

[T]*Level 1 Centers are not required to provide heart and/or lung transplant services in-house. If a Level 1 Center does not have one of the required transplant services in-house, a contract demonstrating access to the external service is required.*

Transplant Designation is required for Level 1 Centers and optional for Level 2 Centers. Transplant Designation indicates that a center provides access to heart and/or lung transplant services, either in-house ([T]) or out of house ([Ø]). A Center will receive Transplant Designation by patient population (adult, pediatric, neonatal) and support type (cardiac and/or pulmonary).

ECLS Referral Designation

ECLS Referral Designation is a non-certified recognition available for non-ECLS centers that identify patients for ECLS treatment and have strong partnerships to nearby ECLS centers. To qualify for designation as an ECLS Referral Center, the institution must meet the following criteria:

- Have awareness of ECLS modes and their indications,
- Be able to identify early signs of potential ECLS candidacy – particularly for ECMO,
- Collaborate with nearby ECLS centers to identify potential ECLS patients,
- Initiate patient transfer to an ECLS center for ECLS care, and
- Provide no ECLS care (including cannulation, initiation, or definitive patient selection).

Certification Nomenclature

There are three components to ELSO's ECLS Certification nomenclature: patient population(s), ECLS support type(s), and level(s). For clarity, only one patient population should be represented in each certification nomenclature. The long form nomenclature is:

ELSO + [Patient Population] + [Level Designation] + ECLS Center Certification: [ECLS Support Type(s)]
Example: ELSO Adult Level 2 ECLS Center Certification: Pulmonary, Cardiac, and ECPR

For brevity, a short form is available:

ECLS + [Patient Population] + [Level Designation]-[First letter of each indication]*
****Pulmonary = P; Cardiac = C; ECPR = E***

If the Center also provides access to cardiac or lung transplant, the Transplant Designation is added to the cardiac and/or pulmonary support type.

In House Transplant = Transplant^{T}; Out of House Transplant = Transplant^{Ø}

Hospital A Medical Center		
Adult	***Pediatric***	***Neonatal***
Level 1 *Pulmonary^{T}* *Cardiac^{Ø}* *ECPR*	*Level 2* *Pulmonary^{Ø}* *Cardiac*	*Level 3* *ECPR*
Long Form		
ELSO Adult Level 1 ECLS Center Certification: Pulmonary (Transplant^{T}), Cardiac (Transplant^{Ø}), and ECPR ELSO Pediatric Level 2 ECLS Center Certification: Pulmonary (Transplant^{Ø}) and Cardiac ELSO Neonatal Level 3 ECLS Center Certification: ECPR		
Short Form		
ECLS Adult Level 1-R^{T}C^{Ø} ECLS Pediatric Level 2-R^{Ø}C ECLS Neonatal Level 3-E		

Definitions

For the sake of clarity and conciseness, several common definitions are used.

- ***ECLS (Extracorporeal Life Support)*** is an umbrella term for all extracorporeal life support technologies, including Extracorporeal Membrane Oxygenation (ECMO), Extracorporeal Carbon Dioxide Removal (ECCO2R), Extracorporeal Cardiopulmonary Resuscitation (ECPR), Extracorporeal Interval Support for Organ Retrieval (EISOR), and other forms of life support that utilize an artificial organ to support the patient. While this term is not inclusive of Continuous Renal Replacement Therapy (CRRT), the simultaneous deployment of ECLS and CRRT may require specific care considerations. [1]
- ***ECMO (Extracorporeal Membrane Oxygenation)*** is defined as the provision of oxygen and carbon dioxide exchange using an extracorporeal circuit consisting of a blood pump, artificial lung, and vascular access cannulas, using blood flows sufficient to support oxygenation and concomitantly enhance carbon dioxide removal.[1]
- ***Extracorporeal Carbon Dioxide Removal (ECCO2R)*** is similar to ECMO in that it is designed to remove carbon dioxide using an extracorporeal circuit consisting of a drainage cannula, a pump, a membrane lung, and a return cannula. However, ECCO2R does not provide significant oxygenation and is typically performed at a lower blood flow rate.[2]
- ***Extracorporeal Cardiopulmonary Resuscitation (ECPR)*** is defined as the initiation of ECMO in cases of cardiac arrest, particularly those that are refractory to traditional resuscitation (CPR). ECPR has many applications, including in-hospital and out-of-hospital.
- ***Extracorporeal Interval Support for Organ Retrieval (EISOR)*** is defined as the use of extracorporeal technology to provide perfusion of organs awaiting recovery after declaration of cardiac death.
- ***Institution*** is defined as the hospital or medical center that houses the ECLS Program and serves as the site of care for all inpatient and/or outpatient clinical services.
- ***ECLS Program*** or ***Program*** is defined as the ECLS program itself, including leadership, clinical staff, and administrative personnel dedicated exclusively or primarily to the provision of ECLS services. Note that where ECMO is the primary modality of ECLS care, the terms ECMO and ECLS may be interchangeable. However, where ECMO is provided alongside other forms of ECLS (such as ECCO2R, ECPR, and others), ECLS is intended to cover the full spectrum of services.
- ***ECLS Coordinator*** and ***ECLS Specialist*** are terms used to define particular roles within the ECLS Program. These roles and responsibilities are further defined in the Program below. Some ECLS Centers may use one term or the other; for the purposes of these Program, ***ECLS Coordinator*** and ***ECLS Specialist*** are interchangeable with ***ECMO Coordinator*** and ***ECMO Specialist***.
- ***Methodology*** refers to the Methodology document, which defines and describes the ECLS Center Certification program developed by ELSO and the CCTF.
- ***Blueprint*** refers to this document, which is a guide to help Level 1 ECLS Centers – and those that may wish to become Level 1 Designated – in developing and managing their ECLS program.
- ***ECLS Level 1 Certified Centers (Level 1 Centers)*** refers to any center currently certified as ECLS Level 1, or a program seeking to become ECLS Level 1 Certified by ELSO.

[1] *Maastricht Treaty for ECLS Nomenclature* https://doi.org/10.1186/s13054-019-2334-8

[2] *Bench to bedside review: Extracorporeal carbon dioxide removal, past present and future* https://doi.org/10.1186/cc11356

Overview

ECLS Level 1 Centers are those that provide all locally available modes of cardiopulmonary support, including but not exclusively ECLS. Level 1 Centers must provide full ECLS transport capabilities*; be able to perform ECLS cannulations at external medical facilities**; provide access to heart and lung transplant services[T]; and be open to internal and external ECLS consults at all times.

**Access to ECLS Transport: Key features are responsiveness, competence, and ability to perform all types of ECLS transport.*

***Cannulation at an external facility: send a team from the Level 1 Center to an external facility, perform an ECLS cannulation at the external facility, and transport the patient to the Level 1 Center.*

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Program and Organization

Program Governance

Level 1 Centers model their leadership structure closely to the ELSO ECLS Center Certification Methodology. Three leadership roles are crucial to the ECLS program: Program Director, Associate Program Director(s), and the ECLS Coordinator. A Level 1 Center will have each of these roles filled (or co-filled, if desired). Each role is further defined below.

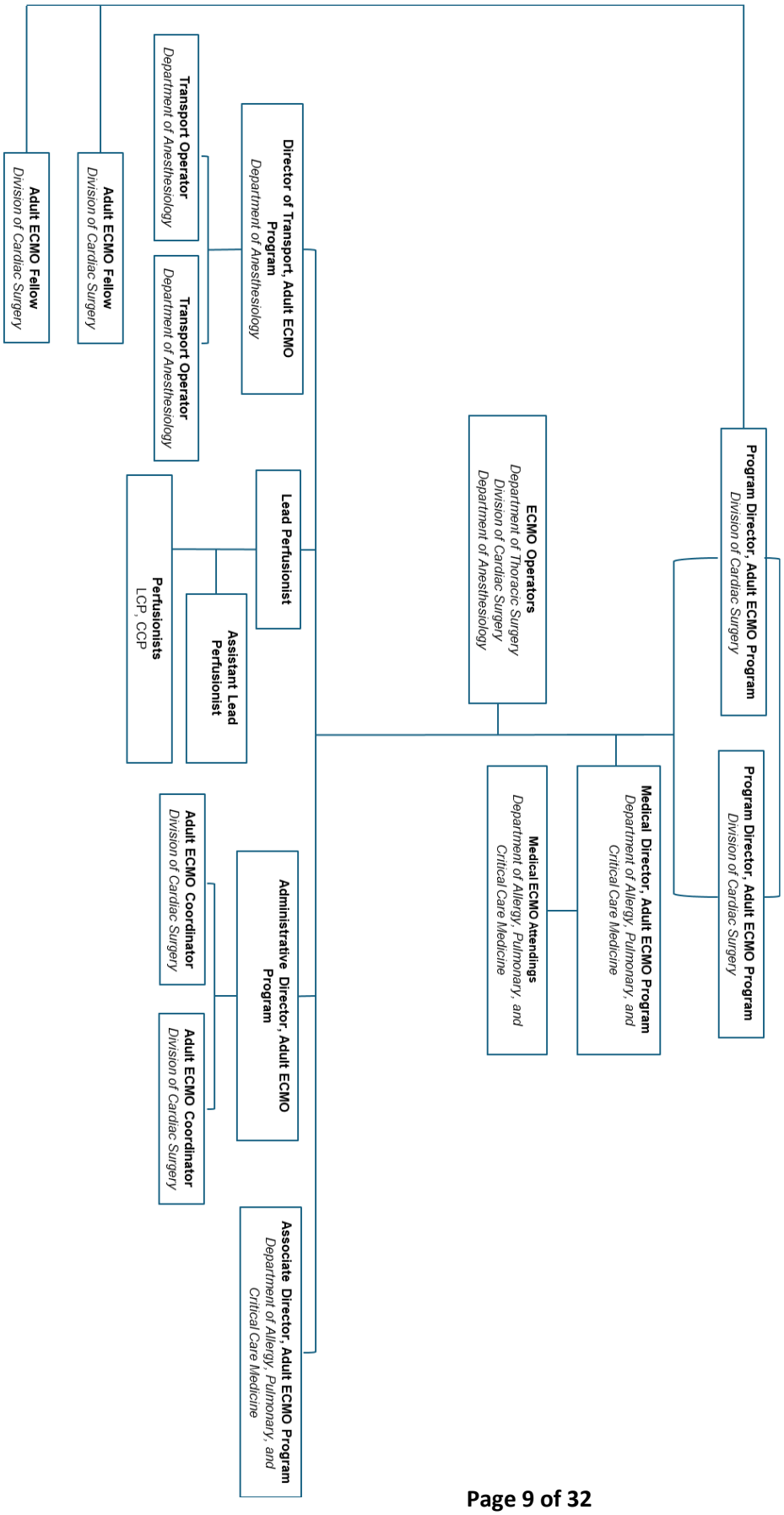
Program Director

A *Program Director (PD)* will lead the ECLS program. Typically, this leadership role is held by one person; in some institutions, the ECLS program is co-led by an *ECLS Medical Director* and an *ECLS Surgical Director*. Alternately, a PD role may be designated by patient population (adult, pediatric and/or neonatal), often by way of an Adult ECLS Program Director and a Neonatal & Pediatric ECLS Program Director, or similar titles. Any PD continues to have direct ECLS patient care responsibilities in their role.

The PD position should be held by a physician(s) who has the training, experience, and expertise to run the ECLS program. More than just an expert in the field, the PD must have the qualities of a leader: cross-functional harmony, clarity of mission, and advocacy for ECLS at the institutional level. The PD will collaborate within the ECLS team and with all stakeholders to ensure that the ECLS program has proper support, management, and quality. Examples include advocating for adequate training funds for the ECLS team, maintaining adequate staffing levels for the size and scope of program, and other resources area well-managed, such as equipment, time, or physical space.

The PD typically reports to either department-level leadership, such as a Chair or Associate Chair, or a director-level position in a multidisciplinary center, such as the heart and vascular center. The PD will advocate for support across domains: financially, administratively, clinically, and if necessary, politically within the larger institutional framework. The PD will also engage senior institutional leadership in the ECLS program, both in its successes and its opportunities for improvement. The PD should be the voice of the ECLS program in these conversations.

FIGURE 1: EXAMPLE ECLS PROGRAM ORGANIZATIONAL CHART



An *Associate Program Director (APD)* may be designated in a multi-population or support program, comprised of one or more physicians with specific responsibility for one or more ECLS patient populations. Examples include Adult ECMO, Pulmonary ECMO, or specific areas such as ECLS Transport. The PD and other senior leadership will determine which roles are most necessary based on program needs and ECLS team composition. A Level 1 Center will have 1-3 APD for the ECLS program.

The APD will specialize in and advocate for specific elements of the ECLS program. These roles cover both bedside care and administrative responsibilities in relatively equal portions. The APD is an important catalyst between the PD and staff-level positions. In the example of an ECLS program that was part of the Pilot Phase, there was an APD that oversaw the ECLS Transport program. This physician was heavily engaged in the day-to-day operations of the transport program and routinely carried out transport missions by air and ground. This APD was highly effective in her role; she was directly relatable to the staff she oversaw, while also having the senior vantage point of an ECLS program leader.

The *ECLS Coordinator (Coordinator)* is a critical non-physician leadership role in the ECLS program. The Coordinator is responsible for the supervision and training of the bedside ECLS staff, typically called the ECLS Specialists. ECLS Specialists can be perfusionists, nurses, respiratory therapists, or other professionals based on the structure of the ECLS program. The Coordinator is a highly experienced ECLS specialist with clinical and leadership skills. They work closely with the PD(s) and APD(s) to ensure adequate staffing, develop program policy & procedures, and lead day-to-day operations of the ECLS program. Like other ECLS leadership roles, the Coordinator balances clinical and administrative responsibilities in a ratio that varies by institution, but typically comprises at least 50% clinical time.

Institutional Support for the ECLS Program

An ECLS program provides the opportunity for an institution to provide life support to its sickest patients, including those patients that will potentially be referred for access to ECLS. ECLS can be a bridge to transplant. The topic of finance and billing for ECLS is more fully described in a later section.

Evidence of adequate institutional support include:

- ***Dedicated & Consistent Funds for Staff Education and Training:*** Training and education of each ECLS team member is foundational to patient safety, effective use of extracorporeal therapies, and the success of the ECLS program. Didactics, simulation lab, and proctored clinical hours are necessary components of an ECLS training program. Funds should be specifically allocated to each of these training areas to ensure full team completion.
- ***Team Staffing:*** A consistent and well-established staffing model ensures that the ECLS team has adequate coverage for the number of patients in house plus room for any referrals, transfers, or consultations. Many ECLS centers use an *n+1* model, where the number of staff available is scaled to the number of patients currently on ECLS plus 1 more patient. If another patient is added to the ECLS team's care, the *+1* staffer will care for the added patient, and an on-call person is contacted to fill the *+1* role. Other staffing models include hybrid or flexible staffing models. A Level 1 Center will have a clearly defined staffing plan, including roles and responsibilities for the ECLS team.
- ***Financial Support of Resources, Technology, and Program Needs:*** ECLS is resource-intense; required elements include high startup costs (equipment, staff, education and training) plus

ongoing needs (continuing education, certification, maintenance of training). ECLS team members are highly trained. Dedicated space is necessary (e.g., adequate space for training, equipment storage, equipment deployed during patient care, space for patient ambulation). The institution and the ECLS program must have a reasonable expectation of the costs associated with ECLS care. While patient care revenues can offset ECLS care costs, financial drivers should be but one consideration when developing an ECLS program. An ECLS program with the equipment, space, and programmatic needs met will be a safe and reliable ECLS program.

- ***Credentialing and Privileging:*** Institutions should establish the competencies and means of demonstrating knowledge that will be used to grant ECLS privileges. ELSO provides a list of metrics that are important in ECLS care, by role or care type. Privileging processes should be in place based on these (and other) competencies. Remediation plans should be available for those providers that require more support. The ECLS program and the institution must jointly decide how, when, and why each provider is granted ECLS care privileges, and must further specify which mode(s) and role(s) – cannulation, management, or otherwise – that a provider has been granted. ECLS credentialing is fully described later in this document.
- ***Policies & Processes:*** ECLS-related policies and procedures should be in place. These should be developed by the ECLS team and updated regularly based on new evidence that may require updated policies and procedures. The ECLS team should be able to update relevant content when needed. Content should refer to the most recent evidence and guidance from ELSO or other societies, depending on the specific policy or procedure.

In summary, the relationship between and referring institution and a Level 1 Center should be collaborative. An ECLS program should be able to adequately advocate for its needs; meanwhile, the institution should recognize the value of an ECLS program to its portfolio of care services. The mutual respect shown for one another serves to benefit the patients and families served by the institution.

Program Financials

An ECLS program budget should include the expected revenue and expenses affiliated with the program. Revenue affiliated with the ECLS program may include referrals for ECLS evaluation that would not have come to the institution otherwise. Tracking all referrals will be important in demonstrating the value of the ECLS program.

Revenue

Specific billing practices will vary by country. All activities related to ECLS should be captured and billed in a timely manner. The ECLS program and institutional leadership should collaborate to ensure that earned revenue is fulfilled for ECLS services.

In the United States, Current Procedural Terminology (CPT) codes are captured for the specific activities and procedures related to ECMO. The rules for billing CPT codes must be adhered to; for example, a program cannot bill for initiation (codes 33946/7) and management (33948/9) on the same day. Modifiers to CPT codes may also be appropriate, depending on the workload and/or complexity associated with each procedure on a specific patient. CPT codes are continuously updated, added, or modified, including payment rate. Outside the US, similar billing processes may also be necessary. Please refer to local regulation and policy on healthcare services payment.

Market share is a concept that may not pertain everywhere. Where it does, institutions should capture the referred patient volume related to ECLS. Not all patients will require ECLS services; yet they should be acknowledged in terms of the overall institutional value of the program. The institution and ECLS program leadership should closely monitor all ECLS financial performance.

Expenses
Resource requirements should include ECLS staff and estimated support time including overtime and transport time requirements, ECLS equipment, education and training for the ECLS team, quality improvement initiatives, and administrative support for updating policies and procedures. Data to support program costs can come from several sources, including time reporting systems, supply chain costs, capital planning, etc. All program expenses should be captured to help set expectations for resources as appropriate. Assignment of indirect costs may also be necessary based on institutional policy & procedure.

Budget
An annual budget should be prepared for the ECLS program. Education, training, equipment, staffing, quality improvement, and other resource requirements should be anticipated, as reflected in the budget. Administrative support is indicated by timely approved budgets of reasonable revenue and expense expectations for the program.

Budgets can be incorporated into another department's budget, depending on how the ECLS program is organized within the institution. The program performance should be budgeted and tracked throughout the year.

Clinical Services
A Level 1 Center will have a wide range of clinical services available via consultation where appropriate. The patient population(s) served by these service lines will be commensurate with the patient population(s) served by the ECLS program. For example, a pediatric-only hospital would not be expected to have access to adult services, and vice versa for an adult-only hospital. Limited exceptions may be made for institutions that are cardiac- or respiratory-only ECLS programs. Where services are shared across multiple sites, these may also be considered appropriate, depending on the level of care required.

Table 2 describes recommended proximity for clinical services. Those listed as Proximate to ECLS Service are the services most often engaged in ECLS care. Proximate services deliver care that is directly relevant to the ECLS patient – and often have ECLS-specific training, which may be time-sensitive for optimal patient support. Such providers may include physicians, nurses, therapists, and other specialized medical professions. For more information on those providers, please see the *Education, Training & Credentialing* section.

Consult-Only providers generally do not participate in ECLS care on a routine basis but may be involved on a case-by-case basis based on the patient's need. These providers do not need ECLS-specific training; however, they should not be the only provider caring for the provider. General ECLS education can be helpful for providers who routinely consult on ECLS patients.

Table 2. Hospital Services Proximity to ECLS Service

Proximate to ECLS Service	*May Be Consult-Only (In-House or Telehealth)*
• Anesthesiology • Cardiology • Cardiovascular Surgery • Cardiovascular Perfusion • Critical Care • Neonatology • Palliative Care • Pharmacy • Pulmonology • Radiology • Physical Medicine & Rehabilitation • Respiratory Therapy	• Gastroenterology • General Surgery • Hematology • Infectious Disease • Nephrology • Neurology • Neurosurgery • Psychology & Psychiatry • Medical Ethics • Transplant Services

NOTE: Level 1 Centers are not required to provide heart and/or lung transplant services in-house. If a Level 1 Center does not have one of the required transplant services in-house, a contract demonstrating access to the external service is required.

General Operational Services

A Level 1 Center will have hospital services commensurate with a medical hub. These services will expand far beyond the scope of ECLS and may vary by country and/or region. In a Level 1 Center, general operational services are shared services amongst all care units in the hospital. Specific to ECLS, the following services should be available in close proximity to the ECLS unit:

- Blood Gas Services
- Hematologic Point of Care Testing
- Blood Bank
- Radiology Services
- Operating Room/Procedure Room, and
- Pathology Services.

Level 1 Centers will often expand these offerings to offer specialized services, such as hybrid operating rooms, interventional suites, and other technology-enabled procedure rooms. While not required for Level 1 status, specialized procedure areas are indicative of a larger investment in ECLS care and associated service lines.

General operational services should remain open 24 hours, 7 days a week, 365 days a year at any Level 1 Center. This includes immediate access to blood gas testing, blood bank services, and laboratory services as indicated. Imaging may comprise both point-of-care services such as ultrasound, or advanced imaging, including CAT scans and similar. At a Level 1 Center, there should be minimal-to-no delay for any general hospital service that is required for an ECLS patient.

Supply Chain and Backup ECLS Components

Level 1 Centers will have ready a full ECMO circuit, typically primed with saline, in a dedicated space near the ECLS unit. Any primed circuit will be labeled with the expiration date clearly identified. Sixty (60) days is considered a common standard for primed ECLS circuits, but there may be adaptations or exceptions based on circumstance. In addition to one or more primed ECLS circuits, Level 1 Centers will have a robust supply chain for ECLS components. They will have on site all backup components of an ECMO circuit, including:

Table 3. Common ECMO/ECLS Supplies

Proximate to ECLS Care Area
• Blood Pump • Heater Unit/Warming Unit (if needed) • Membrane Lung or Oxygenator • Disposable ECLS Equipment • Connectors • Cannulas • Portable Oxygen Supply for Transport • Other Disposable Products • Primed ECMO Circuit (no older than 30 days) • Components Specific to Other Forms of ECLS (if offered)

Where modes other than ECMO are provided at the institution, Level 1 Centers are expected to have any additional components on site, with a clear system for procurement of these parts. Particularly important are capital expenses, such as blood pumps, and disposable parts needed for each ECLS run.

As supply chain and capital purchase plans expand far beyond the ECLS program, it is expected that the ECLS program will participate in institution- or region-specific supply chain programs. Relevant to the program support elements that were described in the previous section, ECLS program leadership should collaborate directly with the institution to ensure that the ECLS program has all the necessary equipment to meet current program operations, with room for growth as indicated.

Education & Training

Education Overview

A Level 1 Center is expected to have a robust training and education program for their ECLS team. ECLS education should include both ECLS Specialists and physician providers specific to their specialty and ECLS role (management and/or cannulation). Completion of ECLS training should be in addition to any residencies, fellowships, or other general postgraduate training. Where Level 1 Centers provide ECLS services other than ECMO, equivalent training should be provided on those modes as well.

Individual certification in ECLS (E-AEC, E-NPEC, CES-A, CES-P, or other) is highly encouraged. Note that the ELSO individual certifications are not required. Several references to ELSO's individual certifications can be found throughout this document; while ELSO strongly endorses its training and certification programs, these are not requirements for Center Certification at any level.

Level 1 Centers may have access to on-site training facilities for didactic and/or simulation, but are not required to have them. A center may choose to train its staff entirely in-house, entirely offsite, or a combination of both. Typically, teams that train offsite will include some additional hours on-site to engage in any policies specific to the ECLS center.

Didactic Training
Didactic training is a lecture-based mode of training encompassing a course or course(s) with specific ECMO and/or ECLS training. The focus of didactic training is the lecture itself: the concepts, cases, and methods of teaching should reflect modern learners and include content relevant to ECLS practice. Notably, didactic training for ECLS is distinct from general critical care courses in that the content is directly relevant to ECLS practice. Typical didactic training for initial ECLS education is around 8 hours, with supplementary training for knowledge maintenance as needed.

Suggested topics include the following areas:

- Introduction to ECMO
- Circuit Components
- Cannulation & Configuration
- ECMO Physiology
- V-V ECMO (Respiratory Support)
- V-A ECMO (Cardiac/Circulatory Support)
- Patient Management
- ECMO Complications
- Literature Review

Additional areas of study may include specific indications based on patient population, region-specific training, and/or institutional policy training. ELSO strongly recommends that Level 1 Centers align their education and training models with the ELSO Guideline on Education and Training.

Simulation Training
Simulation Training is distinct from other types of training in that it specifically engages the learner in hands-on activities with minimal lecture time. Simulation training should engage each learner directly; demonstrative sessions do not qualify as simulation training. Effective simulation training gives each learner multiple touches within a given scenario such that they can demonstrate proficiency in the technical skills being taught.

Effective simulation training at a Level 1 Center should use ECLS equipment that closely resembles the institution's clinical environment. Simulation training can be completed in-house or at another site.

Simulation training should cover the following five (5) simulations:

- Drainage Insufficiency
- Air Embolism
- Pump Failure
- Membrane Lung Failure
- Gas Failure

Proctored Clinical Hours

Proctored clinical hours must be completed in the institution's live patient care setting with live ECLS patients. A proctored clinical hour specifically indicates that a learner is being supervised by a more experienced colleague for the entirety of the training time. Proctored clinical hours are a vital connection between concepts of didactic training, the controlled environments of simulation training, and the active clinical environment. ELSO recommends that new ECLS Specialists complete a minimum of 16-32 proctored clinical hours (equivalent to 2-4 ECLS care shifts).

Table 4. Typical ECLS Training Outline

Didactic Training	*Simulation Training*	*Clinical Hours*
• Introduction to ECMO • Circuit Components • Cannulation & Configuration • ECMO Physiology • Respiratory Support (VV ECMO) • Cardiac/Circulatory Support • (VA ECMO) • Patient Management • ECMO Complications • Literature Review	• Drainage Insufficiency • Air Embolism • Pump Failure • Membrane Lung Failure • Gas Failure	16-32 Proctored Clinical Hours (equivalent to 2-4 ECLS care shifts) ***Maintenance of Training:*** One 8-hour shift every eight weeks; can be supplemented with additional Simulation Training

Re-Training

ELSO recommends that ECLS Specialists complete one 8-hour shift every eight weeks to maintain clinical skills. If this volume cannot be maintained on an individual basis, additional simulation training may take place of some clinical hours. At no point should simulation training completely replace active clinical practice. If clinical service lapses, a learner is recommended to participate in additional proctored clinical hours upon return to clinical service.

Re-training for an individual or the entire ECLS team may be deemed necessary at certain points. Examples include a change to ECLS inclusion criteria, an adverse patient event, or the implementation of new components. The ECLS Program should determine what level of additional training is needed specific to the indication. Re-training should never be assigned as a punitive measure; training is a safe space to learn and prevent clinical errors.

ECLS Team Staffing

During the Pilot Phase, ELSO identified two primary modes of ECLS team staffing. Each model factors the number of ECLS patients currently in-house and anticipated volume. A common model is *n+1*, where the number of ECLS Specialists in-house equals the number of patients currently on ECLS plus one. Each ECLS Specialist is assigned to an ECLS Patient in a 1:1 ratio, with the additional ECLS Specialist being available for any ECLS initiations or accepted transfers. Centers utilizing an *n+1* model will have a core group of ECLS Specialists to ensure adequate amounts of bedside clinical time and re-training as appropriate. Additional ECLS Specialists will only be onboarded when ECLS volumes or acuity warrants additional hires. Many centers utilize this model.

Flexible staffing models are also used, rotating between 2:1 and 3:2 ECLS Specialist-to-Patient ratio depending on acuity and the input from the bedside team. This flexible model requires many ECLS Specialists who are also trained in standard critical care and/or can otherwise be assigned to another care area if ECLS volumes are lower. The benefit of a flexible staffing model is that the ECLS team can readily pull additional trained ECLS staff in times of surge or high acuity. Centers should ensure that trained ECLS Specialists receive adequate bedside clinical time. Flexible models can be appropriate for centers with wide variations in ECLS volume and/or a large corps of trained ECLS Specialists.

ECLS Credentialing

A robust credentialing program is essential to the success of the ECLS program – and the safety of its patients. ELSO offers a framework for how credentialing should be considered; it is ultimately up to the institution and its regulators to implement an ECLS credentialing program.

A Level 1 Center will have each of the following characteristics, plus any additional as deemed necessary. Their credentialing program may exceed these standards and/or add supplementary criteria to meet regulatory requirements. Where possible, a Level 1 Center should align their credentialing program with those recommended below.

Policies by ECLS Mode and Role

A Level 1 Center will develop and maintain a policy for credentialing ECLS providers specified by ECLS mode and role (i.e. cardiac ECMO open cannulation or respiratory ECMO management, etc.) Such policies should be specific to the profession being credentialed and should be applied evenly across all providers. Credentialing for one ECLS mode or role should not be considered a blanket credential for all ECLS modes or roles.

In Level 1 ECLS Centers, it will be common for individual practitioners to be granted privileges only for specific role(s) and/or ECLS mode(s) while not being granted privileges for others. Not all who meet an institution's credentialing criteria will be automatically approved for the respective ECLS privileges. Institutions reserve the sole discretion over who receives ECLS privileges at their center.

Table 5. ECLS Credentialing Policy Components

ECLS Credentialing Policy Components
• Define ECLS Mode (cardiac, respiratory, ECPR) and Role (cannulation or management) • Minimum education requirements specific to the individual's profession • Minimum post-graduate medical training (residency, fellowship, post-fellowship training) – ***if relevant*** • Re-education and retraining policies • Granting of emergency privileges for transporting and/or consulting providers • Mandatory and Suggested KPI ***(see Tables 6 & 7)***

A Note on Volume: ELSO does not require minimum case volumes or proctored clinical hours for ECLS credentialing. Case volume and proctored hours are specific to the individual, their experience level, and the complexity of the procedure(s) being credentialed.

Define ECLS Mode: Each ECLS credentialing policy should clearly define the ECLS Mode (cardiac, respiratory, ECPR) and Role (cannulation or management) desired by the applicant. Cannulation may be further defined by procedure type (open, percutaneous, or hybrid). This specificity clearly identifies who should perform a given role and the process for being granted such privileges.
Minimum Education Requirements: Credentialing education requirements should include specific degrees, post-graduate medical training, and post-fellowship training, as deemed necessary by the ECLS center. Certain types of cannulation and/or ECLS management may require additional ECLS-specific training.

Re-education and Retraining: Re-education and retraining policies should establish the criteria for mandated re-training. Re-education is not punitive; it is an opportunity for a practitioner to recognize gaps in knowledge and reestablish safe ECLS practice. Re-education policies may indicate a certain timeframe, a particular type of event, or other indicators as chosen by the institution.

Emergency Privileges: Emergency privileges can be granted in case-specific circumstances. Examples include a surge in patient volume, cannulation at a neighboring facility, or another facility's staff arriving to cannulate at the ECLS center. The ECLS program should clearly identify how emergency privileges can be granted, the scope of the privileges, and the timeline for granting of permanent privileges, if deemed necessary.

Individual Certification
A Level 1 Center should strive to have 50% or more of its ECLS clinical staff achieve one of the ECLS individual certifications that exist. This certification should be relevant to the patient population served, such that some ECLS Specialists may opt to be certified in multiple patient populations. ELSO certification (E-AEC or E-NPEC) is not required for any Level 1 Center.

KPI/Metrics
A Level 1 Center should employ a robust set of metrics – also known as Key Performance Indicators (KPI) – to supplement ECLS credentialing policies and assess overall ECLS program health. KPI are objective data points that reflect specific measures of competency, skill, and/or ability. KPI can be assessed at a program and/or an individual provider level. Both will be necessary. Proper use of these metrics will inform education, training, and key program aspects.

KPI for Credentialing
Metrics are a key part of the ECLS credentialing process. Effective use of metrics will inform readiness for privileges, maintenance of privileges, and opportunities for re-training. There are two tables below: one for ECLS Cannulation, and one for ECLS Management. The tables are divided into Mandatory and Recommended KPI. *Mandatory KPI* are considered foundational to a credentialing policy and are highly encouraged. The ELSO Center Certification Methodology requires that 3 or more of these are tracked. *Recommended KPI* are those considered to be important in considering privileges, although they should be considered amongst other factors.

Table 6. KPI for ECLS Credentialing - Cannulation

Mandatory KPI ***Must Track 3+ of the Following***	***Recommended KPI*** ***Must Track 2+ of the Following***
• Number of Cannulations Performed* • Use of Ultrasound or Fluoroscopy for Percutaneous Cannulations • Complication Rates* ○ Bleeding ○ Cannula Malposition ○ Limb Ischemia ○ Serious Vascular Event Requiring Endovascular or Surgical Repair • Rate of Re-Cannulation* • Rate of Surgical Intervention to Change Cannulation Configuration	• Patient Selection Criteria Adherence • Cannulation Time* • Location of Cannulation (OR, Cath Lab) • Rate of Bacteremia or Positive Blood Culture • Cannula-Associated Deep Vein Thrombosis • Success Rate of Distal Arterial Reperfusion Cannula Insertion

**By support type (VA, VV, ECPR, etc.) & procedure type (percutaneous, open, hybrid)*

Table 7. KPI for ECLS Credentialing - Management

Mandatory KPI ***Must Track 3+ of the Following***	***Recommended KPI*** ***Must Track 2+ of the Following***
• Number of Cases Managed Per 12 Months • Complication Rates* ○ Air Embolism ○ Circuit or Site Infection ○ Emergent Discontinuation of ECLS ○ Accidental Decannulation • Median Lenth of ECLS Run**	• Rate of Limb Ischemia* • Time to Initiation – from Call to Cannulation (or other defined landmark)* • Weaning Rate – Success weaning off ECLS* • Rate of LV Venting* • Frequency of Training and/or Re-Training** • Frequency of Change in ECLS Mode* • Long-Term Functional Status Post-ECLS* • Frequency and Success of Quality Improvement Initiatives

**By support type (VA, VV, ECPR, etc.) & procedure type (percutaneous, open, hybrid)*
***By Individual Provider and Center-Wide*

KPI for Program Assessment
Level 1 Centers will select, record, and analyze several Key Performance Indicators (KPI). The goal of KPI in this context is to support the health of the entire program – with the goal of delivering safe ECLS care to all patients. Centers should select one or more KPI from each category in the table below.

Data collection can be through internal systems, such as the electronic medical record (EMR) or through registry participation, such as the ELSO Registry. ELSO provides many of these metrics in the center-specific data reports and ELSO Registry Quality Reporting Platform. Other data points will be collected internally. The section on Quality Improvement further describes the use of KPI/metrics for program assessment.

Table 8. Key Performance Indicators (KPI) for ECLS Programs

Category of KPI	*KPI In Each Category*
Assess Patient Based on Established Criteria	• Adequacy of support (end organ perfusion, use of pressors/inotrope) • Frequency of change in strategy (VV to VA, VA to VAV, etc.) • Rate of use of LV venting – by support type, across all support types • Rate of Bleeding Complications • Ventilator settings
Assess ECLS Circuit	• ECLS Flow and/or Pressures • Clotting Ability • Hemolysis Lab Results • Use of Anticoagulation Medication
Assess for Weaning	• Use and Indication of Chest X Ray • Use and Indication of Echocardiogram • Arterial Blood Gases • Pulmonary Artery Pressures
Other Competency/ Performance Measures	• Time to Initiation • Cannulation Success: Initial Cannulation • Rate of Re-Cannulation – by support type, by individual practitioner • Success of Weaning on Time Basis (24 hours, 1 week, etc.) • Complication Rates: Bleeding, Infections, Strokes, Vascular Complications
Team Measures to Consider	• Duration of ECMO Support • Team Training and Competency • Resource Utilization • Patient and Family Engagement • Cost-Effectiveness • Follow-up Care • Long-term Outcomes • Quality Improvement Initiatives • Data Reporting and Documentation

ECLS Care Protocols

Level 1 Centers are expected to have thorough ECLS care protocols in alignment with institutional, regional, and regulatory guidelines. The section below describes the most important areas that should be covered by the center's ECLS care protocols. Additional areas may be considered by ECLS mode, patient population, or scenario-specific (i.e. hypothermia, trauma, or other).

ECLS Patient Selection

A Level 1 Center will have a clearly defined patient selection policy by patient population, mode, and indication for ECLS. ECLS patient selection will include when, how, and who should be involved in considering ECLS care decisions. Typical consultation at a Level 1 Center will include a team of providers from throughout the ECLS care team: surgeons, medical intensivists, ECLS specialists, and others as defined by the center. Several considerations should be made: mode of ECLS support, cannulation strategy, goals of ECLS care, strategy to wean from ECLS, and discontinuation of ECLS care for end-of-life decision making.

Table 9. ECLS Patient Selection Policy Components

ECLS Patient Selection Policy Components

• ***Goal(s) of ECLS Care***
• ***Mode of ECLS Support:*** Relative to the goals of ECLS care; each mode carries its own benefits and risks
• ***Disease-Specific ECLS Indications:*** Variable by indication
• ***Contraindications:*** Variable by case, provider, institution, current capacity, and mode of support. Include, but are not limited to:
  ○ *Incompatibility with Life Following ECLS Care*
  ○ *One or More Pre-Existing Conditions Affecting Quality of Life*
  ○ *Patient's Age, Size, or Other Medical Characteristic*
• ***Futility:*** Failure of conventional therapy and/or a fatal diagnosis
• ***Bridge to Donation:*** If bridge to donation is the primary indication for ECLS, a care plan must be carefully considered to align with the patient's and family's wishes.
• ***Patient Transfer:*** In a Level 1 Center, ECLS patients are unlikely to transfer to an outside hospital. A plan should be formed for any patients being admitted from outside hospitals.
• ***ECLS Team Capacity:*** A Level 1 Center must be always open to ECLS consults. However, patients should only be placed on ECLS when the team can adequately support each patient.

ECLS Cannulation

ECLS Cannulation is a specialized procedure that should only be performed by medical specialists who have been specifically trained and credentialed in the procedure being performed. There are three basic types of cannulations:

- ***Open Cannulation:*** Performed exclusively in the operating room by a surgeon; this procedure involves surgical insertion of the cannula using an open exposure.
- ***Percutaneous Cannulation:*** Performed at the bedside, in a hybrid operating room, or operating room. Involves insertion of a cannula using a small insertion point in the skin. Can be performed by intensivists, surgeons, interventionalists, or any physician specifically trained in cannulation.
- ***Hybrid Cannulation:*** Several hybrid approaches are used depending on the mode of ECLS, patient status, and other indicators as deemed appropriate by the cannulating team.

Cannulation techniques include the three described above (open, percutaneous, hybrid) and extend to other strategies that may be deployed specific to the patient's indication, the mode of ECLS desired, and the clinical course of the patient. The institution should determine which cannulation techniques are available for use in their ECLS program, including policies and procedures for being credentialed in these techniques. A full cannulation policy will include the indication, contraindication, and mode(s) of ECLS that each cannulation technique can support.

Cannulation location will differ by technique, indication, and mode of ECLS. For example, ECPR cannulations can be percutaneous cannulations that occur in a hybrid operating room or in the operating room. Open cannulations will be performed exclusively in the operating room. If a non-surgery team is performing a cannulation, it is typical for a surgery team to be on call in case of

complications. Some percutaneous cannulations can occur at the bedside if the space supports the procedure and the procedure team feels comfortable with proceeding.

ECLS transport after cannulation is a complex operation that requires specialized training. Level 1 Centers will typically not be transporting their cannulated patients out of their own facility. They may be called to cannulate at an external facility, transport an already cannulated patient from another facility, or transport their own patients within the hospital. Each of these scenarios requires a specific plan, specialized transport teams, and an extensive list of transport items. Full consideration of transport should be taken prior to the initiation of ECLS cannulation involving transport.

Cannulation visualization will vary based on cannulation strategy and ECLS mode. Percutaneous cannulation will require a minimum of ultrasound, and possibly fluoroscopy if performed in an interventional suite. Cannulation visualization policy should also consider any post-cannulation imagery to ensure appropriate placement in the vessel and assess post-cannulation injury.

ECLS Management

A Level 1 Center will have a full set of ECLS management protocols for every mode of ECLS that is provided at the institution. These protocols should reference consensus documents, peer-reviewed research, published guidelines, and other widely accepted means of distributing clinical knowledge. Each management protocol should be reviewed at an established cadence to ensure accuracy and completeness. Where necessary, each protocol may adapted to a specific mode of ECLS as needed.

Table 10. List of ECLS Management Protocols

Minimum Required ECLS Management Protocols	
• ECLS Device Settings & Management • Mechanical Ventilation Management • Medication Management • Sedation Management • Infection Management • Anticoagulation Management • Nursing Care – Patient Positioning, Skincare, Wound Care • Cannulation Site Management • ECLS Circuit Management • Patient Monitoring • Complication Troubleshooting • Emergency Protocols • Nutrition Replacement on ECLS	• Fluid and Renal Replacement Therapies on ECLS – including Continuous Renal Replacement Therapy (CRRT)* • Patient Physiotherapy, Mobilization, and Rehabilitation *[Table 10 continues on Page 22]* • Organ Donation Pathway for ECLS Patients • Palliative Care Support • Determination of Neurological Death Criteria on ECLS • Ethical Grounds for Withdrawing ECLS Care • Accessing the ECLS Circuit – including CRRT • Care Considerations for ECCO2R, ECPR, and Additional Modes of ECLS*

**If provided at the institution*

ECLS Transport

ECLS transport (including within the hospital) is a highly specialized service requiring specific training, policies, and protocols. All ELSO Level 1 Centers are required to have full ECLS transport capabilities, either through an in-house program or an established partnership. Key features are responsiveness,

competence, and ability to perform all types of transport. Additionally, all ELSO Level 1 Centers must be able to cannulate a patient at an external facility: sending a team from the Level 1 Center to an external facility, performing an ECLS cannulation at the external facility, and transporting the patient to the Level 1 Center.

ECLS transport protocols will be specific to the mode of transport and may differ from those under normal ECLS care. Policy components for ECLS transport are listed in Table 11. A Level 1 Center should have policies and protocols in place for each of the transport types listed in Table 12.

Table 11. ECLS Transport Policy Components

ECLS Transport Policy Components
• Required clinical documentation • Standardized equipment lists ***(see ELSO Guideline on ECLS Transport)*** • Mobile ECLS team structure and responsibilities • Established mobile ECLS plans: diversion plan, provision of oxygen, patient stabilization, remote access to ECLS team • Clinical governance and risk management • Administrative process for granting emergency ECLS privileges • Transport-specific training and drills

Table 12. Types of ECLS Transport and Criteria for Consideration

Type of ECLS Transport	*Criteria for Consideration*
Primary ECLS Transportation A mobile ECLS team initiates ECLS at an outside facility and, after initial stabilization, the patient is transferred to an ECLS center.	• Patient is a good ECMO candidate; determined by the referring and accepting team. • Timely response is essential. • Adequate preparedness is paramount to avoid delays and optimize patient outcomes.
Secondary ECLS Transportation A patient is currently supported with ECLS but must be transferred to another facility on ECLS support.	• Patient may require specialized management such as transplant or durable mechanical circulatory support. • Patient may require another center's medical expertise. • Family request.
Tertiary ECLS Transportation Hospital A has a patient with ECLS indication and a mobile ECLS team from Hospital B goes to Hospital A. The ECLS team from Hospital B puts the patient on ECLS and transports the patient to Hospital C with ECLS capacity.	• In periods of high demand there may be a Hospital C without mobile ECMO but with ECMO capacity. • A hospital with mobile ECMO team capabilities, but without the capacity to receive a patient, could carry out this transport. • Preparation and coordination between the three institutions is required.
Intra-Facility ECLS Transfer A patient is currently supported with ECLS but must be moved within an Institution.	• Possible reasons for intra-facility transfer: patient may require a diagnostic test (e.g., CT scan), may require a procedure, or be transferring to a different floor.

Repetition is critical for ECLS transport programs. If transport is not a regular part of the ECLS program's practice, the center should consider a partnership with locally available ECLS transport services. Such an arrangement would not disqualify a center from Level 1 status under the ELSO Center Certification program. For more detailed guidance on ECLS transport, please see the ELSO Guideline on ECLS Transport.[3]

ECPR – Extracorporeal Cardiopulmonary Resuscitation

Extracorporeal Cardiopulmonary Resuscitation (ECPR) is a complex application of ECLS in cases of loss of circulation. It is activated in patients where conventional CPR measures are ineffective. ECPR can be applied in the field (out of hospital cardiac arrest) or in-hospital. Out of hospital cardiac arrest is an active area of ECLS study, with several landmark publications assessing its effectiveness and the systems required to effectively deploy ECPR out of the hospital.[4,5,6]

In-hospital ECPR is more commonly used, as these cases typically involve patients whose cardiac arrest was witnessed and were provided with immediate life-saving measures. In-hospital cardiac arrest can involve operative cardiac arrest (either post- or intra-operative cases) as well as those that occur in the normal course of care. Patients in cardiac decline should be closely monitored to determine candidacy for ECLS in preparation for what may be either an ECPR case or an emergent cannulation to cardiac ECMO.

ECLS programs should heed caution when developing an ECPR program involving out of hospital cardiac arrest (OHCA). A successful OHCA ECPR program requires significant experience in ECLS, including in-hospital cardiac arrest. Additionally, any hospital practicing ECPR should have robust policies and practice in the areas described throughout this document. Clinical management, transport, service line capability, and institutional capacity are several key considerations.

These criteria cover what is needed from the ECLS center's point of view; additional planning will be required with local emergency responders and relevant rescue agencies for any OHCA ECLS program. The development of an OHCA ECPR program extends far beyond certification as a Level 1 Center.

General Care Protocol

Except where necessary to provide ECLS care, Level 1 Centers should follow all standard care protocols at their Institution. This includes abiding by any national, state, or regional law and regulation, as well as clinical policies established at the Institution. Any modifications to care policies necessitated by ECLS care should be explicitly documented, either on a case-by-case basis, or as part of the policy itself.

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[3] Extracorporeal Life Support Organization Guideline for Transport and Retrieval of Adult and Pediatric Patients with ECMO Support https://www.elso.org/ecmo-resources/elso-ecmo-guidelines.aspx

[4] Early Extracorporeal CPR for Refractory Out-of-Hospital Cardiac Arrest (Suverein, et al., 2023) https://doi.org/10.1056/NEJMoa2204511

[5] Effect of Intra-arrest Transport, Extracorporeal Cardiopulmonary Resuscitation, and Immediate Invasive Assessment and Treatment on Functional Neurologic Outcome in Refractory Out-of-Hospital Cardiac Arrest (Belohlavek, et al., 2022) https://doi.org/10.1001/jama.2022.1025

[6] Improved Survival With Extracorporeal Cardiopulmonary Resuscitation Despite Progressive Metabolic Derangement Associated With Prolonged Resuscitation (Bartos, et al. 2020) https://doi.org/10.1161/CIRCULATIONAHA.119.042173

Specific areas of focus are as follows:

- *Medical Records Process* – An ECLS program should keep record of all patient care plans as thoroughly as possible. Wherever possible, these records should be kept electronically.
- *Infection Control* – While some Infection Control policies at the institution level may cover ECLS, the ECLS Program should further specify their protocols for the prevention of infection at the cannulation site, in the ECLS circuit, or any other means of infection in ECLS care.
- *Patient Rights* – Each institution should have an established patient rights & responsibilities policy. This policy should be applied in full to the ECLS program. ELSO maintains the dignity and rights of all patients and families to make medical decisions free of fear, bias, or favor.
- *Patient & Family Support* – Patient & Family Support programs may exist at the institution level. While not mandatory, Level 1 Centers should make specific effort to include ECLS-specific information as part of their patient & family support programs.
- *Patient Follow-Up* – As a hub of ECLS care, a Level 1 Center is expected to follow up with and maintain records of post-ECLS outcomes. Such a program may be at the institution, system, regional, and/or national level depending on local variances.

ECLS Case Review & Process Improvement

Evidence-Based Resources

Level 1 Centers will have robust case review & process improvement systems within their ECLS program. Their quality improvement initiatives will include evidence-based resources such as conferences, seminars, and morbidity & mortality reviews. Quality review will extend to additional resources, such as reporting structures for near misses, adverse events, and medical errors; whistleblower policies; and openly share best practices with other ECLS centers.

Level 1 Centers will be innovative in implementing new ECLS technology, and may also participate in research, if part of their institution's mission. They will use data to inform their quality improvement work and regularly seek out the most relevant clinical guidelines, standards, and texts. Where evidence does not yet exist or conclusively point in a specific direction, Level 1 Centers will use the best available knowledge to develop clinical policies that prioritize patient safety.

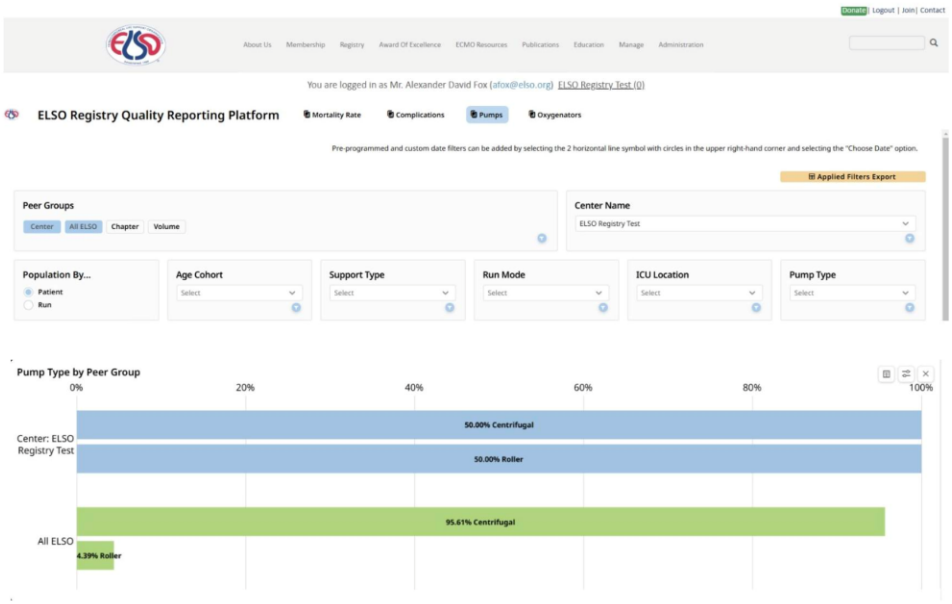
KPI in Quality Review

Level 1 Centers will determine, record, and maintain data for several Key Performance Indicators (KPI). The goal of KPI in this context is to support the health of the entire program – with the goal of delivering safe ECLS care to all patients. Specific KPI are listed for credentialing (both ECLS cannulation and management) and program assessment in the section on KPI and Appendix 2.

Level 1 centers will have robust data reporting and analysis systems. KPI will be reviewed on a regular cadence, typically no less than quarterly. Some KPI may be assessed on a weekly or monthly basis. Data reviews may be part of other quality meetings and/or shared with the team as part of written reports.

Data monitoring can be done in internal data visualization programs or through ELSO's Registry Quality Reporting Platform, which delivers up-to-date data in digestible and interactive charts. These charts are available for all ELSO members who contribute data to the ELSO Registry.

Image 13. ELSO Registry Quality Reporting Platform



ECLS Registry Contribution

All Level 1 Centers are expected to contribute to a clinical registry of ECLS data. Centers are not required to contribute to the ELSO Registry. Contribution to a registry must meet the following criteria:

- Include all patients supported with ECLS at the Institution;
- Occur at a frequent and consistent cadence not greater than 6 months after the date of discharge; and
- Develop and maintain policies and procedures to capture, validate, and transfer data to the chosen database.

The goal of registry contribution is to provide the ECLS Program with an objective look into its own performance, including trend analysis, incident occurrence by mode and/or support type, and cohort comparisons. In the case of the ELSO Registry, centers can compare themselves by volume (low, medium, high), Award of Excellence status (platinum, gold, silver), and geography (by ELSO Chapter). Level 1 Centers will have robust systems in place to ensure that registry data is complete, accurate, and consistently updated. Some may opt for automated systems while others will use manual data entry; both methods are acceptable for the ECLS Center Certification Program.

Privacy & Data Protection Policies

Level 1 Centers are expected to enact data privacy and protection policies that de-identify all patients. Only necessary fields of information should be transferred to a registry – and each should have a clear purpose for collection. Participation in a clinical registry should never interfere with local, national, or international data protection laws. Please review the regulations in your area to ensure compliance.

Summary

The goal of this document is to help Level 1 Centers – and those who may qualify for Level 1 status – to understand the operational, logistical, and clinical responsibilities that come with such status. This blueprint should equip ECLS hubs to advocate for themselves, build robust ECLS programs, and ensure that they continue to meet a global standard for ECLS care.

APPENDIX 1: Level 1 ECLS Center Summary Table

ECLS Level 1 Certified Centers ***Major Hubs of ECLS Care*** ❖ *All Components of an ECLS Center (listed below)* ***PLUS*** ❖ *Active ECLS Transport Program* ❖ *Heart and Lung Transplant Services* ❖ *Always Open to ECLS Consults*	
Program Leadership	○ ECLS Program Director ○ Associate Program Director(s) ○ ECLS Coordinator ○ Medical and Service Line Leadership ○ Clearly Defined ECMO Specialist Role
Required ECLS Services	○ ECMO/ECLS Care ○ ECMO/ECLS Referral ○ ECLS Transport Team ○ Heart and Lung Transplant Services
Required Clinical Services	○ Pediatric/Adult Anesthesiology ○ Pediatric/Adult Cardiology ○ Pediatric/Adult Cardiovascular Surgery ○ Cardiovascular Perfusion ○ Pediatric/Adult Critical Care ○ Pediatric/Adult Gastroenterology ○ Pediatric/Adult General Surgery ○ Pediatric/Adult Hematologist ○ Pediatric/Adult Infectious Disease ○ Neonatology *(Neonatal & Pediatric Programs only)* ○ Pediatric/Adult Nephrology ○ Pediatric/Adult Neurology ○ Pediatric/Adult Neurosurgery ○ Palliative Care & Medical Ethics ○ Psychology & Psychiatry ○ Pediatric/Adult Pulmonology ○ Pediatric/Adult Radiology ○ Rehabilitation & Therapy ○ Respiratory Therapists
Operational Services	○ Administrative Support for ECLS Program ○ Hospital Procurement & Supply Chain ○ Direct Access to ECLS Equipment ○ Data Management or Related Team ○ Biomedical Engineering
Hospital Services	○ Blood Gas Laboratory ○ Hematologic Point-of-Care Testing ○ Blood Bank

	○ Radiology Support (Ultrasound, CAT scan, Interventional Radiology, etc.) ○ Operating Room and/or Hybrid Suite ○ Pathology and/or Microbiological Testing
Education, Training & Credentialing	
Education & Training *(either in-house or access to)*	○ Didactic Training ○ Simulation Training ○ Proctored Clinical Hours
Credentialing *See Appendix I for KPI Requirements*	○ Clear Policies and Procedures for Each Mode of ECLS ○ Separate Credentialing Procedures for ECLS Cannulation & Management ○ Required and Recommended KPI are Selected, Collected, and Verified ○ Individual Certification – *at least 50% of staff* ○ Staffing Model & Hours ○ Ability to Flex ECLS Capacity
ECLS Care Protocols	
ECLS Patient Selection Policies	○ Support Mode ○ Cannulation Strategy ○ ECLS Management ○ Weaning from ECLS ○ Discontinuation of ECLS ○ Post-ECLS Care Plan
ECLS Cannulation	○ Credentialing Policy Specific to Cannulation ○ KPI/Metrics Specific to Cannulation Privileges – *Granting and Renewal* ○ Cannulation Protocols by Population and Support Type
ECLS Management Policies	○ ECLS Device Settings & Management ○ Mechanical Ventilation Management ○ Medication Management ○ Sedation Management ○ Infection Management ○ Anticoagulation Management ○ Nursing Care – Patient Positioning, Skincare, Wound Care ○ Cannulation Site Management ○ ECLS Circuit Management ○ Patient Monitoring ○ Complication Troubleshooting ○ Emergency Protocols ○ Nutrition Replacement on ECLS ○ Fluid and Renal Replacement Therapies on ECLS – including Continuous Renal Replacement Therapy (CRRT) ○ Patient Physiotherapy, Mobilization, and Rehabilitation ○ Organ Donation Pathway for ECLS Patients ○ Palliative Care Support ○ Determination of Neurological Death Criteria on ECLS ○ Ethical Grounds for Withdrawing ECLS Care

	○ Accessing the ECLS Circuit – including CRRT ○ Care Considerations for ECCO2R, ECPR, and Additional Modes of ECLS (if provided at the Institution)
ECPR - Extracorporeal Cardiopulmonary Resuscitation	○ Highly Proficient in ECLS Management & ECLS Transport ○ Access to all ECLS Service Lines ○ Capacity to For Highly Acute Patients ○ Clearly Defined ECLS Care Plan
Other Care Protocols	○ ECLS Management Policies ○ ECPR – Extracorporeal Cardiopulmonary Resuscitation ○ ECLS Transport – either in house or with close partnership ○ Medical Records Process ○ Infection Control ○ Patient Rights & Responsibilities ○ ECLS Patient Follow Up
ECLS Case Review & Process Improvement	
Evidence-Based Resources for Quality Improvement	○ Quality Improvement Meetings, Conferences, Seminars (at least 4x per year) ○ Morbidity and Mortality Conferences ○ Reporting System for Near Misses, Adverse Events, and Errors ○ Use of ECLS Data in Quality Review ○ KPI – Overall Program and Credentialing-Specific Metrics ○ Whistleblower Policy ○ Policy for Introducing New Technology
Contribute to an ECLS Registry	
Active Contributor to an ECLS Registry	○ Include all ECLS Cases ○ Data Submitted to Within 6 months of Patient Discharge
Data Policies & Procedures	○ Validate and Transfer Data to Registry ○ Privacy & Data Protection Policies

APPENDIX 2: Key Performance Indicators/Metrics Summary

Key Performance Indicators (KPI) are important components of an ECLS program's credentialing policies & processes. The tables below summarize the Mandatory and Recommended KPI for ECLS credentialing. There are two tables: one for ECLS Cannulation and the other for ECLS Management.

Key Performance Indicators (KPI) for Credentialing
ECLS Cannulation

Mandatory KPI ***Must Track 3+ of the Following***	***Recommended KPI*** ***Must Track 2+ of the Following***

• Number of Cannulations Performed*
• Use of Ultrasound or Fluoroscopy for Percutaneous Cannulations
• Complication Rates*
  ○ Bleeding
  ○ Cannula Malposition
  ○ Limb Ischemia
  ○ Serious Vascular Event Requiring Endovascular or Surgical Repair
• Rate of Re-Cannulation*
• Rate of Surgical Intervention to Change Cannulation Configuration
	• Patient Selection Criteria Adherence
	• Cannulation Time*
	• Location of Cannulation (OR, Cath Lab)
	• Rate of Bacteremia or Positive Blood Culture
	• Cannula-Associated Deep Vein Thrombosis
	• Success Rate of Distal Arterial Reperfusion Cannula Insertion

Key Performance Indicators (KPI) for Credentialing
ECLS Management

Mandatory KPI ***Must Track 3+ of the Following***	***Recommended KPI*** ***Must Track 2+ of the Following***

• Number of Cases Managed Per 12 Months
• Complication Rates*
  ○ Air Embolism
  ○ Circuit or Site Infection
  ○ Emergent Discontinuation of ECLS
  ○ Accidental Decannulation
• Median Lenth of ECLS Run**
	• Rate of Limb Ischemia*
	• Time to Initiation – from Call to Cannulation (or other defined landmark)*
	• Weaning Rate – Success weaning off ECLS*
	• Rate of LV Venting*
	• Frequency of Training and/or Re-Training**
	• Frequency of Change in ECLS Mode*
	• Long-Term Functional Status Post-ECLS*
	• Frequency and Success of Quality Improvement Initiatives

Key Performance Indicators (KPI) for Program Quality Assessment

Level 1 Centers will select, record, and analyze several Key Performance Indicators (KPI) for assessment of quality and patient safety. The goal of KPI in this context is to support the health of the entire program – with the goal of delivering safe ECLS care to all patients. Centers should select one or more KPI from each category in the table below. These KPI should be tracked on a regular cadence.

Category of KPI	*KPI In Each Category*
Assess Patient Based on Established Criteria	• Adequacy of support (end organ perfusion, pressors/inotrope requirement) • Frequency of change in strategy (VV to VA, VA to VAV, etc.) • Rate of use of LV venting – by support type, across all support types • Rate of Bleeding Complications • Ventilator settings
Assess ECLS Circuit	• ECLS Flow and/or Pressures • Clotting Ability • Hemolysis Lab Results • Use of Anticoagulation Medication
Assess for Weaning	• Use and Indication of Chest X Ray • Use and Indication of Echocardiogram • Arterial Blood Gases • Pulmonary Artery Pressures
Other Competency/Performance Measures	• Time to Initiation • Cannulation Success: Initial Cannulation • Rate of Re-Cannulation – by support type, by individual practitioner • Success of Weaning on Time Basis (24 hours, 1 week, etc.) • Complication Rates: Bleeding, Infections, Strokes, Vascular Complications, other
Team Measures to Consider	• Duration of ECMO Support • Team Training and Competency • Resource Utilization • Patient and Family Engagement • Cost-Effectiveness • Follow-up Care • Long-term Outcomes • Quality Improvement Initiatives • Data Reporting and Documentation