Extracorporeal Life Support Organization (ELSO)

ECLS Center Certification Program Methodology

February 2026

Responsibility for the ECLS Center Certification program – including this document and all related activities – lies solely with the ELSO Board of Directors. Any actions, updates, or modifications are subject to approval by the ELSO Board of Directors.

ECLS Center Certification Task Force

The ECLS Center Certification Task Force (CCTF) was created to develop the ECLS Center Certification program for – and on behalf of – ECLS centers globally. Each member has been selected for their clinical experience in ECLS, knowledge of hospital operations, and expertise with certification, medical education, and/or program development. They are interprofessional, multidisciplinary, and global in their representation.

Members listed in alphabetical order
Darryl Abrams, MD *(Columbia University, New York, NY)*
Huda Alfoudri, MD *(Adan Hospital, Hadiya, Kuwait)*
Marta Velia Antonini, E-AEC, MSc *(Bufalini Hospital, AUSL della Romagna, Cesena, Italy)*
Matthew Bacchetta, MD, MBA *(Vanderbilt University, Nashville, TN)*
Erica Bak, RN, MS *(Rady Children's Hospital, San Diego, CA)*
Joan Balcells Ramirez, MD (*Vall d'Hebron University Hospital, Barcelona, Spain)*
Michael Baram, MD *(Jefferson Health, Philadelphia, PA)*
Ryan Barbaro, MD *(ELSO Board; University of Michigan, Ann Arbor, MI)*
Nicholas Barrett, MD *(Guy's & St. Thomas' NHS Foundation Trust, London, UK)*
Robert Bartlett, MD *(ELSO Founder; University of Michigan, Ann Arbor, MI)*
Peyman Benharash, MD *(UCLA Health, Los Angeles, CA)*
Hwa Jin Cho, MD, PhD *(Chonnam National University, Gwangju, Korea)*
Jeffrey DellaVolpe, MD *(Methodist Hospital, San Antonio, TX)*
K. Barry Deatrick, MD *(University of Michigan, Ann Arbor, MI)*
Alyaa Elhazmi, MD *(Ministry of Health, Saudi Arabia)*
Jo-Anne Fowles, RN, MSc *(Royal Papworth Hospital NHS Trust, Cambridge, UK)*
Alexander Fox, MHSA *(Senior Project Manager, ELSO)**
Whitney Gannon, MSN, MS *(Vanderbilt University, Nashville, TN)*
Vadim Gudzenko, MD *(UCLA Health, Los Angeles, CA)*
Kasia Hryniewicz, MD *(Allina Health, Minneapolis, MN)*
Tatiana Jaramillo, BSN, MBA *(Fundación Clinica Shaio, Bogotá, Colombia)*
Michael Kotwas, CCP, LP *(Rush University and Medical Center, Chicago, IL)*
Jeannie Kukutschka, MD *(Tecnológico de Monterrey; Monterrey, Mexico)*
Michael McMullan, MD *(ELSO Strategic Advisory Council; Seattle Children's Hospital, Seattle, WA)*
Thomas McRae, MD *(TriStar Centennial Medical Center, Nashville, TN)*
Rita Milewski, MD, PhD *(Yale University, New Haven, CT)*
Elizabeth Moore, RN, MBA *(ELSO Education Director; University of Iowa, Iowa City, IA)**
Tracy Morrison, RN *(ELSO Quality Chair; Miami Valley Hospital, Dayton, OH)*
Thomas Mueller, MD *(ELSO Board; University Hospital Regensburg, Germany)*
Raj Ramanan, MD *(ELSO Education Chair; University of Pittsburgh Medical Center, Pittsburgh, PA)*
Kollengode Ramanathan, MD *(ELSO Publications Chair; National University Hospital, Singapore)*
Jordi Riera del Brio, MD *(Vall d'Hebron University Hospital, Barcelona, Spain)*

Peter Rycus, MPH *(Executive Director, ELSO)**
Peter Schellongowski, MD *(Medical University of Vienna, Austria)*
Jayne Sheldrake, RN *(ELSO Strategic Advisory Council; Alfred Health, Melbourne, Australia)*
Christine Stead, MHSA *(Chief Executive Officer, ELSO)**
John Stokes, IV, MD *(Vanderbilt University Medical Center, Nashville, TN)*
Justyna Swol, MD *(Paracelsus Medical University, Nuremberg, Germany)*
Joseph Tonna, MD, MS *(ELSO Registry Chair; University of Utah, Salt Lake City, UT)*
Sage Whitmore, MD *(TriStar Centennial Medical Center, Nashville, TN)*
Soňa Wulczyňská, RN, Bc *(General University Hospital, Prague, Czech Republic)*
Bishoy Zakhary, MD *(Oregon Health Sciences University, Portland, OR)*
**Denotes compensated ELSO staff*

Precedence & History

The earliest programs for hospital standardization and inspection date to the early 20th century. The American College of Surgeons (ACS) led this work in the United States, publishing *The Minimum Standard* in 1918.[1] The ACS standards specify a site visit, specifically noted to be consultative rather than punitive, with a clear focus on improving patient care. *The Minimum Standard* and its successors were the gold standard, eventually evolving into modern-day hospital accreditation programs.

Hospitals – and specialty programs within them – find several options for accreditation and certification. Few such programs exist for ECLS. Even fewer have been developed by ECLS centers or their specialty societies. Previous Joint Statements by ELSO with the Pediatric Cardiac Intensive Care Society (PCICS)[2] and the International ECMO Network (ECMONet)[3] establish a precedent for ECLS as some of the most complex life support technologies available. ECLS requires specific knowledge, skills, and abilities on the part of providers and programs.

The ELSO ECLS Center Certification program is designed to meet this need: a certification program by – and on behalf of – global ECLS centers. ELSO's Center Certification recognizes programs that provide safe ECLS services and provides a blueprint for those seeking to achieve these standards. This program is guided by ELSO's mission to advance and support the safety of extracorporeal life support technologies.

[1] *The American College of Surgeons, Minimum Standards for Hospitals, and the Provision of High-Quality Laboratory Services* https://doi.org/10.5858/arpa.2016-0348-HP
[2] *Joint Statement on Mechanical Circulatory Support in Children: A Consensus Review from the Pediatric Cardiac Intensive Care Society and Extracorporeal Life Support Organization* https://doi.org/10.1097/PCC.0b013e318292dc09
[3] *Position Paper for the Organization of Extracorporeal Membrane Oxygenation Programs for Acute Respiratory Failure in Adult Patients* https://doi.org/10.1164/rccm.201404-0630CP

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 which 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 transfer 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 with 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}

Example

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-P^{T}C^{Ø} ECLS Pediatric Level 2-P^{Ø}C ECLS Neonatal Level 3-E		

Styling

Long Form Nomenclature

- The Long Form must always include the patient population, level designation, ECLS support type, and transplant designation (if awarded).
- Only the designations noted below may be used. These words cannot be altered in any form:
    - *Patient Population*: Adult, Pediatric, Neonatal
    - *Level Designation*: Level 1, Level 2, Level 3
    - *ECLS Support Type:* Cardiac, Pulmonary, ECPR
- ECLS Support Type should be listed in the following order: Cardiac, Pulmonary, ECPR
- The Long Form cannot be abbreviated or modified in any way, other than use of the Short Form.
- Include a comma before the word "and" (known as the serial comma). The symbol "&" should never be used in place of "and".

Transplant Designation

- Transplant Designation should be indicated in parentheses next to the support mode for which it is applicable. The in-house ^{T} or out-of-house $^{\emptyset}$ designation should always follow the Transplant Designation. *Ex: Pulmonary (Transplant^{T})* or *Pulmonary (Transplant$^{\emptyset}$*)
- If multiple Transplant Designations are earned for a specific patient population, they should be indicated for each support type. *Ex: Pulmonary (Transplant^{T}) and Cardiac (Transplant$^{\emptyset}$)*
- The Transplant Designation should never be used without a ^{T} or $^{\emptyset}$ to indicate Transplant Availability. For example, "Pulmonary (Transplant)" is an incomplete designation and is not permitted.

Short Form Nomenclature

- The Short Form designation should never be used without the ECLS indication. For example, "ELSO Adult Level 1" is considered an incomplete designation and is not permitted.
- The ECLS indications should be listed in the following order (if offered): Pulmonary, Cardiac, ECPR.
- Transplant Designation should be indicated in superscript following the Support Type designation *Ex: ECLS Neonatal Level 1-R^{T}C$^{\emptyset}$*
- The Support Type designation should remain unaltered, except for the Transplant Designation.

Multiple Patient Populations

- Centers that receive certification for multiple patient populations will list their certifications separately by patient population in the following order (if applicable): Adult, Pediatric, Neonatal
- Each Patient Population will have its own Long Form and Short Form designations.
- Transplant Designation(s) (if applicable) will be listed next to the Support Type indication for which it is received.
- Patient populations and support types should never be condensed beyond the allowed Short Form designations.

ECLS Center Certification Methodology

The ECLS Center Certification Methodology is a collaborative effort of all listed authors, with additional contributions from ELSO staff. The ECLS Center Certification Task Force has provided subject matter expertise throughout the editorial process. The Methodology is intended to enhance – rather than conflict with – any existing institutional policy, regulation, law, or other governing document. Where conflict exists between the Methodology and another document, the Methodology shall be interpreted as closely as possible without superseding the prevailing regulation. Citations have been provided with links to the most current version of the referenced item.

Definitions

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

- ***ECLS (Extracorporeal Life Support)*** is an umbrella term for extracorporeal life support technologies that includes Extracorporeal Membrane Oxygenation (ECMO) and Extracorporeal Carbon Dioxide Removal (ECCO2R). Extracorporeal Cardiopulmonary Resuscitation (ECPR) and Extracorporeal Interval Support for Organ Retrieval (EISOR) are specific applications of ECMO and are thus included in the ECLS family. Additional forms of life support, mechanical circulatory support, and other artificial organs are not included in the definition of ECLS. [4]
- ***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.[4]
- ***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 this Methodology, ***ECLS Coordinator*** and ***ECLS Specialist*** are interchangeable with ***ECMO Coordinator*** and ***ECMO Specialist***.
- ***Methodology*** refers to this document, which defines and describes the ECLS Center Certification Methodology developed by ELSO and the Center Certification Task Force.

1. Section 1: Program and Organization

1.1. Alignment With Guidelines

The Institution and ECLS Program should align their Program with the latest ELSO guidelines and/or commonly held industry thinking on the organization and development of an ECLS Program.[2,3,5]

[4] *Maastricht Treaty for ECLS Nomenclature* https://doi.org/10.1164/rccm.201710-2130CP

[5] *ELSO Guidelines for ECMO Centers v1.8* https://www.elso.org/ecmo-resources/elso-ecmo-guidelines.aspx

1.2. Define and Notate Key Program Aspects

1.2.1. The ECLS Program should have in place at a minimum the following leadership structure:

1.2.1.1. *Program Director*: A single physician with responsibility for the overall operation of the ECLS Program. This individual should be a physician with specific training in ECLS. They should be appointed to this role for their specific knowledge of and experience in ECLS and critical care. ECLS Centers may opt to select a Program Director for each patient population (Adult, Neonatal, and/or Pediatric).[6]

1.2.1.2. *Associate Program Director(s):* One or more physicians with specific responsibility for one or more ECLS patient populations. Examples include Adult ECMO, Pulmonary/Critical Care, Pediatric, or any other variations as deemed appropriate by the Institution.

1.2.1.3. *ECLS Coordinator*: An ECLS specialist with responsibility for the supervision and training of the technical staff, maintenance of equipment, and collection of patient data. This individual should be an experienced neonatal, pediatric, or adult physician, critical care registered nurse, registered respiratory therapist, or perfusionist with ECLS and critical care experience, or other specialist with specific training and experience in ECLS. The term *ECLS Specialist* is further defined in *Section 2* of this Methodology.

1.2.1.4. *Medical and Service Line Leadership*: Appropriate triad (physician, nursing, administrative) leadership that is accountable for ECLS Program performance and operations.[3]

1.3. Access to Clinical and Support Services

The ECLS Program should have access to clinical and supportive service lines, including associated ancillary staff, to support safe patient care. The use of pediatric, neonatal, and/or adult service lines will be assessed relative to the population(s) for which the ECLS Program is seeking certification. Note that where telehealth or remote services are commonly implemented, those services may be deemed sufficient in some cases. Applicants for only cardiac or pulmonary indications will be assessed relative to the ECLS support types provided.

1.3.1. Physicians and related clinical personnel in the following fields:

1.3.1.1. Pediatric/Adult Anesthesiology
1.3.1.2. Pediatric/Adult Cardiology
1.3.1.3. Pediatric/Adult Cardiovascular Surgery
1.3.1.4. Cardiovascular Perfusion
1.3.1.5. Pediatric/Adult Critical Care
1.3.1.6. Pediatric/Adult Gastroenterology
1.3.1.7. Pediatric/Adult Hematology
1.3.1.8. Pediatric/Adult Infectious Disease
1.3.1.9. Neonatology (*Neonatal & Pediatric ECLS Programs only)*
1.3.1.10. Pediatric/Adult Nephrology
1.3.1.11. Pediatric/Adult Neurology

[6] Joint Society of Critical Care Medicine-Extracorporeal Life Support Organization Task Force Position Paper on the Role of the Intensivist in the Initiation and Management of Extracorporeal Membrane Oxygenation https://doi.org/10.1097/CCM.0000000000004330

1.3.1.12. Pediatric/Adult Neurosurgery
1.3.1.13. Palliative Care & Medical Ethics
1.3.1.14. Psychology & Psychiatry
1.3.1.15. Pediatric/Adult Pulmonology
1.3.1.16. Pediatric/Adult Radiology
1.3.1.17. Rehabilitation & Therapy
1.3.1.18. Respiratory Therapy
1.3.1.19. Pediatric/Adult General Surgery
1.3.1.20. Pediatric/Adult Heart Transplant (required for Level 1 Designation)*
1.3.1.21. Pediatric/Adult Lung Transplant (required for Level 1 Designation)*
1.3.1.22. **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.*

1.3.2. Administrative Support
1.3.3. Operational Support
1.3.3.1. Procurement & Supply Chain
1.3.4. Data Management or Related Team (for Registry Participation)
1.3.5. ECLS Transport Team (*if ECLS transport is provided at the institution*)

1.4. Hospital Services

The Institution should have the following services available. These should be available 24 hours a day, 7 days a week with no gaps in coverage:

1.4.1. Blood Gas Laboratory
1.4.2. Hematologic Point-of-Care Testing
1.4.3. Blood Bank
1.4.4. Radiology Support (Ultrasound, CAT scan, Interventional Radiology, etc.)
1.4.5. Operating Room or Procedure Room (Catheterization Lab, Interventional Suite, etc.)
1.4.6. Pathology and/or Microbiological Testing

1.5. Backup Components

The Institution should have available and located in or directly adjacent to ECLS care units, the following equipment. The ratios of backup-to-equipment in service for each of these items is relative to the number of patients currently on ECLS, the Institution's total ECLS patient capacity, the complexity of ECLS cases treated at the Institution, and the modes of ECLS provided. The Institution should ensure that ECLS care is not halted or made unavailable due to the lack of these necessary resources. Backup components should be available 24 hours a day, 7 days a week with no gaps in service.

1.5.1. Backup Components of ECMO Circuit
1.5.1.1. Blood Pump
1.5.1.2. Heater Unit/Warming Unit (if in regular use at the Institution)
1.5.1.3. Membrane Lung or Oxygenator
1.5.1.4. Disposable ECLS Equipment
1.5.1.5. Connectors
1.5.1.6. Cannulas
1.5.1.7. Portable Oxygen Supply for Transport

1.5.1.8. Other Disposable Products

1.5.2. Backup Components of non-ECMO ECLS Equipment

1.5.2.1. Where ECLS modes beyond ECMO are deployed in an ECLS Program, the Program should stock all components relative to the supply and demand of these components necessary for the ECLS modes provided.

1.5.3. Hospital-wide supply chain system for access to equipment, disposables, and necessary items for patient care:

1.5.3.1. Disposable Products

1.5.3.2. Capital Purchases

1.6. ELSO Center Membership

The Institution is required to maintain active ELSO center membership.[3]

1.7. Institutional Support of ECLS Program

The Institution should provide a minimum level of support to the ECLS Program. The term support is meant to be inclusive of financial means, staffing, administrative time, scheduling, and other resources deemed necessary by mutual agreement of the Institution and the ECLS Program for the delivery of safe ECLS care. Each of these components is further described in *Section 2* of this Center Certification Methodology:[7,8]

1.7.1. Dedicated & Consistent Funds for Staff Education and Training[9]

1.7.1.1. Institutional funding or support for continuing medical education, training, and costs for acquiring and/or delivering such training either in-house or at a reputable training site.

1.7.1.2. A commitment from institutional leadership to support ECLS team training (both in-house and at external facilities) for all modes of ECLS practiced at the Institution.

1.7.1.3. Annual funding to attend conferences (such as the ELSO Annual Meeting) and other major gatherings of ECLS care teams.

1.7.2. Team Staffing[9]

1.7.2.1. The Institution and the ECLS Program should collectively define and maintain adequate non-ECLS team staffing ratios in both critical care and non-intensive settings to promote safe patient care. These Staffing Ratios are further described in *Section 2* of this Center Certification Methodology.

1.7.3. Financial Support of Resources, Technology, and Program Needs[5]

1.7.3.1. The Institution should make available the necessary financial and administrative support for adequate funding of staff, resources, technology, and any ECLS Program needs as mutually agreed to by the ECLS Program and the Institution.

1.7.4. Credentialing Policies & Processes[5]

1.7.4.1. The Institution should clearly define and maintain processes to grant privileges (ECLS and non-ECLS care) at the Institution. These policies and processes should

[7] 42 CFR Part 482 *CONDITIONS OF PARTICIPATION FOR HOSPITALS* https://www.ecfr.gov/current/title-42/chapter-IV/subchapter-G/part-482

[8] *ELSO Guideline for Education and Training* https://www.elso.org/ecmo-resources/elso-ecmo-guidelines.aspx

[9] *Core Principles & Values of Effective Team-Based Health Care* https://nam.edu/perspectives-2012-core-principles-values-of-effective-team-based-health-care/

specifically include ECLS-specific metrics, such as number of cannulations performed, cannulation procedure time, complication rates, and/or other data as deemed appropriate by the Institution. ECLS privileging is further defined in *Section 2* of the Center Certification Methodology. Metrics and Key Performance Indicators for credentialing are defined in *Appendix I* of this document.

1.7.4.2. The Institution should have an independent credentialing policy for each step in the ECLS care cycle: patient selection, cannulation, management, and procedures on ECLS, at a minimum.

1.7.4.3. Such institution-wide Credentialing Policies & Procedures should include processes to accept credentials from training programs as residents, fellows, and other trainees move to new sites.

1.8. Collaboration with Relevant Public and Private Organizations[10]

The Institution should have clear and consistent collaboration through meetings, annual conferences, and other gatherings with relevant medical societies, consortia, and other collaborations that support safe patient care.

1.9. Access to ECLS Clinical Expertise[11]

The Institution and the ECLS Program should collectively develop and deploy a plan to access ECLS clinical expertise at neighboring, peer, or other institutions with which the ECLS Program is connected. These conversations can include topics like access to care, ECLS transport, patient selection, patient follow-up, and sharing of best practices.

2. Section 2: ECLS Team Leadership and Composition

2.1. Alignment with Education and Training Guidelines

The ECLS Program should align their clinical ECLS practice with the relevant ELSO guidelines, peer-reviewed research, and other commonly accepted standards of care for ECLS patients.

2.2. Team Leadership & Reporting Structure[5]

The ECLS Program should clearly define and name leadership roles for their medical staff (*Medical Director*, *ECLS Coordinator*, *Service Line Leadership*) and reporting of all staff up to these roles. The definition of these roles is listed in *Section 1* of this Methodology.

2.3. Define ECLS Specialist

2.3.1. The ECLS Program should clearly define the role of *ECLS Specialist*, consistent with the ELSO Guideline on Education and Training and expanded to include other relevant professions.[5]

2.3.2. *ECLS Specialist*: The technical specialist trained to manage the ECLS system and the clinical needs of the patient on ECLS under the direction of a licensed ECLS-trained provider. Note that ECLS Specialists should be independently trained on each mode of ECLS provided at the Institution.

[10] *A Perspective on Public-Private Collaboration in the Health Sector* https://nam.edu/a-perspective-on-public-private-collaboration-in-the-health-sector/

[11] *Extracorporeal Life Support Organization Mission & Vision* https://www.elso.org/aboutus/visionmission.aspx

2.3.3. The ECLS Coordinator role may include any of the following professions:

2.3.3.1. Advanced Practice Providers (Advanced Practice Registered Nurse, Physician Assistant, Nurse Practitioner, or similar)

2.3.3.2. Nursing (including Registered Nurse, Critical Care Registered Nurse, and other certified acute or critical care trained nurses)

2.3.3.3. Respiratory Therapist

2.3.3.4. Cardiovascular Perfusionist

2.3.3.5. Physicians trained in ECLS who have completed ECLS Specialist training

2.3.3.6. Pharmacist

2.3.3.7. Dietician

2.3.3.8. Paramedic or Similar Transport Specialists

2.3.3.9. Any other clinical professional that has met the Institution's required competency, training, and practice requirements to treat ECLS patients

2.4. ECMO Education & Training: Didactic, Simulation, Proctoring[8]

2.4.1. ECMO Education and Training covers three main components: *Didactic Training*, *Simulation Training*, and *Proctored Clinical Hours*. All are considered integral to the training program. The ECLS Program may offer didactic and simulation training in-house or at an external training facility or combine external and in-house training. The Institution and ECLS Program may elect to host additional training beyond these core components specific to hospital policy, practice, or other relevant clinical training.

2.4.2. *Didactic Training*: A lecture-based course with case presentations to inform the learner of key ECMO concepts. Notably, this course is distinct from a general ICU or critical care course in that it discusses concepts directly as they apply to ECMO. Suggested topics include, but are not limited to:

2.4.2.1. Introduction to ECMO

2.4.2.2. Circuit Components

2.4.2.3. Cannulation & Configuration

2.4.2.4. ECMO Physiology

2.4.2.5. V-V ECMO (Pulmonary Support)

2.4.2.6. V-A ECMO (Cardiac/Circulatory Support)

2.4.2.7. Patient Management

2.4.2.8. ECMO Complications

2.4.2.9. Literature Review

2.4.3. *Simulation Training*: A hands-on, interactive training with minimal lecture time that is designed to simulate key ECLS management techniques in a controlled environment. These courses are akin to wet lab training and should make use of ECLS equipment that is identical to, or closely similar to, that which is typically used in the institution's clinical practice. Recommended simulations include:

2.4.3.1. Drainage Insufficiency

2.4.3.2. Air Embolism

2.4.3.3. Pump Failure

2.4.3.4. Membrane Lung Failure

2.4.3.5. Gas Failure

2.4.4. *Proctored Clinical Hours*: This real-world training is designed to bridge the gap between the concepts of didactic training, the controlled environments of simulation training, and the active clinical environment. Proctored clinical hours are practiced on the Institution's current ECMO patients with supervision from an experienced ECLS Specialist. ELSO recommends that new ECLS Specialists complete a minimum of 16-32 proctored clinical hours (equivalent to 2-4 ECLS care shifts).

2.4.5. *Maintaining Training*: ECLS Specialists should complete one 8-hour shift every eight weeks to maintain clinical skills. In lower volume centers where that is not possible, additional simulation training may take the place of some clinical hours. At no point should simulation training completely replace active clinical practice.

2.4.5.1. In addition to regular ECLS clinical service, the ECLS Center should have a policy outlining the maintenance of training, skills, and abilities policy to ensure that all ECLS staff members are completing an adequate amount of continuous training.

2.5. ECLS Training in ECLS Modes Other Than ECMO

While ECMO remains the primary mode of ECLS support, this ECLS Center Certification Methodology recognizes the use of similar support modes in patient care. In ECLS Centers where these additional modes of support are used, the ECLS Program should expand their training to include these technologies. The ECLS Program is responsible for ensuring that each ECLS Specialist is adequately trained on all mode(s) of support provided to under their care.

2.6. Credentialing[3,5]

2.6.1. The Institution should develop, post, and maintain a set of ECLS credentialing policies. These policies should define the minimum knowledge, skills, and abilities to be considered for ECLS privileges at the Institution, including at a minimum the following elements:

2.6.1.1. Minimum education requirements specific to the individual's profession;

2.6.1.2. Minimum post-graduate medical training (residency, fellowship, post-fellowship training) for physicians;

2.6.1.3. Minimum ECLS training requirements;

2.6.1.4. Re-education and retraining policies; and

2.6.1.5. Granting of emergency privileges for transporting and/or consulting providers

2.6.2. The Institution should maintain a separate credentialing policy and process for each mode of ECLS provided at the Institution. Credentialing policies should separately and independently grant ECLS cannulation and ECLS management privileges.

2.6.3. *Key Performance Indicators:* The ECLS program should select, collect, and track Key Performance Indicators (KPI) for the ECLS Program and by individual ECLS provider (as appropriate). *Appendix I* further describes the required and recommended KPI for ECLS cannulation and ECLS management privileges.

2.6.4. As credentialing and privileging are the exclusive domain of institutions, ELSO makes no specific requirements as to the minimum levels of education, training, or supervision necessary to grant privileges at an institution. ELSO solely requires that an ELSO-certified center has a credentialing policy that is consistent with that institution's practice.

2.7. Individual Certification (E-AEC, E-NPEC, CES-A, CES-P, etc.)[12]

At least 50% of the ECLS care staff should complete or be in progress to complete one of the many individual ECLS certifications that exist. These certification pathways may be specific to the patient population(s) (neonatal/pediatrics or adults) for which the Institution has applied for Certification. *Individual certification (E-AEC or E-NPEC) from ELSO is not required.*

2.8. ECLS Staffing Model & Hours[5]

2.8.1. The ECLS Program should define their staffing model for ECLS care and clearly define expected roles and responsibilities for each team member. All staffing policies–particularly staffing ratios (nurse, ECLS Specialist, ECLS physician)–should consider the institution's resources, equipment levels, training, experience, mode of ECLS support, and individual provider discretion. Required policies include:

2.8.1.1. Patient-to-Nurse Ratio: The Institution should maintain a Patient-to-Nurse ratio of 1 ECLS patient to 1 nurse, or at most 2 ECLS patients to 1 nurse, consistent with institutional policy and procedure for critical care units.

2.8.1.2. Patient-to-ECLS Specialist Ratio: The ECLS Program should maintain a Patient-to-ECLS Specialist ratio of no more than 2 ECLS patients to 1 ECLS Specialist, who maintains clinical duties specific to the ECLS circuit.

2.8.1.3. Patient-to-ECLS Physician Ratio: The ECLS Program should maintain a Patient-to-ECLS Physician ratio of 10 ECLS patients to 1 ECLS Physician. This ratio can flex up to 13 ECLS patients to 1 ECLS Physician in times of high capacity.

2.8.1.4. Role of Trainees (Residents, Fellows, Students): Where medical trainees (in any profession) are part of the ECLS Program's care model, the institution should set a clear policy on appropriate staffing involving trainees. At no time should a trainee be the sole medical provider assigned to an ECLS patient.

2.8.1.5. Role of Each of the Following Professions (if involved in ECLS care):

2.8.1.5.1. Attending ECLS Physician
2.8.1.5.2. Intensive Care Physician
2.8.1.5.3. Supporting Physician (surgeon, proceduralist, consulting service)
2.8.1.5.4. Critical Care Nurse
2.8.1.5.5. Non-ECLS Nurse
2.8.1.5.6. Respiratory Therapist
2.8.1.5.7. Physical Therapist
2.8.1.5.8. Perfusionist
2.8.1.5.9. Clinical Psychologist or other professionals whose practice supports the mental health and wellbeing of patients, their relatives, and/or institution staff
2.8.1.5.10. Other Critical Care Staff as defined by Program or Institution policy

2.9. Ability to Flex ECLS Capacity Based on Equipment, Staffing, and Hospital Capacity[5]

2.9.1. The Institution and ECLS Program should be able to flex their ECLS capacity models up and down to reflect current patient volume, projected need, and anticipated volume in times

[12] *ELSO Adult ECMO Certification (E-AEC)* https://www.elso.org/ecmo-education/certificationexam.aspx

of emergency. Considerations include available equipment (including backups), staffing, hospital capacity, and any emergency situations that may arise.

2.9.2. The ECLS Program may opt to pause or discontinue the provision of one or more modes of ECLS support to ensure adequate staffing and resources can be allocated to currently supported patients. Discontinuation of the ECLS Program in its entirety may be cause for immediate removal of the ECLS Center Certification.

2.10. Multidisciplinary Approach to ECLS Care[5]

ELSO Guidelines and clinical best practices emphasize a multidisciplinary and interprofessional approach to ECLS care. This includes multispecialty meetings, care conversations, and program planning activities. These qualities should be material to and regularly practiced by the ECLS Program.

3. Section 3: Care Protocols

3.1. Alignment with Care Protocols Guidelines

The ECLS Program should align their clinical ECLS practice with the relevant ELSO Guidelines, peer-reviewed research, and other commonly accepted standards of care for ECLS patients.

3.2. Access to Care[3,5,6]

3.2.1. The Institution should have a clearly defined policy for when, how, and who should be involved in considering ECLS care decisions, including patient selection, determination of support mode, cannulation, management, weaning from ECLS, and/or discontinuing ECLS related to end-of-life decision making.

3.2.2. Typical consultation for ECLS care includes multiple medical specialties and a team of providers from throughout the ECLS care team. A multidisciplinary and interprofessional team is desired as part of the ECLS care decision process.

3.3. Consultation & Patient Selection[13]

3.3.1. ELSO Guidelines advise that the primary indication for ECLS is acute severe cardiac or pulmonary failure with high mortality despite conventional therapy. There may be other indications for supporting the heart and/or lungs. Mortality and contraindications are patient-, condition-, and mode-specific and should be carefully considered during the consultation and selection process.

3.3.2. The Institution should have a policy for how and when a patient is considered for ECLS care. This policy should include:

3.3.2.1. *Mode of ECLS Support*: Each mode of ECLS support carries its own benefits and risks. These should be carefully considered for each ECLS candidate.

3.3.2.2. *Disease-Specific ECLS Indications*: Disease-specific ECLS indications are variable and should be considered as part of the total clinical evaluation.

3.3.2.3. *Contraindications*: Contraindications for ECLS vary by case, provider, institutional capacity, and mode of support. These include, but are not limited to:

3.3.2.3.1. The patient's condition is incompatible with life following ECLS care;

[13] *ELSO Guidelines for Cardiopulmonary Extracorporeal Life Support v1.4* https://www.elso.org/ecmo-resources/elso-ecmo-guidelines.aspx

3.3.2.3.2. The patient has one or more preexisting condition(s) which would affect the quality-of-life following ECLS care; and/or

3.3.2.3.3. The patient's age and/or size.

3.3.2.4. *Futility*: Failure of conventional therapy and/or a fatal diagnosis must be considered when evaluating a patient for ECLS therapy.

3.3.2.5. *Bridget to Donation:* While ECLS care is typically used as a bridge to recovery or a bridge to transplant, there may be specific uses for ECLS as a bridge to organ donation (EISOR). EISOR must be carefully considered in consultation with the patient's family, medical ethics teams, and all others whose work involves the procurement of donor organs.

3.3.2.6. *Patient Transfer*: The Institution should set clear policies and procedures for transferring patients out and accepting transfers of ECLS patients from outside hospitals. These include policies for patients under consideration for ECLS, patients actively on ECLS, and those who may be at risk for complications.

3.3.2.7. *Care Planning:* Prior to the initiation of ECLS, the ECLS care team should have a clearly defined goal of care, including ongoing patient management and/or transfer to an outside facility as well as future decannulation and/or weaning protocols for the patient. These plans should be consistent with the Institution's care policies, ELSO Guidelines, and industry best practices, where available and relevant.

3.3.2.8. *ECLS Team Capacity:* As part of the patient selection process, the ECLS team should consider the current capacity to provide the desired level of care. These considerations include staffing, bed availability, supply availability, access to backup equipment, and other institution-specific considerations.

3.3.3. The entire ECLS Team should be made aware of these consultation and patient selection policies, which should be updated based on the latest guidance, research, and experience.

3.4. Cannulation[6,14]

3.4.1. *Cannulation Credentialing*: The institution should create and maintain policies for how cannulation is credentialed and maintained. Typically, cannulation is performed by surgeons, interventionalists, and/or intensivists with extensive cannulation training. The Institution must develop a cannulation credentialing policy for all procedures, techniques, and modes of support provided at the Institution. *For more information on ECLS Credentialing, please see Section 2.6 and Appendix I.*

3.4.2. *Cannulation Techniques*: The technique and approach used in ECLS cannulation will depend on the patient's indication, the mode of ECLS desired, and the clinical course of the patient. The cannulating provider should be trained and credentialed by the Institution to perform the specific cannulation procedure being performed.

3.4.3. *Cannulation Location*: Cannulation is most often performed in an operating room, interventional suite, hybrid OR, or at the bedside. If a non-surgery team is performing the cannulation, consulting procedural teams should be on call in case of complications or other need for procedure-specific care.

[14] *ELSO Guidelines General v1.4* https://www.elso.org/ecmo-resources/elso-ecmo-guidelines.aspx

3.4.4. *Cannulation & Transport:* ECLS patient transport is highly complex and requires specialized training. Institutions should take appropriate caution when transporting and/or mobilizing ECLS patients. In cases where the care team intends to cannulate and then transport a patient, full consideration of the transport plan should be taken prior to cannulation. *For more information on ECLS Patient Transport, see Section 3.8.*

3.4.5. *Cannulation Visualization*: The mode of ECLS support will dictate visualization requirements. Ultrasound, fluoroscopy, or surgical cut down are commonly used to assist in visualization of the vessels and to minimize cannulation-related complications.

3.4.6. *Key Performance Indicators*: The ECLS Program should select, record, and monitor several Key Performance Indicators (KPI) specific to cannulation. Specific required and suggested KPI are further described in *Appendix I.*

3.5. ECLS Management[13, 14]

3.5.1. The ECLS Program must have protocols for all modes of ECLS that are provided at the Institution. These protocols should reference consensus documents, peer-reviewed research, published guidelines, and other widely accepted means of distributing clinical knowledge. They should be periodically reviewed at an established cadence to ensure accuracy and validity. Where necessary, provisions for specific forms of ECLS should be integrated into these care protocols. Expected areas of ECLS management protocols include, but are not limited to:

- 3.5.1.1. ECLS Device Settings & Management
- 3.5.1.2. Mechanical Ventilation Management
- 3.5.1.3. Medication Management
- 3.5.1.4. Sedation Management
- 3.5.1.5. Infection Management
- 3.5.1.6. Anticoagulation Management
- 3.5.1.7. Nursing Care – Patient Positioning, Skincare, Wound Care
- 3.5.1.8. Cannulation Site Management
- 3.5.1.9. ECLS Circuit Management
- 3.5.1.10. Patient Monitoring
- 3.5.1.11. Complication Troubleshooting
- 3.5.1.12. Emergency Protocols
- 3.5.1.13. Nutrition Replacement on ECLS
- 3.5.1.14. Fluid and Renal Replacement Therapies on ECLS – including Continuous Renal Replacement Therapy (CRRT)
- 3.5.1.15. Patient Physiotherapy, Mobilization, and Rehabilitation
- 3.5.1.16. Organ Donation Pathway for ECLS Patients
- 3.5.1.17. Palliative Care Support
- 3.5.1.18. Determination of Neurological Death Criteria on ECLS
- 3.5.1.19. Ethical Grounds for Withdrawing ECLS Care
- 3.5.1.20. Accessing the ECLS Circuit – including CRRT
- 3.5.1.21. Care Considerations for ECCO2R, ECPR, EISOR, and Additional Modes of ECLS (*if provided at the Institution)*

3.6. ECLS Care Other Than ECMO

While ECMO remains the primary mode of ECLS support, this ECLS Center Certification Methodology recognizes the use of similar support modes in patient care. These may include ECCO2R, EISOR, and other emerging technologies. In ECLS Centers where these additional modes of support are provided, the ECLS Program should expand their clinical protocols to include these technologies in their relevant application. The ECLS Program is responsible for ensuring that the Institution's ECLS care protocols cover all ECLS modes offered at the Institution.

3.7. Extracorporeal Cardiopulmonary Resuscitation (ECPR)[15]

3.7.1. Extracorporeal Cardiopulmonary Resuscitation (ECPR) is a highly complex application of ECLS in specific cases of loss of circulation. It is activated in patients where conventional CPR measures are ineffective and can be applied in-hospital (IHCA) or in the field (OHCA).

3.7.2. ECPR should only be practiced by ECLS Programs with established ECLS programs and clearly defined policies in ECLS transport and ECLS management. Other necessary requirements include:

3.7.2.1. Access to ECLS service lines as listed in *Section 2* of this Center Certification Methodology,

3.7.2.2. Capacity to handle highly acute patients, and

3.7.2.3. Capacity to initiate an ECLS transfer to an external facility.

3.7.3. *Out of Hospital Cardiac Arrest (OHCA)*: ECLS for OHCA (cannulated in the field or in-hospital) should only be applied in institutions where there is strong coordination between emergency service providers, the ECLS team, and other hospital providers. ECPR for OHCA is not required for ECPR Designation under the ELSO Center Certification.

3.7.4. Institutions lacking the above capabilities should consider the goals of the ECLS Program before initiating ECPR or ECLS care.

3.8. Transport (In-Hospital, Out of Hospital)[16]

3.8.1. ECLS Transport should only be conducted by highly specialized teams with specific training, policies, and protocols in ECLS Transport. If the Institution's team is not trained in and/or regularly practicing ECLS transport, the Institution or ECLS Program should develop a network of locally available ECLS transport services.

3.8.2. These movements are typically described as in-hospital or hospital-to-hospital transport. Within hospital-to-hospital transport, there are three subtypes. The ECLS Program should have clearly defined policies and procedures for all types of transport performed or participated in by the Institution.

3.8.2.1. *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.

3.8.2.2. *Secondary ECLS Transportation*: A patient is currently supported with ECLS but must be transferred to another facility on ECLS support.

---

[15] *Extracorporeal Cardiopulmonary Resuscitation in Adults. Interim Guideline Consensus Statement From the Extracorporeal Life Support Organization* https://www.elso.org/ecmo-resources/elso-ecmo-guidelines.aspx

[16] *ELSO Guideline for Transport and Retrieval of Adult and Pediatric Patients with ECMO Support* https://www.elso.org/ecmo-resources/elso-ecmo-guidelines.aspx

3.8.2.3. *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.

3.8.2.4. *Intra-facility ECLS Transfer*: A patient is currently supported with ECLS but must be moved within an institution.

3.8.3. The ECLS Program's transport policy should include, at a minimum, the following components:

3.8.3.1. Required Clinical Documentation

3.8.3.2. Standardized Equipment Lists (both ECLS-specific and general to critical care)

3.8.3.3. Mobile ECLS Team Structure and Responsibilities

3.8.3.4. Established Mobile ECLS Plans – filed with the Institution and all relevant authorities

3.8.3.4.1. Diversion Plan

3.8.3.4.2. Provision of Oxygen

3.8.3.4.3. Patient Stabilization

3.8.3.4.4. Remote Access to ECLS Team

3.8.3.5. Clinical Governance and Risk Management

3.8.3.6. Administrative Process of Granting Emergency ECLS Privileges

3.8.3.7. Transport-Specific Training and Drills

3.8.4. *ECLS Transport at Level 1 Centers:* Level 1 ECLS Certified Centers are required to provide full ECLS transport services, either through in-house teams and/or external service providers. Level 1 Centers must also be able to provide cannulation services at an external facility and bring the patient back to their own facility or another facility, as necessary. If ECLS transport is provided by an external team, proof of contract or other formal arrangement must be provided.

3.9. Medical Records Process

The ECLS Program should maintain records of and adhere to the Institution's established medical records process. This includes documentation of all patient care plans, prescriptions, procedures, consultations, laboratory results, radiology reports, surgical outcomes, post-hospital discharge plans, and any other item commonly documented by the Institution. To the extent possible, these records should be maintained electronically.

3.10. Infection Control

The Institution should create and make available an infection control policy that limits the acquisition of hospital-acquired infections. The ECLS Program should make every effort to adhere to and/or exceed these standards within the appropriate context of ECLS care to prevent infection of the cannulation site, circuit, or other means of infection.

3.11. Patient Rights

The Institution should have a patient rights and responsibilities policy. The ECLS Program should follow the Institution's guidance on patient rights and responsibilities. As these are subject to extensive legal, geographic, and institution-level variances, ELSO defers the Institution on the exact policies and procedures prescribed by the ECLS Program. ELSO

maintains the dignity and right of all patients and families to make medical decisions free of fear, bias, or favor.

3.12. Patient & Family Support[17]

The ECLS Program should have programs and resources available to patients, families, and caretakers of ECLS patients. This includes all phases of treatment, from patient selection, cannulation, management, weaning, discontinuation of ECLS care, discharge, and post-ECLS care. Adequate psychological and social work support should be made available by the ECLS Program to meet these needs.

3.13. Patient Follow-Up[13]

The ECLS Program and Institution should employ best practice concerning joint efforts to follow up with and maintain records of post-ECLS outcomes. These can be for scientific publication, use in quality improvement initiatives, or any other use as allowed by local law and institutional policy. Patient follow-up can extend to outpatient clinics, outside hospital admission, and any other extended form of treatment.

4. Section 4: Case Review & Process Improvement

4.1. Alignment with Case Review and Process Improvement Guidelines

The ECLS Program should align their clinical ECLS practice with the relevant ECLS guidelines, peer-reviewed research, and other commonly accepted standards of case review and process improvement as they relate to patient care.

4.2. Evidence-Based Resources

4.2.1. The ECLS Program should develop and make available the following evidence-based resources for effective case review, process improvement, and related quality initiatives. These should be completed regularly throughout the institution and within the ECLS Program. These events and processes should always follow hospital rules and regulations on quality improvement, protection of health data, and any other relevant policy. The following should be completed at least quarterly (4 times per year):

- 4.2.1.1. Quality Improvement Meetings, Conferences, and Seminars[5]
- 4.2.1.2. Quality Improvement Processes
- 4.2.1.3. Morbidity & Mortality Conferences[18]

4.3. Reporting Structure for Near Misses, Adverse Events, and Errors[19]

The Institution should have a clearly defined policy and process for reporting near misses, adverse events, and medical errors. As part of that process, the focus should be on identification of root causes, review of existing policies, and implementation of any changes in care protocols due to the event. Except in cases of extreme negligence, the review should focus

[17] *ELSO Resources on Patients & Families* https://www.elso.org/ecmo-resources/patientsandfamilies.aspx
[18] *Error in Medicine: The Role of the Morbidity and Mortality Conference* https://doi.org/10.1001/virtualmentor.2005.7.4.msoc1-0504
[19] *Reporting Patient Safety Events* https://psnet.ahrq.gov/primer/reporting-patient-safety-events

on quality improvement, not on punitive action on any personnel or team. The ECLS Program should ensure these reporting structures are actively established.

4.4. Use of Data in Quality Review[2,3,5,9]

The ECLS Program should – through a combined effort to contribute to internal quality improvement initiatives, and as part of data collection for registry contribution – make use of clinical data in quality review programs. This data should be collected and distributed for the program's benefit to improve patient outcomes at the institution. Where relevant, this data may be shared, in part or in whole, with benchmarking agencies, governmental bodies, and other external entities.

4.5. Key Performance Indicators

4.5.1. The ECLS Program and the Institution should determine, record, and maintain several Key Performance Indicators (KPI) to offer an objective view into the ECLS Program's performance. KPI may be recorded at the program or individual provider level, as appropriate. Institutions should select several KPI from each of the following categories and may include other KPI that are not listed below. Institutions may select the specific endpoint(s) or method(s) used to measure each listed item. Specific KPI for ECLS privileging are included in *Appendix I*.[2,3,5,9]

4.5.2. Assess Patient Based on Established Criteria

- 4.5.2.1. Adequacy of Support (end organ perfusion, pressors/inotrope requirement)
- 4.5.2.2. Frequency of Change in Strategy (VV to VA, VA to VAV, etc.)
- 4.5.2.3. Rate of Use of LV Venting – *by support type, across all support types*
- 4.5.2.4. Rate of Bleeding Complications
- 4.5.2.5. Ventilator Settings

4.5.3. Assess Circuit

- 4.5.3.1. ECLS Flow and/or Pressures
- 4.5.3.2. Clotting Ability
- 4.5.3.3. Hemolysis Lab Results
- 4.5.3.4. Use of Anticoagulation Medication

4.5.4. Assess for Weaning

- 4.5.4.1. Use and Indication of Chest X Ray
- 4.5.4.2. Use and Indication of Echocardiogram
- 4.5.4.3. Arterial Blood Gases
- 4.5.4.4. Pulmonary Artery Pressures

4.5.5. Other Competency/Performance Measures

- 4.5.5.1. Time to Initiation
- 4.5.5.2. Cannulation Success: Initial Cannulation
- 4.5.5.3. Rate of Re-Cannulation – *by support type, by individual practitioner*
- 4.5.5.4. Success of Weaning on Time Basis (24 hours, 1 week, etc.)
- 4.5.5.5. Complication Rates: Bleeding, Infections, Strokes, Vascular Complications, other

4.5.6. Other Measures to Consider

4.5.6.1. *Duration of ECMO Support*: Track the average and maximum duration of ECMO support to assess the program's ability to provide prolonged care when necessary.

4.5.6.2. *Team Training and Competency*: Monitor the training and competency of the ECMO team, including physicians, specialists, nurses, and perfusionists.

4.5.6.3. *Resource Utilization*: Evaluate the efficient use of resources, including ECMO equipment and staff time.

4.5.6.4. *Patient and Family Engagement:* Track engagement of patients' families in the ECLS care and post-ECLS care journey.

4.5.6.5. *Cost-Effectiveness*: Analyze the cost of ECMO treatment relative to patient outcomes and benefits.

4.5.6.6. *Follow-up Care*: Assess the quality of follow-up care provided to ECMO survivors after discharge.

4.5.6.7. *Long-term Outcomes (LTO)*: Assess LTOs in patients following discharge. Functional status, QoL, mental health etc.

4.5.6.8. *Quality Improvement Initiatives*: Track the implementation and impact of quality improvement initiatives within the ECMO program

4.5.6.9. *Data Reporting and Documentation*: Ensure accurate and timely documentation of ECMO cases, which can be vital for research and quality assessment. Assess compliance with and accuracy of reporting to ELSO for those centers that do.

4.6. Sharing of Best Practices[8]

The ECLS Program should promote and provide opportunities for sharing best practices within the Institution and with other institutions. This can be through internal meetings, department gatherings, external webinars, and any other format that seeks to benefit all attendees through shared knowledge.

4.7. Whistleblower Policy[20]

The Institution should have a clearly defined and distributed whistleblower policy. This policy should at a minimum establish the necessary reporting structure, qualification of circumstances that fall under such policy, and a no-punishment statement for any reporters. The ECLS Program should ensure that all ECLS team members are aware of the Institution's Whistleblower Policy.

4.8. Introduction of New Technologies

The ECLS Program should actively apprise itself of new technologies, techniques, and procedures. Where relevant and consistent with the Institution's policies, the ECLS Program should test and implement new technologies in the clinical environment. These may be part of research programs, device development protocols, or as an update to existing clinical practice.

[20] *Whistleblowing and Organizational Ethics* https://doi.org/10.1191/0969733006ne882oa

4.9. Sharing of Site Research Programs

Where research is a core activity of the Institution, the ECLS Program should make use of shared site research programs to participate in and facilitate research operations. This can be through government-funded programs, granting foundations, private funding, or any other relevant source of research funds.

5. Section 5: Contribution to the ELSO Registry

5.1. Contribution to a Registry

5.1.1. The ECLS Program is required to be an active contributor to the ELSO Registry. This contribution should meet, at a minimum, the following criteria:

5.1.1.1. Include all patients supported with ECLS at the Institution;

5.1.1.2. Occur at a frequent and consistent cadence not greater than 6 months after the date of discharge; and

5.1.1.3. Develop and maintain policies and procedures to capture, validate, and transfer data to the ELSO Registry.

5.2. Privacy & Data Protection Policies

The Institution should develop, disseminate, and maintain data privacy and protection policies to de-identify all patients, transfer only the necessary fields of information, and comply with all local, national, and international data protection laws.

ECLS Center Certification Process

The ECLS Center Certification program incorporates an external review process and a mandatory site visit. The review process contains several checks and balances to exclude conflicts of interest in ECLS Center Certification decisions.

Step 1: Application

The ECLS Center Certification Application will be built on a digital framework within the ELSO website (www.elso.org). ECLS Center Certification applicants must meet the program requirements as described in the above ECLS Center Certification Methodology and will be asked to provide proof of compliance as part of the application process.

All applications will be subject to an ECLS Center Certification Application Fee plus any costs associated with the Site Visit. A full list of fees will be available on ELSO's website.

Step 2: Site Visit

Centers that meet ELSO's criteria for ECLS Center Certification based on the written application will be invited to complete a mandatory Site Visit. The Site Visit will be completed by one or more reviewer(s) selected at ELSO's discretion.

In addition to new Applications, Site Visits will be required by ELSO in each of the following situations during the application or certified period:

- Change in program leadership (Medical Director, ECLS Coordinator, and/or other senior leaders);
- Change in program structure and/or policy; and/or
- Other significant changes, events, or activities at ELSO's discretion.

ECLS Certification Decisions

All decisions made by ELSO regarding the candidacy of an ECLS Center Certification applicant are considered final. ELSO will offer feedback to all applicants who complete the Site Visit in the form of a Certification Report. Any unsuccessful candidates will be given the opportunity to either resubmit their application, reapply for consideration in a future year, or be asked to make changes to the ECLS Program prior to reconsideration. All certification decisions are made at ELSO's sole discretion.

Certification Finalization

Applicants that successfully meet the guidance in this Methodology; complete both the Application and Site Visit; and complete all necessary steps will be notified via email of their certification status, including Certification Designation and Population(s) certified. A subsequent contract will be sent to the Institution and ECLS Program for signatures. Upon completion of all steps and a fully executed contract, a certificate will be mailed to the institution for display in the appropriate area. ELSO will also list the name, contact information, and certification level/designation/support type for all ECLS Certified Centers on the ELSO website.

Term of Certification

ECLS Certified Centers will maintain that designation for three (3) years, after which an ECLS Program must complete a recertification process to be determined by ELSO and published on ELSO's website. Subject to the above changes in program structure, a Site Visit will be required at least every three years.

Revocation of Certification

Participation in the ECLS Center Certification program is subject to continued compliance with this Methodology and all other applicable policies, Bylaws, contracts, and other governing documents. ELSO reserves the sole right to revoke certification, with or without advance notice. In cases where Certification is revoked, ELSO will identify the issue(s) resulting in such determination.

Appendix I: Key Performance Indicators or Metrics for ECLS Privileging

The ECLS Center must measure and analyze Key Performance Indicators (KPI) or metrics specific to both ECLS cannulation and ECLS management. Institutions may select the specific endpoint(s) or method(s) used to measure each listed item. These metrics should be analyzed at a program and individual provider level, where possible. Metrics should be used to inform ECLS credentialing policies and processes; they should also be used to inform education, training, and other key program aspects.

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

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

****Program-wide and by individual provider***

Appendix II: Key Performance Indicators or Metrics for ECLS Program Quality Assessment

The ECLS Center must measure and analyze Key Performance Indicators (KPI) or metrics for overall program assessment and quality improvement. Institutions may select the specific endpoint(s) or method(s) used to measure each listed item. These metrics should be analyzed at a program and individual provider level, where possible. Metrics should be used to inform program quality, education, training, and the success of quality improvement activities.

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