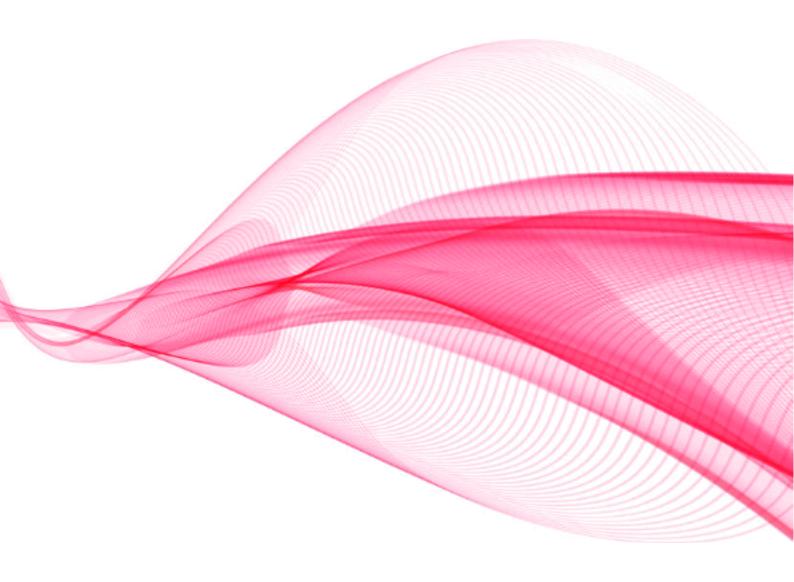
Recommendations for the Standards of Monitoring and Safety During Extracorporeal Membrane Oxygenation (ECMO)

SOCIETY DOCUMENTS





Recommendations for the Standards of Monitoring and Safety During Extracorporeal Membrane Oxygenation (ECMO)

Published by the Society of Clinical Perfusion Scientists of Great Britain and Ireland

November 2025

Recommendations for the Standards of Monitoring and Safety During Extracorporeal Membrane Oxygenation (ECMO)

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Introduction

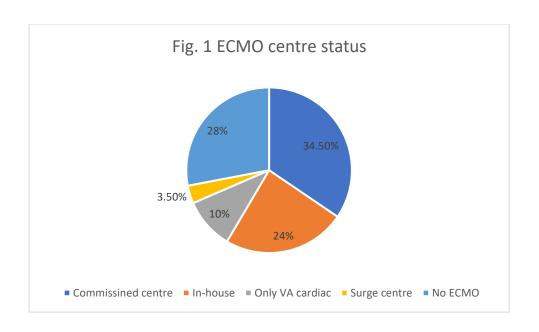
The use of extracorporeal membrane oxygenation (ECMO) has emerged and become an established therapy for respiratory and acute cardiac failure over the last 50 years.

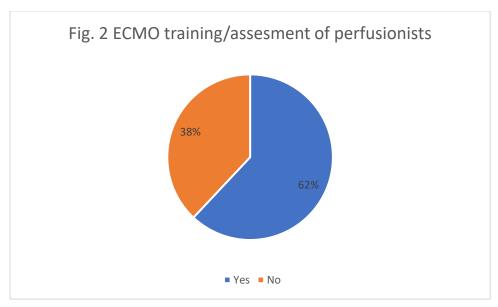
Across the UK and Ireland there are 6 commissioned adult respiratory ECMO centres (plus one satellite centre) (1) and 6 (plus one surge centre) for paediatrics. In addition, other centres took on the provision of ECMO as 'surge' centres during the Covid-19 pandemic. Furthermore, although not a commissioned service, there is an expectation that all centres performing cardiac surgery should have the ability to place a patient on ECMO (2). This provision is of particular relevance to cardiac transplant centres where the incidence of post-surgical ECMO tends to be higher.

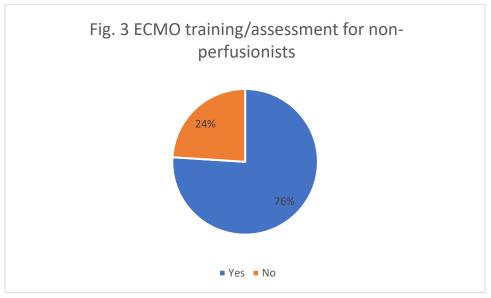
Prior to the generation of this document, chief perfusionists were surveyed to gain insight into the range of roles, responsibilities and governance for clinical perfusion scientists with regard to current practices in ECMO in individual centres across the UK and Ireland.

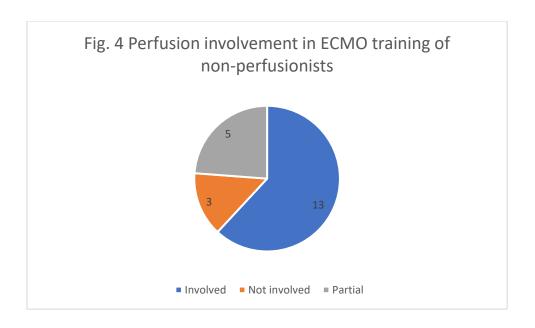
Although conventions have emerged regarding staffing and responsibilities alongside a general consensus that clinical perfusionists have a distinct role in the provision of ECMO, the responsibilities and governance of clinical perfusion scientists in ECMO remains fragmented and localised.

The response rate to the survey was 54%. (29/52). From the responding centres 73% provided ECMO in some form (21/29). Those centres providing ECMO did so as a mixture of commissioned centres (35%), surge centres (3%), in-house cases only (24%), or Veno-Arterial ECMO only (10%), 2 of which provided ECMO via transfer to another centre, with the remaining 28% of centres providing no ECMO service (fig. 1). Of the 21 centres providing ECMO, approximately half (11/21) provide an ECMO retrieval service. Of those 11, there were 4 centres where a perfusionist is not always present for an ECMO retrieval. Regarding ECMO training and assessment, there was greater provision for non-perfusionists than for perfusionists (76% vs 62%) (figs. 2 & 3). 14% (3/21) of centres had no perfusion involvement in ECMO training. Of the remaining 18 centres, perfusionists were integral in ECMO training in 13, (62%) with 5 centres describing a partial or limited involvement of the perfusion team (24%) (for example, "only when asked", "only for new staff") (fig. 4). The impact of ECMO on the perfusion service's ability to support the cardiac surgical programme was relatively evenly distributed, with 43% (9/21) reporting a tangible impact, and 29% (6/21) reporting no impact.









Recommendations for standards of staffing, safety and monitoring for extracorporeal membrane oxygenation

This document is intended to act as a guide for hospitals performing ECMO to provide a governance framework for clinical perfusion services in the safe and effective provision of ECMO for both adult and paediatric services.

This document is intended to be used in conjunction with the Society of Clinical Perfusionists Scientists (SCPS) Code of Practice, and Recommendations for Standards of Monitoring and Safety During Cardiopulmonary Bypass documents (3, 4) and local protocols. Sources of reference include National Institute for Health and Care Excellence (NICE) guidelines for ECMO, NHS England ECMO documents, Paediatric Critical Care Society (PCCS) ECMO standards, Extracorporeal Life Support Organisation (ELSO) documents & American Society of Extracorporeal Technology guidelines, as well as more general governance resources for clinical perfusion as referenced in the SCPS Recommendations for Standards of Monitoring and Safety During Cardiopulmonary Bypass document (4).

<u>Definitions and word usage for the purposes of this document</u>

Should: Indicates a recommendation.

Shall: Indicates a mandatory requirement.

Protocol: An institution-specific document, derived from professional standards and guidelines.

Hospitals providing ECMO

ECMO services shall be co-located with cardiothoracic services (5) and shall only be carried out by clinical teams with specific training and expertise in the procedure (6, 7) with perfusion services readily available (8).

By implication, ECMO may only be undertaken in hospitals which employ clinical perfusion scientists as they are mandatory for the conduct of open-heart surgery. As healthcare scientists specifically trained in extra-corporeal circulation technology, perfusionists shall be actively involved in the provision of ECMO.

The safe conduct of ECMO is the joint responsibility of the multi-disciplinary team comprising intensivists, cardiac surgeons, cardiologists, clinical perfusion scientists, ECMO specialist nurses, and the wider team of supporting professionals (9,10.) Preparation, assembly and priming of the ECMO circuit is the responsibility of a clinical perfusion scientist. Initiation of ECMO is primarily the responsibility of a clinical perfusion scientist and the cannulating surgeon or physician. Once ECMO flow has been established and the patient is stable, the routine monitoring and management of the ECMO circuit may be handed over to the intensive care team or may remain the responsibility of the clinical perfusion service, according to local policies and protocols.

Staffing levels for perfusionists should reflect the level of ECMO activity within a particular service with consideration to perfusion commitment to the ECMO service in parallel to surgical activity and should abide by the N+1 principle as described in the SCPS recommendations (4). The need and level of emergency cover for ECMO should be assessed locally and form part of the perfusion department's on-call/emergency cover rota. Any centre offering E-CPR shall have perfusion cover for the service. Protocols/SOPs must be in place for the preparation and storage of pre-primed ECMO circuits.

It is recommended that all ECMO activity is submitted to the ELSO registry.

The following definitions for ECMO staff groups apply (adapted from PCCS education standards 2018) (9).

ECMO perfusionist

Clinical perfusion scientist providing care for patients going on, or being supported with, ECMO. They shall be registered with the College of Clinical Perfusion Scientists GB & Ireland.

ECMO clinical specialist

Medical staff providing 24 hour on-call coverage for ECMO patients. This doctor may be a neonatologist, paediatric or adult critical-care specialist, a neonatology or critical care fellow, or other doctor who has completed at least three years of postgraduate paediatric, surgical, or adult medical training and has specific ECMO training.

ECMO nurse specialist

The technical specialist nurse trained to manage the ECMO system and the clinical needs of the patient on ECMO under the direction of a licensed ECMO-trained physician (11).

ECMO cannulator

A doctor (surgeon/cardiologist/intensivist) who cannulates or decannulates a patient for ECMO or can perform intervention on a patient on ECMO.

ECMO Preceptor

An ECMO perfusionist or nurse specialist who can assess staff who are training in ECMO

Training and education of ECMO perfusionists

An ECMO perfusionist is defined as a qualified and College-registered member of clinical perfusion staff, working as part of the cardiac surgical team who has:

Successfully undertaken an ELSO accredited UK ECMO course (adult or paediatric) –
 (experienced staff who may not have attended an ECMO course should not be
 preventing from continuing to practice but should attend a course when available to
 do so).

- 2. Ongoing practice in ECMO
- 3. Completed at least one ECMO preceptored bedside shift (experienced ECMO perfusionists who have not previously completed a preceptored shift should not be prevented from continuing to practice).

There should also be local definitions and standards of education and experience for all other ECMO professionals defined above. Locally defined roles for other members of the multidisciplinary team should also be in place.

It is recommended that all members of the ECMO multidisciplinary team attend wet lab simulation training at least every two years. Suggested skills are listed in appendix 1.

Mobile ECMO (hospital-to-hospital)

Where mobile ECMO is undertaken, if there is the potential for the patient to be cannulated and placed on ECMO at the referring hospital, a suitably experienced Perfusionist who has completed all relevant local competencies shall be present throughout the retrieval. The perfusionist is responsible for ensuring all necessary equipment is available and functional. The perfusionist has primary responsibility for management of the ECMO circuit during all phases of transport (6). If the patient is already established on ECMO at the referring hospital, a perfusionist should be present throughout the retrieval. If this is not the case, then a risk assessment for the individual case shall be undertaken and responsibility for the management of the ECMO circuit shall lie with the consultant leading the retrieval (10,12,13).

Mobile ECMO (internal patient transfer)

When a patient on ECMO is moved within the hospital for an intervention a perfusionist shall be present at all times until the patient returns to the intensive care unit and is handed over to the ICU team.

When a patient on ECMO is moved within the hospital for diagnostic investigation a perfusionist should be present at all times until the patient returns to the intensive care unit. When a diagnostic procedure involves intervention on the ECMO circuit (eg. CT-angio with radiopaque contrast injection requiring interruption of ECMO flow and circuit clamping) a perfusionist shall be present.

Awake patient mobilisation

A perfusionist shall be present when an awake patient on ECMO is mobilised out of bed.

Interventions on ECMO

When interventions take place involving the cannulation site/s a perfusionist shall be present (for both peripheral and central cannulation).

When a chest exploration takes place for a centrally cannulated patient a perfusionist shall be present.

For elective interventions involving the opening of the ECMO circuit a perfusionist shall be present.

Guidelines for Perfusion Training in Prehospital ECPR Programs

The use of extracorporeal cardiopulmonary resuscitation (ECPR) for patients experiencing out-of-hospital cardiac arrest may frequently involve initiation of ECMO in situations where it is not possible for a perfusionist to attend. In these cases, ECMO will most likely be initiated by doctors and/or paramedics.

Training, assessment, and supervision of non-perfusionists initiating ECMO will be the responsibility of an accredited and suitably experienced perfusionist. Comprehensive practical and written competencies must be completed on a regular basis by all staff involved in initiation of ECMO without perfusion presence. Practical training should mirror the scenarios detailed in Appendix 1. Continuous monitoring of the service should be conducted by the supervising perfusionist, including regular debriefs and reflective practice.

Monitoring standards

Mandatory

Continuous

Blood flow generated by the pump Pre- and post-oxygenator pressure Pre-pump pressure (roller pump) Water temperature (heater-cooler unit)

Intermittent

Hb/Hct ACT Full blood count Clotting screen Blood gas measurements

<u>Desirable</u>

SvO2%
SaO2%
Pre-pump pressure (centrifugal pump)
Blood temperature
APTT
Anti Xa
Thrombo-elastometry

Safety standards

Mandatory

Power failure alarm

High flow alarm (centrifugal pump)
Low flow alarm (centrifugal pump)
Retrograde flow alarm (centrifugal pump)

High pressure alarm (servo-regulated for roller pump) Low pressure alarm (servo-regulated for roller pump) Hand crank/alternative pump drive unit

Desirable

Bubble detector/alarm

Patient monitoring should be as per local intensive care/ambulance retrieval protocols but should include:

ECG, systemic arterial pressure, central venous pressure, core body temperature, pulse oximetry, near infrared spectroscopy.

Protocols

Local protocols and Standard Operating Procedures for the conduct of ECMO must be in place and include medicines management and descriptions of roles and responsibilities (14). These should include both routine and emergency procedures including interventions on ECMO. All training and protocol development should include input and oversight from the Perfusion department.

All centres undertaking ECMO should have a suitable Quality Management System in place including relevant SOPs, Medicine Management protocols, and identification of clinical roles and responsibilities.

Checklists

Checklists must be in place for circuit preparation (assembly and priming), post-cannulation, circuit handover between staff, mobile ECMO (both pre- and post-transfer), and any other relevant circuit interventions.

Appendix 1 - Suggestions for Simulation Training

Core Competencies for ECMO water drills

- o Recognition and management of flow issues
- o Recognition and management of retrograde flow
- o Evacuation of air from circuit
- o Management of console / motor drive failure
- o Attachment of dialysis circuit
- Change of 3-way tap / pigtail

Suggested areas to cover in ECMO Simulation sessions

- o E-CPR
- Teamwork at cannulation / chest exploration
- o Management of air entrainment
- Team management of bleeding
- Non-technical skills seizures on ECMO / transport of ECMO patient to CT or theatre
- How to identify a failing circuit
- o How to identify coagulopathy (DIC, Hit etc.)
- Accidental decannulation

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