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How we provide transfusion support for neonatal and pediatric patients on extracorporeal membrane oxygenation

Shan Yuan, Elsa Tsukahara, Kim De La Cruz, and Robert B. Kelly

Extracorporeal membrane oxygenation (ECMO) provides lifesaving hemodynamic and respiratory support to neonatal and pediatric patients with a variety of congenital or acquired cardiopulmonary defects. Successful ECMO support requires close collaboration among multiple services, including critical care medicine, perfusion, and transfusion medicine services. Neonatal and pediatric ECMO patients require significant transfusion support, both at the time of cannulation and after the ECMO circuit has been established, often with little advance notice. Thus a number of communication and logistic issues must be addressed through a multidisciplinary approach to ensure both good patient outcome and judicious use of resources. In this article, we describe our protocol for transfusion support for ECMO and potential ECMO patients, which was developed to address a number of issues, including identifying and stratifiying ECMO candidate patients, streamlining the ordering and communication processes, and improving blood product turnaround times and availability. Additional measures of quality improvement are also discussed. As the number of centers performing ECMO procedures remains high, we believe that our experience may be of interest to our colleagues in transfusion medicine and critical care.

xtracorporeal membrane oxygenation (ECMO) can provide lifesaving hemodynamic and respiratory support to pediatric patients with a variety of congenital or acquired cardiopulmonary defects, such as neonates with congenital heart disease after cardiovascular surgery, congenital diaphragmatic hernia, meconium aspiration syndrome, and persistent pulmonary hypertension of the newborn.1-3 ECMO is frequently used to rescue patients during cardiac arrest when traditional cardiopulmonary resuscitative measures fail, otherwise known as extracorporeal cardiopulmonary resuscitation (ECPR).4,5 ECMO has also been successfully employed in children with pertussis, cardiomyopathy, myocarditis, and toxic ingestion.^{1,6,7} ECMO is never a destination therapy, and patients must be eventually weaned off ECMO support and possibly transitioned to a ventricular assist device or receive an orthotopic heart or lung transplantation.

The Extracorporeal Life Support Organization (ELSO) maintains an active international registry of neonatal,

ABBREVIATIONS: CPR = cardiopulmonary resuscitation; ECMO = extracorporeal membrane oxygenation; ECPR = extracorporeal cardiopulmonary resuscitation; ELSO = Extracorporeal Life Support Organization; PICU = pediatric intensive care unit; TA-GVHD = transfusion-associated graft-versus-host disease; UCLA = University of California, Los Angeles.

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doi: 10.1111/j.1537-2995.2012.03688.x **TRANSFUSION** 2013;53:1157-1165. pediatric, and adult ECMO recipients. As of July 2011, a total of 29,839 neonatal patients and 11,779 pediatric patients had received ECMO. In 2010, a total of 2701 neonatal and pediatric ECMO cases were reported, which represent a 46% increase in the number of cases compared to 2000. As of July 2011, overall neonatal and pediatric cardiac ECMO recipient survival rates to discharge or transfer are 39 and 48%, respectively, while overall neonatal and pediatric to discharge or transfer are 75 and 56%, respectively. Overall neonatal and pediatric ECPR recipient survival rates are 39 and 40%, respectively.⁸

Given the complexity of ECMO patient care, and the high risk of numerous devastating complications, including infection and hemorrhage, ECMO is typically reserved for use in tertiary care medical centers, where the full range of specialty consultative services is available. The care for an ECMO patient typically requires close collaboration among critical care medicine, nursing, respiratory therapy, perfusion, surgery, neurology, cardiology, and transfusion medicine services. Aided by open communication and objective insight into current practices, multidisciplinary quality improvement efforts such as the development of protocols, guidelines, and simulation training can significantly improve clinical practices and patient outcomes.⁹

Mattel Children's Hospital University of California, Los Angeles (UCLA) is a university-affiliated, tertiary care children's hospital recognized by ELSO as a Center of Excellence. The Center of Excellence recognition represents ELSO's extensive review and determination that a hospital is committed to multidisciplinary ECMO care according to currently accepted standards. The designation also recognizes a hospital's commitment to ECMO education and quality improvement. Centers applying for the designation are required to provide documentation of more than 3000 hours of close bedside patient monitoring per year, as well as long-term outcomes. It is also expected that each site undertakes various performance and quality improvement projects based on the challenges specific to each center and provides continued educational opportunities, including wet lab exercises, emergency scenario rehearsals, and lectures to ECMO support team members.

ECPR as well as respiratory and cardiac ECMO support are provided at our institution to selected neonatal and pediatric patients. Between 2008 and 2011, we provided ECMO support to 42 patients under the age of 21. Thirty-one patients received ECMO for cardiac support, seven patients received ECPR, and four patients received ECMO for pulmonary support. In this report, we outline the challenges in providing transfusion support to neonatal and pediatric ECMO patients and describe our protocol for ECMO transfusion support. Our protocol was developed through continued multidisciplinary efforts,

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with the goals of both improved patient outcome and judicious utilization of blood bank resources. As the number of ECMO procedures performed annually and the number of ECMO centers both remain high internationally, we believe that our experience will be of interest to our colleagues in transfusion medicine as well as in neonatal and pediatric critical care.

THE ROLE AND CHALLENGES OF TRANSFUSION MEDICINE SUPPORT FOR NEONATAL AND PEDIATRIC ECMO PATIENTS

Neonatal and pediatric ECMO patients require significant transfusion support. ECMO involves the use of cannulae that drain blood from the venous circulation and return oxygenated and ventilated blood to either the venous (venovenous ECMO) or arterial (venoarterial ECMO) circulation. For a patient with a body weight less than 10 kg, 2 red blood cell (RBC) units are typically required to prime the ECMO circuit to avoid hemodynamic instability and hemodilution caused by the standard saline circuit priming solution. Furthermore, patients may require transfusions of various blood components after ECMO has been initiated. ECMO circuits utilizing a centrifugal pump can cause significant hemolysis and resultant anemia.¹⁰ A 40% to 50% decrease in platelet (PLT) count is also not uncommon.¹¹ A certain degree of coagulopathy develops as a result of the activation of PLTs and the coagulation system by foreign surfaces comprising the ECMO circuit.12 In addition, mandatory anticoagulation with heparin increases the risk of hemorrhage. Among all neonatal and pediatric cardiac ECMO patients (from birth to less than 16 years of age), surgical site bleeding is the second most common complication, occurring in approximately 30% of all age subgroups.8 As a result of these factors, neonatal and pediatric patients on ECMO may require significant transfusion support. A 2-year, multicenter study identified that 21 of the 45 neonatal intensive care unit patients who received more than 20 PLT transfusions were on ECMO.¹³ In another study of 34 infants on ECMO, for each kilogram of body weight, the patients on average received 24.6 mL of PLTs, 60.3 mL of RBCs, and 50.0 mL of plasma transfusions each day.14

Providing transfusion support for this group of patients, especially at the time of an urgent ECMO initiation, poses some challenges similar to trauma patients or other patients with sudden large bleeds. For example, in the case of urgent ECMO procedures, the transfusion service usually receives little advance notice to prepare the blood products needed. Because many of these patients are emergently transferred from outside hospitals, a current specimen for compatibility testing and historical information on blood type are often not available. As ECMO support in small infants cannot be initiated without the priming RBC units, blood product turnaround times can directly impact patient outcome. Furthermore, due to the young age and underlying medical condition of many patients, saline washing and irradiation of the priming RBC units may be indicated. Clear communication with the clinical team is crucial when assessing whether the benefits of these modifications outweigh the risks associated with accompanying delays. In addition, the need for prompt supply of various blood products continues after ECMO support has been initiated, not only because bleeding complications are common and may develop unexpectedly, but also because additional priming units may be needed immediately if the ECMO circuit requires emergent changing. Thus, a number of logistic and communication issues need to be addressed to support the transfusion needs of these patients safely, effectively, and efficiently.

IDENTIFICATION OF POTENTIAL ECMO CANDIDATES

The early and prompt identification of potential ECMO recipients is crucial to the success of any ECMO program. Upon the admission of a patient with complex cardiovascular disease, heart failure, arrhythmia, sepsis, or acute respiratory distress syndrome to a pediatric intensive care unit (PICU) or pediatric cardiothoracic unit, we recommend a multidisciplinary evaluation to determine whether ECMO should be considered if resistant shock (including cardiac arrest) or respiratory failure occurs. Such an evaluation should include participation by critical care medicine, cardiology, surgery, and perfusion services.

Absolute contraindications to ECMO at our institution include a severe intracranial hemorrhage or severe neurologic injury, an existing "do not resuscitate" order, an uncontrollable coagulopathy, poor prognosis, a lack of candidacy for a ventricular assist device or orthotopic heart or lung transplantation, or a lack of appropriate vascular access for cannulation. To facilitate a thorough review of each potential ECMO candidate, an ECMO evaluation form (Appendix A) was created and made accessible online through the UCLA Health System's Intranet. This checklist includes an evaluation of ECMO indication, contraindications, possible complications, and a documentation of consent for procedure. If the likelihood of ECMO is high, the patient will be considered on "standby" for ECMO support. At our institution, the perfusion services are then immediately paged to provide a detailed evaluation of the potential cannulation approach, cannulae size recommendations, a determination of the patient's body surface area, and a review of any previous cannulation history. If a patient acutely decompensates from a respiratory or cardiovascular standpoint and fails traditional medical intervention before ECMO

standby can be instituted and a detailed evaluation can be completed, ECMO initiation becomes urgent. Urgent ECMO activation is indicated for patients for whom ECMO stabilization had been unexpected but is now required for immediate cardiac (severe heart failure or arrhythmia) or pulmonary support (severe hypoxia or hypercarbia), or in cases of cardiopulmonary resuscitation (CPR) failure (ECPR).

WHAT SHOULD BE ADDRESSED WITH THE BLOOD BANK BEFORE ECMO CANNULATION?

With the continual quality review of our practices at our institution, we recognized that to facilitate timely transfusion support, seven main issues should be addressed and clarified promptly in the communication between the blood bank and the clinical team:

1. How urgent is the procedure?

ECMO candidates are stratified as those who will need ECMO support immediately (urgent ECMO) or as those who may need ECMO support in the near future (standby ECMO). This distinction will affect subsequent blood bank actions and the patient's transfusion support.

2. Is RBC priming of the ECMO circuit needed?

- For patients weighing more than 10 kg, the transient hypovolemia during cannulation is well tolerated, and the hemodilution caused by the ECMO circuit saline priming solution usually does not significantly decrease a patient's hematocrit (Hct). Therefore, ECMO circuit priming with RBC units is not absolutely necessary. Conversely, RBC priming is needed for all patients weighing less than 10 kg. Therefore, for such patients, early notification of the blood bank is crucial to facilitate expedited preparation and delivery of the RBC priming units.
- 3. Who is the "point person" on the clinical team? To minimize miscommunication and duplicate communications with the blood bank, a clinical provider should be designated as the person responsible for the initiation, modification, and cancellation of all blood products orders for each ECMO case.
- 4. **Is there a signed consent for blood transfusion?** For all patients, the consent for blood transfusion needs to signed and placed in the patient's chart *before* transfusion.

5. Is there a specimen for blood typing and antibody screening?

The blood typing and antibody screening results from a current specimen should ideally be available and used for selecting and crossmatching the RBC units used for priming. In their absence, group O, D– and uncrossmatched RBC units may be issued.

- 6. **Do the RBC units need to be irradiated or washed?** Saline-washed or irradiated products are often indicated based on the patient's age or medical condition. Unmodified products, however, may be considered to have more rapidly available blood products. To minimize delays, the decision regarding whether RBC units should be washed and irradiated needs to be made and communicated to the blood bank promptly for every individual case.
- 7. **To what location should the blood products be sent?** RBC units should be delivered to the specified bedside location for an urgent case or to the PICU blood product refrigerator for a standby case.

TRANSFUSION SUPPORT FOR STANDBY ECMO CASES

After a patient is identified as a standby ECMO patient, the ECMO standby blood product order protocol is completed and followed by the clinical team (Appendix B). This form is designed to standardize the ordering process and capture the information necessary for the blood bank to initiate transfusion support as outlined. The form serves as a reminder to the clinical team that the transfusion consent form should be signed and a current type and screen specimen should be provided. The blood product order is usually accompanied or preceded by a phone call to the blood bank to ensure prompt notification, so that the products can be prepared and sent as soon as possible.

RBC units provided at our institution for ECMO patients are fresh (less than 10 days old) and unwashed. Although washing would minimize the risk of hyperkalemia, this process would also lead to increased labor and wastage, given that washed units expire in 24 hours and thus units must be replenished daily. Using fresh units effectively reduces the extent of potassium leakage and accumulation, which are more pronounced in older units. Thus, we feel that the potential risks associated with unwashed RBC products are balanced by the considerable advantages of having readily available RBC units and the reduced strain on the resources of the transfusion service. If justified by the patient's clinical status (for example, extreme prematurity or immune deficiency), cytomegalovirus-seronegative and/or irradiated RBC units are provided. Currently, all RBC units transfused at our center are leukoreduced.

The RBC inventory at UCLA consists almost entirely of CPDA-preserved units; therefore, only CPDA units are provided to ECMO and ECMO standby patients. Despite the theoretical concerns for the mannitol and adenine contents in units preserved with additive solutions, some centers have reported that such units (AS-1, AS-3) have been well tolerated by infants on ECMO.¹⁵

For standby orders, the priming RBC units are delivered as soon as possible to the PICU blood product refrigerator as designated units for the patient. Subsequently, blood bank personnel are responsible for monitoring the refrigerator every morning, removing units older than 10 days or otherwise unsuitable, and restocking with appropriate units. In addition, in keeping with the regulatory stipulation that the crossmatch result for nonneonatal patients is only valid for 3 days, RBC units in the refrigerator are replaced at least every 72 hours. This is done for all patients (including neonates, who do not require a new type and crossmatch) to maintain consistency and ensure patient safety. To ensure that RBC units are available at all times for ECMO standby patients, units can only be exchanged in the PICU after the replacement units have been delivered.

The clinical team is responsible for performing ongoing evaluations of any standby ECMO patient's continued candidacy, canceling the standby ECMO Blood Product Order Protocol as appropriate, and communicating to the blood bank such a cancellation. To discontinue the provision of standby RBC units, blood bank staff must confirm with the patient's nurse before removing the RBC units from the PICU blood product refrigerator.

TRANSFUSION SUPPORT FOR URGENT ECMO CASES

The identification of potential ECMO patients far in advance is not always possible. Critical care medicine physicians in tertiary care children's hospitals often care for pediatric patients requiring stabilization after surgery or transport from another hospital. Additionally, an unexpected cardiac arrest would also pose challenges to the ability of the multidisciplinary ECMO team to implement ECPR in a coordinated and timely manner. Urgent ECMO activation is indicated for patients for whom ECMO stabilization had been unexpected but is now required for immediate cardiac (severe heart failure or arrhythmia) or pulmonary support (severe hypoxia or hypercarbia) or in cases of CPR failure (ECPR). The two foremost goals of urgent ECMO initiation must be patient safety and efficiency. Compared to providing care to a standby ECMO patient, there is greater urgency and need to streamline and standardize communication among the bedside physician, the blood bank, the surgical team, and perfusion services.

Once the decision to proceed with ECMO has been made, the critical care physician at the bedside is designated as the leader of the team and the point person for the blood bank. The PICU secretary then contacts the cardiothoracic surgeon to cannulate the patient. Perfusion services maintains at least one non–RBC-primed centrifugal ECMO circuit adjacent to the PICU at all times, and the on-call perfusionist is notified via page about the impending case. The blood bank is notified by a phone call via a specific blood bank "hotline" reserved for trauma and ECMO patients only. To provide a guide for subsequent blood bank actions and ensure critical data required to complete the blood product order are obtained, the ECMO transfusion support checklist (Appendix C) was developed and is utilized by the blood bank staff whenever such cases arise.

For patients weighing less than 10 kg, 2 RBC units are prepared immediately and sent to the specified bedside location. If the blood type and antibody screen results from a current specimen are unavailable either due to lack of time or specimen, group O, D–, uncrossmatched RBC units are issued.

Time permitting, the RBC units for patients less than 4 months of age (a surrogate for weighing less than 10 kg) are, by default, also irradiated and saline washed, as the risks for transfusion-associated graft-versus-host disease (TA-GVHD) or hyperkalemia are often unclear in such urgent cases involving young infants. Patients requiring ECMO (for indications other than CPR failure) have a high likelihood of being acidemic from poor cardiac output and anaerobic metabolism and are more likely to have impaired renal function. Both conditions lead to a higher likelihood of hyperkalemia before ECMO initiation. Thus, in trying to prevent a cardiac arrest or an arrhythmia during ECMO cannulation, we recommend limiting the degree hyperkalemia may contribute to either of these possibilities, whereby weaning from ECMO may be difficult or impossible. However, given the additional time required for irradiation and saline washing at our institution (10 and 45 min, respectively), the critical care medicine physician may choose to override the default requirements for irradiation and saline washing based on their clinical judgment of the patient's risks for TA-GVHD and hyperkalemia versus the benefit of more immediately available ECMO support. For example, for a patient receiving cardiopulmonary resuscitation, the risk of cardiac arrest from hyperkalemia associated with non-saline-washed RBC units is irrelevant, because the patient is already receiving chest compressions. In this case, timely initiation of ECMO is of greater importance. On the other hand, since irradiation requires significantly less time, the need to forgo irradiation due to time constraint is less common. The time required to contact the perfusionist, prepare cannulae, and move the ECMO circuit to the bedside before the surgeon's arrival can already easily take at least 10 minutes. Furthermore, given the grave consequences of TA-GVHD, clinicians are strongly encouraged to use irradiated RBC units when the patient's immune status is unclear. When the decision to forgo irradiation or washing has been made by the designated critical care

medicine physician, it is documented by the blood bank staff on the ECMO transfusion support checklist (Appendix C).

TRANSFUSION SUPPORT WHILE PATIENTS ARE ON ECMO SUPPORT

Once ECMO is initiated, sudden bleeding and unanticipated disruptions in the ECMO circuit that require repriming may occur, which means that the need for RBC units may arise urgently. To ensure that RBC units are readily available in such emergencies, 2 unwashed RBC units are also sent to the PICU blood product refrigerator for patients on ECMO and weighing less than 10 kg, and four are sent for patients weighing more than 10 kg. If a RBC unit in the PICU refrigerator is used in such an emergency, any unused portion should be returned to the blood bank rather than put back in the refrigerator. The blood bank will replace the used unit in the PICU refrigerator immediately. In addition, 2 or 4 RBC units are also set aside for such patients in the blood bank as "keep ahead" units should the transfusion need of the patient exceed the available RBC units in the PICU. These units are irradiated as indicated by the patient's clinical need.

The prevention of both ECMO circuit thromboses and hemorrhagic complications requires close patient monitoring. ECMO anticoagulation must be assessed continuously by the critical care medicine physician and bedside perfusionist. The decision to adjust anticoagulation must involve an assessment of the patient, which must include the evaluation for the presence of any ongoing bleeding and a visual inspection of the ECMO circuit. At our institution, activated clotting time is the preferred point-of-care testing method for monitoring an ECMO patient's degree of anticoagulation. Our center also periodically uses anti-Factor Xa levels and antithrombin III activities to guide patient anticoagulation strategies.

Although guidelines for transfusion for neonatal and pediatric ECMO patients are available in the literature,¹⁶ there are limited data and consensus in the recommendations provided by different ECMO centers. Given our extensive pediatric ECMO experience, we recommend transfusions with the goals of maintaining an activated clotting time of 180 to 220 seconds, a Hct greater than 30%, a PLT count greater than 50×10^9 /L (greater than 100×10^9 /L if cerebral hemorrhage is present), an international normalized ratio less than 2.0, and a fibrinogen level greater than 150 mg/dL in the absence of surgical bleeding. We recommend establishing these guidelines in conjunction with transfusion medicine to maintain open communication and to prompt continued evaluations of the current literature. Given the multitude of patient circumstances and variables involved, such variables may require adjustment by individual ECMO providers.

ADDITIONAL MECHANISMS FOR CONTINUED QUALITY IMPROVEMENT

We recommend the creation of an active committee dedicated to the oversight of an institution's ECMO program. ECMO committee meetings at the UCLA Health System

include representatives with both adult and pediatric ECMO experience from surgery, critical care medicine, cardiology, perfusion services, and transfusion medicine. The ECMO committee meets quarterly to review and discuss centerspecific and international survival data, as well as trends and data in recent ECMO literature. The quarterly committee meetings serve as a forum for multidisciplinary discussions and provide the leadership for various quality improvement initiatives.

We further recommend instituting a mechanism that facilitates review of the transfusion support process associated with each ECMO case within 24 hours of initiation. This review should include detailed documentations of the timeline for blood products order placement, delivery, and administration. Such a review process facilitates continued open communication among key stakeholders and identifies areas for performance improvement. The results of such reviews at our center have led to many improvements in our processes, such as revisions to our ECMO initiation protocol and the development of various checklists.

Finally, continued education has also played a key role in the success of our quality improvement efforts. Personnel involved in various pertinent areas were all in-serviced and informed about any upcoming process changes, as well as implementation of useful tools such as the ECMO standby blood products order protocol and the ECMO transfusion support checklist. Didactic lectures were given to the blood bank staff by the medical director for pediatUCLA Health System

ECMO Evaluation Form

Date:

Primary Diagnosis

ECMO Indication (check all that apply)

- Hypoxia
- □ Intractable shock
- Respiratory failure
- Inability to separate from cardiopulmonary bypass
- ECPR Cardiac Arrest
- Congenital Defect
- Cardiomyopathy
- Cardiogenic shock
- Myocarditis
- Other____

Consent

- □ Adult or □ Notified family yes/no
- □ Emergent, no consent

Contraindications

- □ Severe intracranial hemorrhage or severe neurological injury
- Poor prognosis
- Lack of commitment to ongoing care (DNR)
- Uncontrollable coagulopathy
- If applicable, not an assist device or transplant candidate
- Lack of vascular access
- NONE proceed with ECMO

Possible complications (discussed with family, if possible)

- Fluid retention
- Mechanical failure of ECMO circuit
- Vascular thrombosis
- □ Limb ischemia (femoral cannulation)
- Renal
- Cardiovascular
- Metabolic
- Infectious
- Neurologic
- Hemorrhagic

(MD,NP,PA,Resident,Fellow) Signature ____ Date Time ____

ric ECMO and perfusion services to provide a general clinical background on ECMO. Similarly, the clinical providers also received education to help them better understand the benefits and potential disadvantages of irradiation and saline washing products, the constraints of blood bank resources, and reasonable expectations for blood product availability.

APPENDIX A: ECMO CANDIDACY EVALUATION FORM

Date of Birth

Secondary Diagnosis _____

APPENDIX B: ECMO STANDBY BLOOD PRODUCT ORDER PROTOCOL



Inpatients

- 1. CHECK ALL APPROPRIATE ORDERS
- 2. DATE AND TIME ALL ORDERS

3. SPECIFY DURATION OF ORDER

Patient Label

	BLOOD PRODUCTS ORDER PROTOCOL		
1.	Indication: ECMO STANDBY		
2.	SEND Blood Type and Antibody Screen Specimen Contact Blood Bank to assess specimen availability		
	Send new specimen Q72 hours if >4 months of age.		
3.	Other Parameters: Red Blood Cells: <u>2</u> units STAT • Products are stored in PICU Blood Refrigerator		
4.	 Special Instructions: a. Irradiated blood products are <u>not</u> required UNLESS patient has pre-existing irradiation requirement. b. CMV seronegative blood products are <u>not</u> required UNLESS patient has pre-existing CMV seronegative blood products requirement. c. Saline Washed is <u>not</u> required for Standby RBCs 		
5.	This order <u>ends</u> when standby is cancelled by MD/NP. Standby RBC to be returned to Blood Bank.		
6.	Consent to Blood Transfusion completed and in patient's chart.		

MD/NP Signature:	RN Signature:	
Pager: Date:/ Time:	Date: <u>/_/</u> Time:	

APPENDIX C: ECMO TRANSFUSION SUPPORT CHECKLIST



o Ensure Plasma, Cryo , and Platelets are Available

ECMO TRANSFUSION SUPPORT CHECKLIST / GUIDELINE

CONFLICT OF INTEREST

None.

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