# Extracorporeal Life Support Organization (ELSO)

# ECLS Center Certification Program Level 3 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 which treat patients aged 18 years and older.
- ***ELSO Pediatric ECLS Center Certification*** designates ECLS programs which 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 which 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*<br>*Pulmonary$^{T}$*<br>*Cardiac$^{Ø}$*<br>*ECPR* | *Level 2*<br>*Pulmonary$^{Ø}$*<br>*Cardiac* | *Level 3*<br>*ECPR* |
| ***Long Form*** | | |
| ELSO Adult Level 1 ECLS Center Certification: Pulmonary (Transplant$^{T}$), Cardiac (Transplant$^{Ø}$), and ECPR<br>ELSO Pediatric Level 2 ECLS Center Certification: Pulmonary (Transplant$^{Ø}$) and Cardiac<br>ELSO Neonatal Level 3 ECLS Center Certification: ECPR | | |
| ***Short Form*** | | |
| ECLS Adult Level 1-R$^{T}$C$^{Ø}$<br>ECLS Pediatric Level 2-R$^{Ø}$C<br>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.
- ***Packet*** refers to this document, which is a guide to help Level 3 ECLS Centers – and those that may wish to become Level 3 Designated – in developing and managing their ECLS program.
- ***ECLS Level 3 Certified Centers (Level 3 Centers)*** refers to any center currently certified as ECLS Level 3, 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 3 Centers are medical centers with limited ECLS services that serve primarily as patient selection and cannulation facilities. In some regions, this may be known as a "spoke" center, with "hubs" being larger medical centers in the region/state/country. ECLS Level 3 facilities may provide short-term ECLS services with the goal of transferring the patient to ECLS Level 1 or Level 2 (or equivalent) facilities. ECLS Level 3 facilities are not expected to have in-house ECLS transport or heart/lung transplant; but they should have a strong network for ECLS transport with external service providers.

***Program and Organization***

*Program Governance*

Level 3 Centers model their leadership structure on the ELSO ECLS Center Certification Methodology but may have reduced leadership roles depending on program volume and scope. Two leadership roles are crucial to the ECLS program: Program Director and the ECLS Coordinator. Associate Program Director(s) may be found but are less common in smaller volume programs or those with reduced scope. These roles may be filled by two people (co-directors or co-coordinators) as needed. Each role is further defined below, including their reporting relationships within the program and externally.

*Program Director*

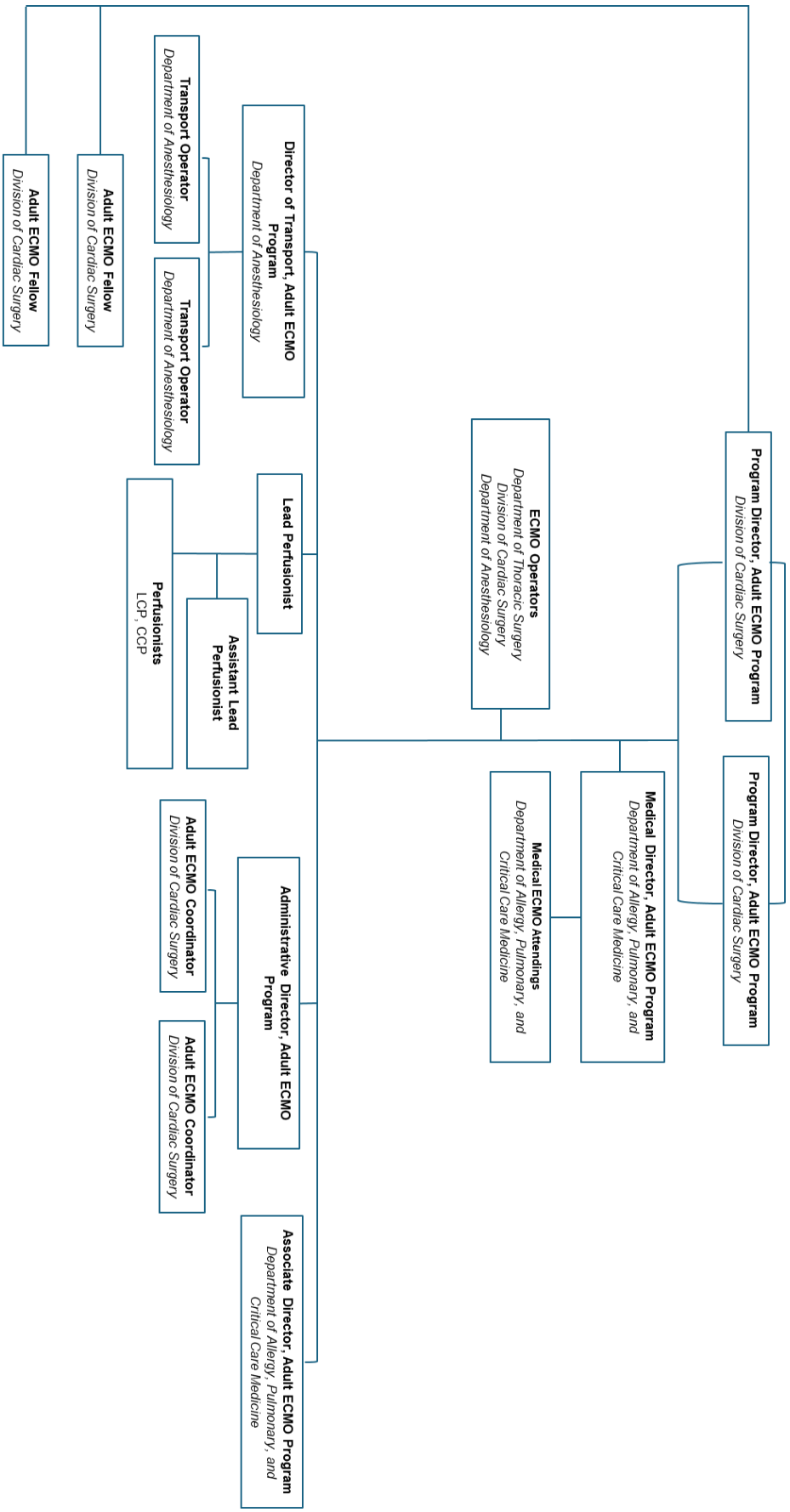
A *Program Director (PD)* will lead the ECLS program. Typically, this leadership role is held by one person; in some institutions, the ECLS program is co-led by an *ECLS Medical Director* and an *ECLS Surgical Director*. Alternately, a PD role may be designated by patient population (adult, pediatric 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.

*Associate Program Directors (APD)* are less common in Level 3 centers. APD are one or more physicians with specific responsibility for a specific ECLS patient populations. Examples include Adult ECMO, Pulmonary ECMO, or specific areas such as ECLS Transport, if offered. The PD and other senior leadership will determine if APD roles are necessary based ECLS volume and scope of services.

# FIGURE 1: EXAMPLE ECLS PROGRAM ORGANIZATIONAL CHART



Should a Level 3 Center choose to engage APDs, this role should be specifically identified and enabled. APDs specialize in and advocate for specific elements of the ECLS program. They cover both bedside care and administrative responsibilities in relatively equal portions. In the one example from the Pilot Phase of the ECLS Center Certification, 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. While Level 3 Centers will likely not have an ECLS transport program, the same principles can be applied to other specialty areas, such as surgery, cardiac ECLS, or by patient population, such as adult, pediatric, or neonatal.

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 ECLS therapy. ECLS can be a bridge to transplant, bridge to recovery, or bridge to another therapy, or deployed for other indications. Due to the complex care required, Level 3 ECLS Centers should have direct referral networks with neighboring Level 1 and Level 2 ECLS Centers (or their equivalents). 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. Due to variations in patient volume, Level 3 ECLS Centers may use an *n+1* model, a flexible staffing model (1:2 or 2:3 providers per ECLS patient), or other arrangements. Level 3 Centers should ensure that the ECLS team is adequately staffed for the current or projected number of ECLS patients, 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. ECLS credentialing processes should include these and any other competencies deemed necessary by the institution and ECLS program. 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 and/or management – 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.

The relationship between and referring institution and a Level 3 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. Financial drivers considered, an ECLS program should exist for the benefit and safety of an institution's patients.

***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 3 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<br>• Cardiology<br>• Cardiovascular Perfusion<br>• Cardiovascular Surgery<br>• Critical Care<br>• Neonatology<br>• Pharmacy<br>• Physical Medicine & Rehabilitation<br>• Pulmonology<br>• Radiology<br>• Respiratory Therapy | • Gastroenterology<br>• General Surgery<br>• Hematology<br>• Infectious Disease<br>• Nephrology<br>• Neurology<br>• Neurosurgery<br>• Palliative Care & Medical Ethics<br>• Psychology & Psychiatry |

*General Operational Services*

A Level 3 Center will have hospital services commensurate with a major medical center. These services will expand far beyond the scope of ECLS and may vary by country and/or region. In a Level 3 Center, general operational services are shared services amongst all care units in the hospital. Specific to ECLS, the following services should be available at all times 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 3 Centers can expand these offerings to specialized services, such as hybrid operating rooms, interventional suites, and other technology-enabled procedure rooms. While not required, 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 3 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 3 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 3 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 3 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<br>• Cannulas<br>• Components Specific to Other Forms of ECLS (*if offered*)<br>• Connectors<br>• Disposable ECLS Equipment<br>• Heater Unit/Warming Unit (*if needed*)<br>• Membrane Lung or Oxygenator<br>• Other Disposable Products<br>• Portable Oxygen Supply for Transport<br>• Primed ECMO Circuit (no older than 30 days) |

Where modes other than ECMO are provided, Level 3 Centers are expected to have any additional components on site, with a formal procurement system for 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*

Although Level 3 Centers will typically treat ECLS patients for only a portion of their ECLS runs, the entire ECLS team should be fully trained and able to treat ECLS patients for as long as necessary. Training for Level 3 Centers is no different than that for Level 1 and 2 Centers. 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 3 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 3 Centers may have access to on-site training facilities for didactic and/or simulation, but will often look to external training for some or all ECLS training. ELSO lists a variety of options on its website, including ELSO Courses, ELSO Endorsed Courses, and non-ELSO courses. 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 3 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. Where possible, simulation training should use ECLS equipment that closely resembles the institution's clinical environment. Simulation training can be completed on site, at a training center, or in a combination of both. 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<br>• Circuit Components<br>• Cannulation & Configuration<br>• ECMO Physiology<br>• Respiratory Support (VV ECMO)<br>• Cardiac/Circulatory Support<br>• (VA ECMO)<br>• Patient Management<br>• ECMO Complications<br>• Literature Review | • Drainage Insufficiency<br>• Air Embolism<br>• Pump Failure<br>• Membrane Lung Failure<br>• Gas Failure | 16-32 Proctored Clinical Hours (equivalent to 2-4 ECLS care shifts)<br><br>***Maintenance of Training:*** One 8-hour shift every eight weeks; can be supplemented with additional Simulation Training |

*Re-Training*

Level 3 Centers may experience variations in ECLS volume over time. 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 should participate in additional proctored hours upon return to ECLS service.

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

***ECLS Team Staffing***

Level 3 Centers may experience staffing circumstances unique to their patient volume. If ECLS care is a regular part of the clinical practice, the ECLS program should deploy a consistent staffing model, such as the *n+1* or flexible staffing model. Level 3 centers opt for other staffing models if ECLS patient volume is variable or inconsistent.

*N+1 Model*: 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 initiations or accepted transfers. Centers utilizing an *n+1* model will have a core group of ECLS Specialists to ensure adequate clinical time and re-training as appropriate. Additional ECLS Specialists will only be onboarded when ECLS volumes or acuity warrants.

*Flexible Staffing Model*: Flexible staffing models typically rotate 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 a team of ECLS Specialists who are also trained in standard critical care. This model allows ECLS Specialists to support other care areas if ECLS volumes are lower. Flexible staffing models allow an ECLS program to pull additional trained ECLS staff as needed. Flexible models can be appropriate for centers with wide variations in ECLS volume.

***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 3 Center will have each of the following protocols, plus any additional as deemed necessary by hospital leadership and the ECLS program. Their credentialing program may exceed these standards and/or add supplementary criteria to meet regulatory requirements. Where possible, a Level 3 Center should align their credentialing program with those recommended below.

*Policies by ECLS Mode and Role*

A Level 3 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 each provider type and 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.

It is 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)<br>• Minimum education requirements specific to the individual's profession<br>• Minimum post-graduate medical training (residency, fellowship, post-fellowship training) – ***if relevant***<br>• Re-education and retraining policies<br>• Granting of emergency privileges for transporting and/or consulting providers<br>• Mandatory and Suggested KPI ***(see Tables 6 & 7)*** |

*A Note on Volume:* ELSO does not set, recommend, nor 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, 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 3 Center should promote ECLS individual certification within is its ECLS clinical staff. Certification should be relevant to the patient population served, such that some ECLS Specialists may be certified in multiple patient populations. ELSO certification (E-AEC or E-NPEC) is not required for any Level 3 Center.

***KPI/Metrics***

A Level 3 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 core part of the ECLS credentialing process. Effective use of metrics will inform readiness for privileges, maintenance of privileges, and opportunities for re-training. *Mandatory KPI* are considered essential to a credentialing policy; all are highly encouraged. ELSO requires that 3 or more of these are tracked. *Recommended KPI* are those considered important in considering privileges, though they should be considered in the appropriate context.

***Table 6. KPI for ECLS Credentialing - Cannulation***

| ***Mandatory KPI*** <br> ***Must Track 3+ of the Following*** | ***Recommended KPI*** <br> ***Must Track 2+ of the Following*** |
|---|---|
| • Number of Cannulations Performed* <br> • Use of Ultrasound or Fluoroscopy for Percutaneous Cannulations <br> • Complication Rates* <br> ○ Bleeding <br> ○ Cannula Malposition <br> ○ Limb Ischemia <br> ○ Serious Vascular Event Requiring Endovascular or Surgical Repair <br> • Rate of Re-Cannulation* <br> • Rate of Surgical Intervention to Change Cannulation Configuration | • Patient Selection Criteria Adherence <br> • Cannulation Time* <br> • Location of Cannulation (OR, Cath Lab) <br> • Rate of Bacteremia or Positive Blood Culture <br> • Cannula-Associated Deep Vein Thrombosis <br> • 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*** <br> ***Must Track 3+ of the Following*** | ***Recommended KPI*** <br> ***Must Track 2+ of the Following*** |
|---|---|
| • Number of Cases Managed Per 12 Months <br> • Complication Rates* <br> ○ Air Embolism <br> ○ Circuit or Site Infection <br> ○ Emergent Discontinuation of ECLS <br> ○ Accidental Decannulation <br> • Median Lenth of ECLS Run** | • Rate of Limb Ischemia* <br> • Time to Initiation – from Call to Cannulation (or other defined landmark)* <br> • Weaning Rate – Success weaning off ECLS* <br> • Rate of LV Venting* <br> • Frequency of Training and/or Re-Training** <br> • Frequency of Change in ECLS Mode* <br> • Long-Term Functional Status Post-ECLS* <br> • 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 3 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 ) <br> • Frequency of change in strategy (VV to VA, VA to VAV, etc.) <br> • Rate of use of LV venting – by support type, across all support types <br> • Rate of Bleeding Complications <br> • Ventilator settings |
| **Assess ECLS Circuit** | • ECLS Flow and/or Pressures <br> • Clotting Ability <br> • Hemolysis Lab Results <br> • Use of Anticoagulation Medication |
| **Assess for Weaning** | • Use and Indication of Chest X Ray <br> • Use and Indication of Echocardiogram <br> • Arterial Blood Gases <br> • Pulmonary Artery Pressures |

| | |
|---|---|
| **Other Competency/ Performance Measures** | • Time to Initiation<br>• Cannulation Success: Initial Cannulation<br>• Rate of Re-Cannulation – by support type, by individual practitioner<br>• Success of Weaning on Time Basis (24 hours, 1 week, etc.)<br>• Complication Rates: Bleeding, Infections, Strokes, Vascular Complications |
| **Team Measures to Consider** | • Duration of ECMO Support<br>• Team Training and Competency<br>• Resource Utilization<br>• Patient and Family Engagement<br>• Cost-Effectiveness<br>• Follow-up Care<br>• Long-term Outcomes<br>• Quality Improvement Initiatives<br>• Data Reporting and Documentation |

***ECLS Care Protocols***

Level 3 Centers may have variations in their ECLS Care Protocols based on their typical length of ECLS run. As most patients at a Level 3 Center will be transferred to a Level 1 or Level 2 (or equivalent) center, Level 3 Centers may focus their ECLS protocols on the condition(s), indication(s), and/or population(s) most frequently treated at the center, including center-specific scenarios (i.e. hypothermia or trauma).

*ECLS Patient Selection*

A Level 3 Center will have a clearly defined ECLS patient selection policy by patient population, mode, and indication. This protocol will indicate when, how, and who should be involved in ECLS care decisions. ECLS patient selection should include a team of ECLS providers: surgeons, medical intensivists, ECLS specialists, and others as defined by the center. Case-specific considerations may be necessary.

***Table 9. ECLS Patient Selection Policy Components***

| *ECLS Patient Selection Policy Components* |
|---|
| • ***Goal(s) of ECLS Care***<br>• ***Mode of ECLS Support:*** Relative to the goals of ECLS care; each mode carries its own benefits and risks<br>• ***Disease-Specific ECLS Indications:*** Variable by indication<br>• ***Contraindications:*** Variable by case, provider, institution, current capacity, and mode of support. Include, but are not limited to:<br>  ○ *Incompatibility with Life Following ECLS Care*<br>  ○ *One or More Pre-Existing Conditions Affecting Quality of Life*<br>  ○ *Patient's Age, Size, or Other Medical Characteristic*<br>• ***Futility:*** Failure of conventional therapy and/or a fatal diagnosis<br>• ***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.<br>• ***Patient Transfer:*** Most patients in a Level 3 Center will be transferred to Level 1 or 2 or equivalent centers. A plan for transfer should be made prior to initiation of ECLS.<br>• ***ECLS Team Capacity:*** A Level 3 Center can be open or closed to ECLS consults. 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.

- ***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 3 Centers will only transport their cannulated patients out of their own facility if their teams are adequately trained in ECLS transport. If not properly trained, a Level 3 Center should coordinate with local ECLS transport providers – including partner facilities – to transfer their ECLS patients. The transport plan should be completed prior to initiation of ECLS.

*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 3 Center may have all or many of the below clinical ECLS protocols based on the mode(s) of ECLS provided and indication(s) treated. All protocols should reference consensus documents, peer-reviewed research, published guidelines, and other widely accepted means of distributing clinical knowledge. ELSO recommends an established cadence for protocol review to ensure accuracy and completeness. Where necessary, each protocol may be adapted to a specific mode of ECLS as needed.

***Table 10. List of ECLS Management Protocols***

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

**If provided at the institution*

*ECLS Transport*

ECLS transport (including within the hospital) is a highly specialized service requiring specific training, policies, and protocols. ECLS transport protocols will be specific to the mode of transport and differ from those under normal ECLS care. Level 3 Centers are not expected to have in-house ECLS transport but should collaborate with the ECLS team and any transport providers to develop protocols for each type of transport provided. Further information can be found in the ELSO Guideline on ECLS Transport.[3]

***Table 11. ECLS Transport Policy Components***

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

[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

***Table 12. Types of ECLS Transport and Criteria for Consideration***

| *Type of ECLS Transport* | *Criteria for Consideration* |
|---|---|
| **Primary ECLS Transportation**<br><br>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.<br>• Timely response is essential.<br>• Adequate preparedness is paramount to avoid delays and optimize patient outcomes. |
| **Secondary ECLS Transportation**<br><br>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.<br>• Patient may require another center's medical expertise.<br>• Family request. |
| **Tertiary ECLS Transportation**<br><br>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.<br>• A hospital with mobile ECMO team capabilities, but without the capacity to receive a patient, could carry out this transport.<br>• Preparation and coordination between the three institutions is required. |
| **Intra-Facility ECLS Transfer**<br><br>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. |

*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]

Level 3 ECLS programs should heed caution when developing any ECPR program. Level 3 Centers are not advised to start an ECLS program with the primary goal of offering ECPR services, either in-hospital or out of hospital. Both forms of ECPR require significant experience in ECLS, including a robust protocol for

[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

all forms of cardiac support beyond ECLS. Additional requirements include a robust ECLS transport network, clear protocols with local emergency services, and clear plans of action for each OHCA patient.

Patients in cardiac decline should be closely monitored to determine candidacy for ECLS in preparation for emergent cannulation to cardiac ECMO. This includes patients in the normal course of care, as well as those on cardiopulmonary bypass for surgical procedures.

*General Care Protocol*

Except where necessary to provide ECLS care, Level 3 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.

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* – While not mandatory, Level 3 Centers should make specific effort to include ECLS-specific information as part of their patient & family support programs.
- *Patient Follow-Up* – A Level 3 Center is not expected to follow ECLS patient outcomes, as most patients will be transferred to outside facilities.

***ECLS Case Review & Process Improvement***

*Evidence-Based Resources*

Level 3 Centers will have 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 3 Centers may be involved 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 3 Centers will use the best available knowledge to develop clinical policies that prioritize patient safety.

*KPI in Quality Review*

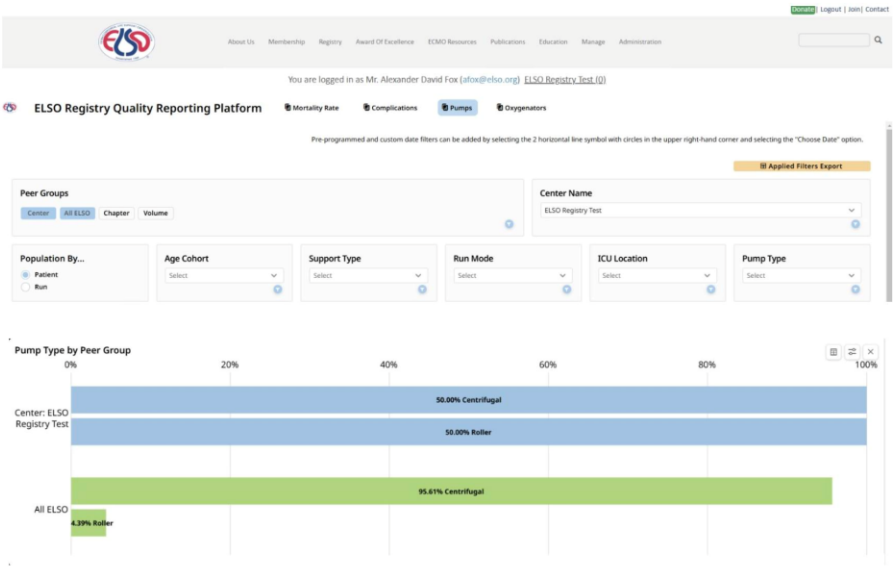
Level 3 Centers will determine, record, and maintain data for several Key Performance Indicators (KPI). The goal of KPI in this context is to support the health of the entire program – with the goal of delivering

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 3 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 and/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***




***<u>ECLS Registry Contribution</u>***

All Level 3 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 3 Centers will have 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 3 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 3 Centers – and those who may qualify for Level 3 designation – to understand the operational, logistical, and clinical responsibilities that come with such status. This packet of information should equip ECLS centers to advocate for themselves, build robust ECLS programs, and ensure that they continue to meet a global standard for ECLS care.

***APPENDIX 1: Level 3 ECLS Center Summary Table***

| ***Level 3 Designated Certified ECLS Centers***<br>***Cannulation-Only & Short Term ECLS Care Facilities***<br>***Must Have Access to ECLS Transport****<br><br>****Either in-house or through committed service providers*** | |
|---|---|
| ***Program Leadership*** | ○ ECLS Program Director<br>○ ECLS Coordinator<br>○ Medical and Service Line Leadership<br>○ Clearly Defined ECMO Specialist Role |
| ***Required ECLS Services*** | ○ ECMO/ECLS Care<br>○ ECMO/ECLS Referral<br>○ Access to ECLS Transport – either in-house or via service provider |
| ***Required Clinical Services*** | ○ Anesthesiology<br>○ Cardiology<br>○ Cardiovascular Perfusion<br>○ Cardiovascular Surgery<br>○ Critical Care<br>○ Neonatology<br>○ Pharmacy<br>○ Physical Medicine & Rehabilitation<br>○ Pulmonology<br>○ Radiology<br>○ Respiratory Therapy |
| ***Recommended Clinical Services – May Be Available by Consult Only*** | ○ Gastroenterology<br>○ General Surgery<br>○ Hematology<br>○ Infectious Disease<br>○ Palliative Care & Medical Ethics<br>○ Nephrology<br>○ Neurology<br>○ Neurosurgery<br>○ Psychology & Psychiatry |
| ***Operational Services*** | ○ Administrative Support for ECLS Program<br>○ Hospital Procurement & Supply Chain<br>○ Direct Access to ECLS Equipment<br>○ Data Management or Related Team<br>○ Biomedical Engineering |
| ***Hospital Services – Available 24/7*** | ○ Blood Gas Laboratory<br>○ Hematologic Point-of-Care Testing<br>○ Blood Bank<br>○ Radiology Support (Ultrasound, CAT scan, Interventional, etc.)<br>○ Operating Room and/or Hybrid Suite<br>○ Pathology and/or Microbiological Testing |

| ***Education, Training & Credentialing*** | |
|---|---|
| ***Education & Training***<br>*(either in-house or access to)* | ○ Didactic Training<br>○ Simulation Training<br>○ Proctored Clinical Hours |
| ***Credentialing***<br>*See Appendix I for KPI Requirements* | ○ Clear Policies and Procedures for Each Mode of ECLS<br>○ Separate Credentialing Procedures for ECLS Cannulation & Management<br>○ Required and Recommended KPI are Selected, Collected, and Verified<br>○ Individual Certification – *at least 50% of staff*<br>○ Staffing Model & Hours<br>○ Ability to Flex ECLS Capacity |
| ***ECLS Care Protocols*** | |
| ***ECLS Patient Selection Policies*** | ○ Support Mode<br>○ Cannulation Strategy<br>○ ECLS Management<br>○ Weaning from ECLS<br>○ Discontinuation of ECLS<br>○ Post-ECLS Care Plan |
| ***ECLS Cannulation*** | ○ Credentialing Policy Specific to Cannulation<br>○ KPI/Metrics Specific to Cannulation Privileges – *Granting and Renewal*<br>○ Cannulation Protocols by Population and Support Type |
| ***Required ECLS Management Policies*** | ○ Accessing the ECLS Circuit – including CRRT*<br>○ Anticoagulation Management<br>○ Cannulation Site Management<br>○ Complication Troubleshooting<br>○ Determination of Neurological Death<br>○ ECLS Circuit Management<br>○ ECLS Device Settings & Management<br>○ Emergency Protocols<br>○ Ethical Grounds for Withdrawing ECLS Care<br>○ Infection Management<br>○ Mechanical Ventilation Management<br>○ Medication Management<br>○ Nursing Care – Patient Positioning, Skincare, Wound Care<br>○ Palliative Care Support<br>○ Patient Monitoring<br>○ Sedation Management |
| ***Recommended ECLS Management Policies*** | ○ Care Considerations for ECCO2R, ECPR, and Additional Modes of ECLS*<br>○ Fluid and Renal Replacement Therapies on ECLS – including Continuous Renal Replacement Therapy (CRRT)*<br>○ Nutrition Replacement on ECLS<br>○ Organ Donation Pathway for ECLS Patients<br>○ Patient Physiotherapy, Mobilization, and Rehabilitation |

| | |
|---|---|
| ***ECPR - Extracorporeal Cardiopulmonary Resuscitation*** | ○ Not Recommended for ECLS Level 3 Programs<br>○ Highly Proficient in ECLS Management & ECLS Transport<br>○ Access to all ECLS Service Lines<br>○ Capacity to For Highly Acute Patients<br>○ Clearly Defined ECLS Care Plan |
| ***Other Care Protocols*** | ○ Medical Records Process<br>○ Infection Control<br>○ Patient Rights & Responsibilities<br>○ 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)<br>○ Morbidity and Mortality Conferences<br>○ Reporting System for Near Misses, Adverse Events, and Errors<br>○ Use of ECLS Data in Quality Review<br>○ KPI – Overall Program and Credentialing-Specific Metrics<br>○ Whistleblower Policy<br>○ Policy for Introducing New Technology |
| ***Contribute to an ECLS Registry*** | |
| ***Active Contributor to an ECLS Registry*** | ○ Include all ECLS Cases<br>○ Data Submitted to Within 6 months of Patient Discharge or Transfer |
| ***Data Policies & Procedures*** | ○ Validate and Transfer Data to Registry<br>○ 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*** <br> ***Must Track 3+ of the Following*** | ***Recommended KPI*** <br> ***Must Track 2+ of the Following*** |
|---|---|
| • Number of Cannulations Performed* <br> • Use of Ultrasound or Fluoroscopy for Percutaneous Cannulations <br> • Complication Rates* <br> ○ Bleeding <br> ○ Cannula Malposition <br> ○ Limb Ischemia <br> ○ Serious Vascular Event Requiring Endovascular or Surgical Repair <br> • Rate of Re-Cannulation* <br> • Rate of Surgical Intervention to Change Cannulation Configuration | • Patient Selection Criteria Adherence <br> • Cannulation Time* <br> • Location of Cannulation (OR, Cath Lab) <br> • Rate of Bacteremia or Positive Blood Culture <br> • Cannula-Associated Deep Vein Thrombosis <br> • Success Rate of Distal Arterial Reperfusion Cannula Insertion |

## Key Performance Indicators (KPI) for Credentialing
## ECLS Management

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

# Key Performance Indicators (KPI) for Program Quality Assessment

Level 3 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)<br>• Frequency of change in strategy (VV to VA, VA to VAV, etc.)<br>• Rate of use of LV venting – by support type, across all support types<br>• Rate of Bleeding Complications<br>• Ventilator settings |
| **Assess ECLS Circuit** | • ECLS Flow and/or Pressures<br>• Clotting Ability<br>• Hemolysis Lab Results<br>• Use of Anticoagulation Medication |
| **Assess for Weaning** | • Use and Indication of Chest X Ray<br>• Use and Indication of Echocardiogram<br>• Arterial Blood Gases<br>• Pulmonary Artery Pressures |
| **Other Competency/Performance Measures** | • Time to Initiation<br>• Cannulation Success: Initial Cannulation<br>• Rate of Re-Cannulation – by support type, by individual practitioner<br>• Success of Weaning on Time Basis (24 hours, 1 week, etc.)<br>• Complication Rates: Bleeding, Infections, Strokes, Vascular Complications, other |
| **Team Measures to Consider** | • Duration of ECMO Support<br>• Team Training and Competency<br>• Resource Utilization<br>• Patient and Family Engagement<br>• Cost-Effectiveness<br>• Follow-up Care<br>• Long-term Outcomes<br>• Quality Improvement Initiatives<br>• Data Reporting and Documentation |