

# Multi-specialty consensus on fundamental ECMO-skills, experts' opinion: a study protocol

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**Abstract:** Extra Corporeal Membrane Oxygenation (ECMO) can be a life-saving option in critically ill patients. The aim of this study is to generate consensus on essential ECMO skills for developing an e-learning program and fine-tuning of the existing ECMO-simulation program at Ghent University Hospital, Belgium.

A "Modified Delphi questionnaire" approach will be used. This technique is a method for systematic solicitation and collection of judgments on a particular topic. A set of carefully designed sequential questionnaires interspersed with summarized information and feedback of opinions derived from earlier responses is used. Experts, being physicians from different subspecialties, nurses and perfusionists, from different parts in the world are invited to participate using the software platform RedCap® (Research Electronic Data Capture, Nashville, Tennessee). Topics are based on the existing theoretical program and the Extracorporeal Life Support Organization (ELSO) guidelines for didactic sessions, added with new and possible interesting content.

In the first round, experts are asked to score 56 statements about knowledge skills, technical skills and attitude on a 5-point Likert-scale. Additional items, suggestions on wording or any unclarities and comments can be added. Based on the information obtained from round one, the second round Delphi questionnaire will be developed.

A statement will be considered to be a key competency when the internal consistency shows a Cronbach Alpha score >80% and at least 80% of the experts agreed (rating 4/5) or strongly agreed (rating 5/5) with the statement. For statistical analysis SPSS 26.0 (Statistical Package for the Social Sciences, IBM Company, US) will be used.

**Keywords:** ECMO; modified Delphi consensus; e-learning; essential skills.

## INTRODUCTION

### *Extracorporeal membrane oxygenation*

When conventional therapy is reaching its limits, Extra Corporeal Membrane Oxygenation (ECMO) might be a life-saving option in critical ill patients.

ECMO is not a new therapy and has been implemented since the 1970s (1, 2). Nevertheless,

several clinicians are anxious about bleeding complications and high mortality rates. Due to promising results during the large Influenza A outbreak in 2009 and technological advances in circuits, the use of ECMO has increased (2-4). Furthermore, the COVID19 pandemic pushed several hospitals to the limits of their resources. ECMO has demonstrated to provide an important bridging option to recovery (3,5). However, these good outcomes in ECMO patients are influenced by the centre's experience and the number of patients treated annually (6).

According to ELSO, an "ECMO Specialist" is defined as "a technical specialist trained to manage the ECMO system and the clinical needs of the patient on ECMO under the direction and supervision of a licensed ECMO trained physician. The individual functioning as the ECMO Specialist should have a strong critical care background in neonatal, paediatric and/or adult critical care." (2). It must be acknowledged that this definition and profession is mostly used in the United States of America and United Kingdom, where the ECMO specialist is not a physician.

There is no doubt that high-quality and repeated training in this advanced high-tech therapy is mandatory to ensure high-quality care. Defining essential ECMO skills may be difficult since management of ECMO involves multiple

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*Paper submitted on May 20, 2021 and accepted on May 26, 2021.*

*Conflict of interest: None.*

caregivers with different subspecialties (physicians, perfusionists and nurses), with a different background and approach to the patient. Indications for ECMO, as well as difficulties, encountered during the run and weaning of ECMO should be discussed multidisciplinary.

The intention of this study is to obtain a consensus about knowledge skills, technical skills and attitudes that should be included in e-learning and simulation sessions for caregivers involved in the care of ECMO patients.

### *Theoretical background*

The background presented in this paper is based on this ELSO guidelines (2) and on an extensive literature review (1,7-12). The ELSO guidelines encompass recommendations on indications, installation, maintenance and weaning of ECMO.

ECMO is not a curative, but a supportive treatment. It is a cardiopulmonary bypass system to support the failing respiratory system and/or the failing circulatory system until recovery or as a bridge to transplantation or implantation of a support heart (Left ventricular assist device, LVAD) in case of intractable heart failure. The ECMO configuration depends on the type of support the patient may need.

The main objective of veno-venous ECMO (VV-ECMO) is to maintain gas exchange (oxygenation (O<sub>2</sub>) and removal of carbon dioxide (CO<sub>2</sub>)) in isolated lung failure, where cardiac output is preserved. In veno-arterial ECMO (VA-ECMO) the venous blood is returned arterially after oxygenation and decarboxylation, bypassing the heart. As such, this configuration supports both the respiratory and cardiac function. A special type of VA-ECMO is Extracorporeal Cardiopulmonary Resuscitation (ECPR) to support the circulation and vital organs in patients with refractory cardiac arrest, unresponsive to cardiopulmonary resuscitation (13, 14).

ECMO therapy is indicated in severe respiratory or circulatory distress in patients with high mortality risk, in whom conventional therapy has been unsuccessful. (1, 7, 9, 11). However, there is no absolute indication, various parameters must be considered, including haemodynamics, oxygenation, metabolic state, age, chance for healing etc. Being cautious and weighing all pros and cons in order to decide not to start ECMO support is usually based on certainty or possibility of a poor outcome, difficult or impossible rehabilitation and older age (2, 3, 15, 16).

### *Learning process*

Caring for ECMO patients is caring for the most critically ill patients in a highly technical environment. Human error can have disastrous consequences. Therefore, it is essential that an institute that provides ECMO therapy sets up a proper training program for the staff. Unfortunately, current training courses are often theoretical and cover topics that may not always be relevant or applicable in daily practice. Different methods exist to acquire knowledge and skills: traditional methods of learning such as lectures and manuals but also modern technologies including e-learning modules, simulation based training and bed-side training under supervision with formative feedback (17-20). Training has changed significantly in recent decades. William Halsted's model 'See one, do one, teach one' is outdated. Training is increasingly becoming proficiency-based instead of time-based. Patient's safety and cost-effectiveness have become the main focus in healthcare but may reduce training opportunities.

ELSO recommends a didactic ECMO training of at least 32-44 hours. This training consists of 6-8h training on pathophysiology and disease criteria, 6-8h on ECMO physiology, 4-8h on ECMO equipment and the basics of the different procedures, 4-8h on diagnosing and management of emergencies and finally at least 12h of bed-side training with a trained supervisor (1, 17). It is almost impossible to acquire the expertise in daily practice and therefore, alternative modalities for acquiring knowledge and skills required to care for ECMO patients should be developed and used (1, 8).

### *E-learning*

Online textbooks, podcasts, etc. are not only trendy, but they are easily accessible in a world where the internet and multimedia are an integral part of everyday life. Compulsory lectures are losing popularity and textbooks are often already outdated when being published. Most students prefer to study whenever and wherever at their own pace (18). Several advantages of E-learning have been demonstrated in the literature such as accessibility, ease of use, cost-effectiveness and user satisfaction (18-20). It is possible to gather international expertise over country boundaries. Platforms allow to discuss and exchange knowledge as shown by Ruiz et al and de Leeuw et al (18, 19).

*AIM OF THE STUDY*

As stated above, ECMO is a low-volume, high-risk treatment for a limited number of extremely sick patients (21). Considering the complexity, it is poorly defined which knowledge, technical skills and attitude a caregiver should have to treat and care for ECMO patients. Another fact that adds to the complexity of ECMO training, is that not only physicians, but also nurses and perfusionists are involved in the continuous care of these patients, each trained and sometimes working in silo's.

The purpose of this master thesis is to gather consensus about knowledge, technical skills and attitudes that are mandatory to provide high-quality ECMO-therapy. These consensus statements will be implemented in an e-learning program and simulation-based training sessions at Ghent University hospital.

*MATERIALS AND METHODS**Ethics*

This is a prospective, observational study in which the International Council for Harmonisation (ICH) Good Clinical Practice (GCP) guidelines is followed. Approval by the local research medical Ethics Committee of Ghent University Hospital has been obtained on 30/07/2020 (reference number BC-07929).

*Study procedure*

This study is conducted using a modified Delphi questionnaire approach. A personal link to the survey is added as an attachment to the invitation e-mail. All participants have to give written consent prior to the start of the study and anonymity is guaranteed. Information on demographics and expertise is collected through a questionnaire in the first round of the survey. Participants have six weeks to complete each round, with reminders being sent to non-responders weekly. Responses are collected through the online software platform Redcap<sup>o</sup> (Research Electronic Data Capture, Nashville, Tennessee).

*The statements*

The statements of the first round of the Delphi questionnaire were gathered before the start of the study by a local research team consisting of an intensivist, a vascular surgeon/educationalist,

a perfusionist and a trainee in anaesthesiology. The statements were based on the guidelines of the ELSO literature: "Extracorporeal Life Support: The ELSO Red Book (5<sup>th</sup> Edition), the "ECMO specialist training manual (4<sup>th</sup> Edition), the handbook of the course of "ECMO-course for physicians and nurses" of the Leiden University Medical Center and the educational program from the Ghent University Hospital. In total, the first Delphi round consists of 56 statements (33 knowledge, 11 technical skill and 12 attitude statements).

The statements will be rated using a 5-point Likert scale ranging from '1 totally disagree', '2 disagree', '3 neutral', '4 agree', to '5 totally agree'. Additional statements can be suggested by the panellists in the first Delphi round. After the first round, participants' comments about the Delphi statements and suggestions for new statements will be processed and distribution parameters (mean and standard deviation) will be calculated. The results will be processed anonymously and discussed within the research team. The second-round survey will be sent to the experts who have completed the first round. This will include the adjusted Delphi statements, with the distribution parameters, and newly added statements.

*Expert panel*

A heterogeneous expert panel of physicians, nurses and perfusionists worldwide is identified through purposive sampling. An expert is defined as health care professional working in a high-volume centre (more than 20 ECMO-runs annually), specialized in care of ECMO patients. The study aims to have at least 5-10 experts per discipline.

*Statistics*

Statistical analysis will be conducted using SPSS 26.0 (Statistical Package for the Social Sciences, IBM Company, Armonk, NY, USA). The results of the first round, the second round and for the participants who completed both rounds will be analysed.

Internal consistency will be checked using the Cronbach's Alpha score (22). The interrater agreement will be determined by the intraclass correlation coefficient. The Kruskal-Wallis H test will be used to evaluate responses between the different disciplines (physicians, nurses or perfusionists) and the Wilcoxon signed rank test will be used to deduce statistically significant differences in the responses between the two rounds. A p-value

< 0.05 will be considered statistically significant (23). The final ranking of the statements will be made using the mean values of the second-round ratings.

### *Consensus*

There are no formal criteria to define consensus in an expert panel (16, 21, 24). Two commonly used measurements will be used in this study. First, the Cronbach's Alpha score, for which an alpha value of 0.80 has been chosen as an indicator of consensus. Secondly, the percentage of experts (dis)agreeing with a statement. If at least 80% of the experts score an item as "(dis)agree" or "strongly (dis)agree", it is considered as panel (dis)agreement. The intra-class correlation coefficient will be used as the reliability index for the interrater consistency and agreement.

## DISCUSSION

### *General*

ECMO therapy has shown to reduce mortality in patients with respiratory or cardiac failure. In order to provide safe, high-quality patient care, every healthcare worker involved in ECMO-care must be thoroughly trained. This study aims to provide consensus on which skills (knowledge, technical skills and attitude) should be included in an ECMO training program. This training program will be used to support the learning process of inexperienced caregivers and it will also serve as a refresher course for more experienced colleagues who need to update their knowledge on new procedural skills.

A Delphi questionnaire is sent by e-mail to 106 caregivers in 13 different countries. The expert panel consists of physicians, nurses and perfusionists. The goal is to reach a multidisciplinary and international consensus. Both young and older experts are included so experience and new insights are intertwined.

The timing of this Delphi questionnaire is remarkable. At the time the questionnaires have been sent out, the Covid 19 pandemic was spreading worldwide. ECMO was often the last resort to allow the affected lungs time to recover, so the workload and expertise with ECMO has increased significantly in several hospitals and countries. Due to the increased exposure to ECMO care, caregivers were sometimes confronted with gaps in their knowledge and technical skills. It is therefore possible that the answers will be more pronounced in the second round.

### *LIMITATIONS*

Since this study uses the Delphi methodology, it may be subject to some limiting characteristics for this type of research.

First, dropouts are inevitable. Especially during the Covid-19 pandemic, time might have been too scarce to motivate clinicians to put extra time in filling out a questionnaire.

Secondly, Delphi studies might be criticised because the topics are chosen by the research group, potentially inducing bias. To counteract this, a thorough literature study has preceded the drafting of the statements. Moreover, the experts themselves are given the opportunity to add topics and change the propositions.

Third, selection bias cannot be ruled out, since experts need to match quality requirements, so selection of experts at random or based on free participation is not feasible. The experts were chosen based on their expertise with ECMO care. In order to reduce selection bias, a large group of experts was recruited (106) among all ECMO caregivers (physicians, nurses, perfusionists). However, the fact that only motivated participants will fill out the questionnaire may also lead to selection bias.

Fourth, all experts work in different hospitals and countries. By this, participants' answers might be influenced by local traditions and hospital policies.

### *Future perspective*

Since ECMO therapy is constantly evolving, consensus about essential skills should be regularly updated. The agreement on competencies from this study will be implemented in the curricula of physicians in training but will also form an essential part of the continuing education of nurses, physicians and perfusionists active in the care of ECMO patients at Ghent University Hospital. The courses will include traditional lectures, but also interactive study methods such as e-learning and simulation-based inter-professional training. It is important to master not only theoretical knowledge, but also practice experience and troubleshooting. Forums for discussion appear to be important for more profound learning. If all these elements are incorporated, one will be able to approach an ECMO patient in a holistic way. A well-functioning training program will ultimately ensure fewer complications, quicker diagnosis of problems and good team performance (25-27).

## CONCLUSION

To provide optimal care for patients undergoing ECMO therapy, appropriate training for healthcare professionals is a must. Nevertheless, today's training consists mainly of theoretical lectures, peer-to-peer knowledge transmission and simulation based training. The aim of this study is to reach consensus among an international multidisciplinary team of experts on key competencies in knowledge, technical skills and attitudinal skills regarding ECMO therapy. These skills can be considered essential components of a training program. These skills will also enhance simulation scenarios in the hands-on training sessions. ECMO education begins with the initial training, but even experienced ECMO caregivers need continuous training sessions especially with regard to ECMO emergency management, interdisciplinary teamwork and good communication (28).

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## Addendum

KNOWLEDGE
R1: K1 Knowledge of the relevant vascular anatomy.
R1: K2 Knowledge of the components of the ECMO circuit: drainage cannula, centrifugal pump, oxygenator, heating element, return cannula,
R1: K3 Knowledge of the indications for V-A ECMO.
R1: K4 Knowledge of the indications for V-V ECMO.
R1: K5 Knowledge of the indications for ECPR (Extracorporeal CardioPulmonary Resuscitation) ECMO.
R1: K6 Knowledge of when 'to convert' to another ECMO construction.
R1: K7 Pre-ECMO evaluation including RESP-score and SAVE-score (RESP= Respiratory Extracorporeal membrane Oxygenation Survival.
R1: K8 Knowledge of the contraindications.
R1: K9 Knowledge of ECMO physiology: Optimization of oxygenation.
R1: K10 Knowledge of ECMO physiology: Optimization of pCO <sub>2</sub> .
R1: K11 Knowledge of ECMO physiology: in V-A ECMO: Optimization of blood flow and native cardiac function.
R1: K12 Knowing how to interpretation of cardiac ultrasound images during placement and follow-up.
R1: K13 Knowledge of risks associated with the procedure.
R1: K14 Knowledge of how to interpret the blood gasses, venous and arterial.
R1: K15 Knowledge of the weaning process of ECMO including clinical signs of pulmonary or cardiac recovery.
R1: K16 Knowledge of ECMO weaning: pump/gas flow weaning techniques.
R1: K17 Knowledge of the principles of coagulation and anticoagulation.
R1: K18 Being able to use and implement the local heparin protocol.
R1: K19 Knowledge about outcome data of ECMO patients.
R1: K20 Knowledge of prevention, diagnosis and treatment of recirculation.
R1: K21 Knowledge of prevention, diagnosis and treatment of Harlequin syndrome.
R1: K22 Knowledge of diagnosis and policy of cardiac stunning.
R1: K23 Knowledge of the symptoms and clinical signs of limb ischemia and prevention of it.
R1: K24 Knowledge of treatment of cardiac arrest on ECMO.
R1: K25 Knowledge of the principles of lung ventilation during ECMO.
R1: K26 Knowledge about the influence of haemoglobin level on the required blood flow.
R1: K27 Knowledge of the 'Rated Flow' is for a specific oxygenator.
R1: K28 Knowledge of the indications for sedation during ECMO.
R1: K29 Knowledge of infection prevention and treatment.
R1: K30 Knowledge of the use of Target Dosed Monitoring of antibiotics.
R1: K31 Knowledge of positioning and mobilization of patients on ECMO.

R1: K32 Knowledge of the principles of ECMO nomenclature.
R1: K33 Knowledge about lung ventilation during ECMO is not recommended.
<b>TECHNICAL SKILLS</b>
R1: T1 Being able to prepare and review of the checklist: i.e. ordering blood, reanimation medication, equipment.
R1: T2 Handcranking.
R1: T3 Be able to measure the vessel diameter and perform ultrasound guided puncture in peripheral ECMO.
R1: T4 Being able to insert the guidewire correct and give attention for any signs of obstruction.
R1: T5 Being able to insert/connect of the cannulas correct.
R1: T6 Being able to prime of the circuit.
R1: T7 Circuit checks.
R1: T8 Organisation of the decannulation procedure: personnel, medication, potential hazards, preparing instruments for vessel reconstruction.
R1: T9 Transfusion of blood and blood products: why, which thresholds, how and possible complications on ECMO.
R1: T10 Being able to change the oxygenator.
R1: T11 For physicians: being able to place an Avalon® cannula.
<b>ATTITUDE</b>
R1: A1 Know his/her limits and call for help if needed.
R1: A2 Profound situational awareness of the patient and his medical condition.
R1: A3 To obtain an informed consent from the patient or family.
R1: A4 Know the skills and responsibilities of the different team members.
R1: A5 For physicians: lead the team.
R1: A6 To use closed loop communication in procedures, transport, mobilization.
R1: A7 Handovers and communication should be structured and standardized e.g. using ISBAR.
R1: A8 There has to be an experienced team available 24/24 7/7 for trouble-shooting.
R1: A9 Be able to make difficult decisions, including when to stop the ECLS if one encounters futility.
R1: A10 To follow-up and register patient's outcomes in a database.
R1: A11 Being an ELSO-member (Extracorporeal Life Support Organization).
R1: A12 Be able to consider the risks/ benefits for every ECMO run.