



ELSO GUIDELINES FOR ECMO CENTERS

PURPOSE

These guidelines developed by the Extracorporeal Life Support Organization, outline the ideal institutional requirements needed for effective use of extracorporeal membrane oxygenation (ECMO). The Extracorporeal Life Support Organization recognizes that differences in regional and institutional regulations especially concerning hospital policies may result in variations from these guidelines. These guidelines will be reviewed and updated every three years in an attempt to keep the document current.

INFORMATION AND BACKGROUND

Extracorporeal Membrane Oxygenation (ECMO) was first used successfully for neonates with respiratory failure in 1975. Today it is an accepted treatment modality for neonatal, pediatric and adult patients with respiratory and/or cardiac failure failing to respond to maximal medical therapy.

ECMO is defined as the use of a cardiopulmonary bypass circuit for temporary life support for patients with potentially reversible cardiac and/or respiratory failure. ECMO provides a mechanism for gas exchange as well as cardiac support thereby allowing for recovery from existing lung and/or cardiac disease.

It has been estimated that approximately 2800 newborns could benefit from ECMO annually in the US (one of every 1309 live births). Pediatric and adult patients are being successfully treated in increasing numbers.

GENERAL

- A. ECMO centers should be located in tertiary centers with a tertiary level Neonatal Intensive Care Unit, Pediatric Intensive Care Unit and/or Adult Intensive Care Unit.
- B. ECMO Centers should be located in geographic areas that can support a minimum of 6 ECMO patients per center per year. The cost effectiveness of providing fewer than 6 cases per year combined with the loss, or lack of clinical expertise associated with treating fewer than this number of patients per year should be taken into account when developing a new program.
- C. ECMO Centers should be actively involved in the Extracorporeal Life Support Organization (ELSO) including participation in the ELSO Registry.

ORGANIZATION

- A. **General Structure:** The ECMO center should be located in a tertiary level intensive care unit with the following components.
 - 1. There should be a single physician ECMO program director with responsibility for the overall operation of the center. While there may be several associate directors with specific interests or focus in limited areas of ECMO care, the primary medical director should be responsible for assuring appropriate specialist training and performance, directing quality improvement meetings and projects, assuring proper and valid data submission to ELSO, and should also be responsible for the credentialing of other physicians who care for ECMO patients or who manage the ECMO circuit.
 - 2. There should be an ECMO coordinator with responsibility for the supervision and training of the technical staff, maintenance of equipment, and collection of patient data.
 - 3. The multi-disciplinary ECMO Team should have quality assurance review procedures in place for annual ECMO evaluation internally.
 - 4. Formal Policy and Procedures outlining the indications and contraindications for ECMO, clinical management of the ECMO patient, maintenance of equipment, termination of ECMO therapy, and follow-up of the ECMO patient should be available for review.
 - 5. Appropriate laboratory space for training and continuing medical education should be available.

B. Staffing Issues:

1. The ECMO staff should meet the requirements of their subspecialty training as set forth by their specific governing board (American Board of Surgery, American Board of Pediatrics, etc.). In addition, ECMO staff should meet the training requirements described below.
2. The medical director should be a board certified neonatologist, a board certified critical-care specialist, or a board certified pediatric, cardiovascular, thoracic surgeon, trauma surgeon, or other board certified specialist with specific training and experience in ECMO support.
3. The ECMO coordinator may be an experienced neonatal, pediatric, or adult intensive care registered nurse or registered respiratory therapist with a strong ICU background (minimum of 1 year of ICU experience), or a certified clinical perfusionist with ECMO experience.
4. An ECMO-trained physician will provide 24-hour on-call coverage for the ECMO patient. The physician may be a neonatologist, pediatric or adult critical-care specialist, a neonatology or critical care fellow, or other physician who has completed at least three years of post-graduate pediatric, surgical, or adult medical training and has specific ECMO training.
5. There shall be an ECMO clinical specialist as described below to provide 1:1 or 1:2 care throughout the course of ECMO.
6. The ECMO Specialist should have a strong intensive care background (at least 1 year of NICU, PICU, MICU, CCU or other critical care experience preferred) and have attained one of the following:
 - (1) Successful completion of an approved school of nursing and achievement of a passing score on the state written exam given by the Board of Nursing for that state;
OR
 - (2) Successful completion of an accredited school of respiratory therapy and have successfully completed the registry examination for advanced level practitioners and be recognized as a Registered Respiratory Therapist (RRT) by the National Board of Respiratory Care (NBRC).
OR
 - (3) Successful completion of an accredited school of perfusion and national certification through the American Board of Cardiovascular Perfusion (ABCP).
OR

(4) Physicians trained in ECMO who have successfully completed institutional training requirements for the clinical specialists.

OR

(5) Other medical personnel such as biomedical engineers or technicians who received specific ECMO training and have practiced as an ECMO specialist since the initiation of their programs, and who have completed equivalent training in ECMO management as the other specialists, have successfully documented necessary skills as an ECMO specialist, and who have been approved specifically as an ECMO specialist by the medical director. These personnel can be approved institutionally as an ECMO specialist under the “grandfather” principle. However ELSO does not encourage or support the new training of individuals except as outlined in 1-4 above.

7. In clinical settings where the ECMO patient is primarily managed by the ICU nurse (the single care giver model) the ICU nurse should be specifically trained in ECMO patient and circuit management. Nurses with this responsibility should be approved by the program director. The ECMO specialist team is responsible for managing equipment and supplies, circuit preparation, troubleshooting, daily rounds, education, and service administration.
8. Additional support personnel from the permanent hospital staff should be available including:
 - a. Physicians or other medical personnel:
 - Pediatric/adult cardiology
 - Pediatric/adult cardiovascular surgery
 - Pediatric/general surgery
 - Cardiovascular perfusion
 - Pediatric/adult anesthesiology
 - Pediatric/adult neurosurgery
 - Pediatric/general radiology
 - Genetics
 - b. Biomedical engineer
 - c. Respiratory therapists experienced in intensive care (in USA)
9. The following consultants should be available as needed.
 - Pediatric/adult neurology
 - Pediatric/adult nephrology
 - Occupational/physical therapist
 - Developmental/rehabilitation specialist

10. A fully trained and equipped transport team should be available 24 hours a day.
11. Trained individuals capable of providing development follow-up or rehabilitation should be available and capable of providing long-term follow-up to the ECMO patient.

C. Physical Facilities and Equipment

1. If the space allocated for ECMO is located outside the ICU, it should be in close proximity to and have appropriate communication with the ICU to assure additional staff support for any emergency that may arise.
2. An ECMO system consists of a suitable blood pump, a system for servo-regulation to balance venous drainage rate from the patient and blood return to the patient, an appropriate blood heat exchanger and warming unit, appropriate disposable materials including membrane oxygenator tubing packs, and connectors, all suitable for prolonged extracorporeal support.
3. A device for monitoring the level of anticoagulation (ACT or other) with appropriate supplies should be at the bedside.
4. The following equipment should be readily available:
 - a. Backup components of the ECMO system and supplies for all circuit components.
 - b. Adequate lighting to support surgical interventions.
 - c. Surgical instrument set for revision of cannulae or exploration for bleeding complications.
5. The following support facilities with staff should be available on a 24-hour basis.
 - a. A blood gas laboratory
 - b. Laboratory for blood chemistry and hematologic testing
 - c. Blood bank
 - d. Radiographic support including cranial ultrasound and CATscan

- e. Cardiovascular operating room facilities with cardiopulmonary bypass capabilities located within the hospital doing ECMO and available 24 hours a day.

D. Staff Training and Continuing Education

1. Each ECMO center should have a well-defined program for staff training, certification, and re-certification. This program should include: didactic lectures, laboratory training with the ECMO equipment, bedside training, and a defined system for testing proficiency of the team members (See ELSO Guidelines for Training and Continuing Education of ECMO Specialists)
2. Each member of the ECMO team should successfully complete this program.
3. A well-defined program of routine continuing education and emergency training for ECMO staff should be outlined with records documenting participation by active team members.
4. It is recommended that team members not involved in ECMO pump management for > 3 months should be required to go through a re-certification process as defined by the ECMO program.

E. Selection Criteria

1. ECMO is indicated for selected neonatal, pediatric and adult patients with severe, acute cardiac and/or respiratory failure who have failed to respond to conventional medical management.
2. Each ECMO center should develop institutional criteria for ECMO therapy, including indications and contraindications.
3. It is recommended that the ECMO center develop guidelines for transfer of the ECMO patient.

F. Patient Follow-up

Each ECMO center should have a well-defined developmental follow-up program for the ECMO patient with appropriate subspecialty support (refer to ELSO Guidelines for Follow-up).

G. Program Evaluation

1. A well-defined system should be instituted for assuring that formal meetings of key ECMO team members occurs on a routine basis to review

cases, equipment needs, administrative needs, and other pertinent issues. Minutes to these meetings should be available for review.

2. A prompt review of any major complication or death should be held both with ECMO team members and with the responsible Morbidity and Mortality committee in the hospital. These reviews should be conducted under the relevant quality assurance laws for the state where the center is located.
3. Formal clinical-pathological case reviews with a multi-disciplinary approach should be regularly conducted (as outlined by JCAHO regulations).
4. An Annual Data Report, utilizing the center's collated data, or the collated report of data submitted to the ELSO Neonatal ECMO Registry, should be available for quality assurance review.
5. Records documenting maintenance of equipment should be kept (as per JCAHO regulations).