Extracorporeal Life Support (ECLS) Program
UCSF Benioff Children's Hospital Oakland

ECLS Policies & Procedures
2022

UCSF Benioff Children's Hospital
Oakland

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ADMINISTRATION AND ORGANIZATION: POLICY STATEMENTS

PURPOSE:

To provide safe, effective and appropriate care to patients requiring extracorporeal life support.

OBJECTIVES:

Objectives for the ECLS program exist to direct the overall operation of the program.

These objectives are written by the ECLS Program Coordinator(s) and the ECLS Medical Director(s); they are reviewed by the ECLS Coordinator and ECLS Medical Director(s) bi-annually.

These objectives are used to direct the practice of health care personnel involved in the ECLS program.

<u>These objectives are:</u>

1. To provide comprehensive care in all situations associated with ECLS and to meet the standards and guidelines set forth by:
   a. Extracorporeal Life Support Organization (ELSO)
   b. California Children's Services (CCS)
2. To provide an environment for patients and families that is supportive and caring, while meeting the physical and emotional needs of the patient on ECLS.
3. To utilize an interdisciplinary approach in providing family-centered care, support, assistance and appropriate referrals for families of ECLS patients.
4. To provide consultation and referrals to other ECLS centers.
5. To provide transport within the medical facility, of patients receiving ECLS therapy.
6. To provide continuing education for staff of the ECLS Program, as well as for other hospital personnel.
7. To provide an environment in which ECLS team members can use and expand their knowledge and skills.
8. To collect data on all patients who receive ECLS therapy for the UCSF Benioff Children's Hospital Oakland ECLS database and for the ELSO Registry.

Medical Direction:

The responsibility for direction of medical care of the ECLS patient in the NICU is the attending ECLS physician. When ECLS is performed in the PICU, the PICU attending physician directs medical care with consultation from the ECLS attending physician regarding maintenance and function of the ECLS circuit.

Specific responsibilities of the ECLS attending physician in the NICU include:

- Obtaining informed consent from the patient's parents or guardian prior to preparing for the ECLS procedure, or designating another individual to obtain informed consent
- Overseeing all medical and mechanical aspects of care while the patient is on ECLS
- Providing direct patient management
- Writing physician orders
- Writing progress notes
- Providing 24-hour physician coverage
- Coordinating all subspecialty consultations provided to the ECLS patient

The ECLS Medical Director(s) is/are responsible for overall direction of the ECLS Program. The ECLS Medical Director(s) participate(s) in the development of nursing and medical standards of care, protocols and procedures.

The ECLS Medical Director(s) is/are responsible for:

1. Providing medical direction for the day-to-day operation of the ECLS Program;
2. Ensuring physician coverage of the ECLS Program;
3. Generating and updating policies and procedures as they relate to the ECLS Program;
4. Advising and assisting the hospital in implementing these policies and procedures as they relate to the ECLS Program;
5. Advising and assisting in the development and implementation of a quality assessment and improvement programs with respect to the ECLS Program;
6. Participating in Hospital and Medical Staff committees as needed;
7. Working with hospital administration regarding annual development of ECLS Program objectives, operations budget, and capital equipment budget;
8. Fully cooperating with hospital personnel assigned general administrative responsibilities for the operation of the ECLS Program;
9. Advising and assisting in the organization and implementation of an effective utilization review process for the ECLS Program;

10. Advising and assisting in the development and review of on-going ECLS training and continuing education programs for the medical staff, the nursing staff and other support personnel;
11. Ensuring that the ECLS Program is operated in accordance with the requirements of The Joint Commission, ELSO and other relevant federal, state or local agencies;
12. Assisting in the design and development of patient information forms, EMR forms, and consent forms as they relate to the ECLS Program;
13. Ensuring the proper and efficient use of equipment and materials as they relate to the ECLS Program, and make recommendations as to appropriate repair or replacement;
14. Keeping abreast of equipment developments, and making recommendations with respect to procurement of new equipment as applicable to the ECLS Program.
15. Providing on-call coverage for ECLS priming on a regular basis

Nursing Direction:

The ECLS Program Coordinator(s) for the NICU is a Masters prepared RN with requisite ECLS clinical and managerial experience. This individual(s) is/are responsible for the effective organization and management of the ECLS program. She/he has 24-hour responsibility for the effective functioning of the ECLS specialists including their development and evaluation with regard to ECLS; the efficient functioning within the NICU and PICU systems; and the quality of care provided in the setting.

The ECLS Program Coordinator(s) provides support and direct supervision of care delivered by the ECLS specialists on a 24-hour basis.

Specific responsibilities of the ECLS Program Coordinator(s) include:

1. Developing and maintaining written standards, protocols, procedures and guidelines for ECLS
2. Providing ECLS education and training (initial and continuing)
3. Maintaining a comprehensive quality assurance program for ECLS
4. Collaborating with medical, nursing and other departments to evaluate new equipment and procedures and maintaining excellent communication with all staff involved in the program
5. Providing direct care to patients as an ECLS specialist when needed
6. Serving as a resource/consultant to ECLS specialists
7. Participating in the decision making process as a member of the Critical Care Leadership Group, serving on hospital committees and participating in regional and community activities as related to the BCHO ECLS program
8. Providing feedback to referral hospitals regarding the status of patients transported for ECLS candidates

9. Annual review of performance of ACT testing technique of ECLS team members

Nursing Specialist:

The ECLS specialist is a RN who has received mandatory clinical and didactic ECLS training and has passed a written ECLS exam. The ECLS specialist is under supervision of the ECLS Medical Director and the ECLS Coordinator(s).

The ECLS specialists provide support and care for the patient and equipment during ECLS therapy and must have completed and passed a training and preparation course prior to managing the ECLS circuit.

Specific responsibilities of the ECLS specialists include but are not limited to:

1. Responsibility for care provided to the circuit while a patient is on ECLS as specified in ECLS protocols and procedures.
2. Various aspects of direct patient care, including assisting the bedside nurse.
3. Maintaining detailed and complete documentation in EPIC.
4. Collaborating with the bedside nurse to provide total patient care in accordance with the individualized standards of care.
5. Assisting with the set-up or take-down and clean-up of ECLS equipment.
6. Reviewing written ECLS Team updates and actively contributing to the development and continued growth of the ECLS team
7. Refer to ECLS Specialist Shift Responsibility.
8. Attend yearly update classes and all offered wet labs.

Staffing:

While on ECLS support, the patient will have one nurse assigned to provide direct patient care, and an ECLS specialist assigned for pump management and monitoring. The patient's nurse can be either a NICU nurse (if the patient is in the NICU), or a PICU nurse (if the patient is in the PICU), and need not be an ECLS specialist.

Additional support will be provided by ECLS specialists/superusers assigned for break relief and for back up during high acuity periods.

Ancillary Support:

The Respiratory Care Practitioner's responsibilities are unchanged when a patient is on ECLS therapy.

The NICU residents, NNPs and interns do not have direct responsibility for daily management of the ECLS patient in the NICU, though residents and fellows are part of the ECLS patient care team in the PICU.

Biomedical Engineering and Respiratory Therapy Departments are available for consultation based on equipment failure or monitoring problems. They also may assist with and make recommendations about new equipment. They may also be involved in the manufacture of necessary equipment.

OPERATION AND UTILIZATION

Hours of Operation:

The ECLS Program provides ECLS care on a 24-hour per day basis.

Utilization:

Admission Policies:

- The designated bedsides for ECLS in the NICU are spaces A2 – A3, A4 – A5 and A7 and A8 in room A. Occasionally an ECLS patient may be cared for in room B or C if they are too unstable to move into room A, or there is no bed availability.
- The designated bedsides for ECLS in the PICU are determined by availability.

STRUCTURE STANDARDS

Description:

The ECLS program utilizes a modified heart-lung system that can provide life-saving support to neonates and children experiencing severe pulmonary or cardiopulmonary dysfunction unresponsive to conventional therapy. The ECLS program is capable of providing extracorporeal support to two patients at one time with complete system backup. ECLS is provided in the Intensive Care Nursery (ICN), the Pediatric Intensive Care Nursery (PICU), operating room (OR), or cardiac catheterization lab.

A patient being considered as a potential ECLS candidate must meet these initial requirements:

- Birth weight at least 2.0 kg, Gestational age 34 weeks or greater
- Severe refractory respiratory or cardiac failure with high mortality risk despite optimal conventional therapy
- Suspected reversible cardiopulmonary disease

Relative Contraindications to ECLS:

- Most contraindications are relative, balancing the risks of the procedure (including the risk of using valuable resources which could be used for others) vs. the potential benefits. The relative contraindications are:
  1) conditions incompatible with normal life if the patient recovers;
  2) pre-existing conditions which affect the quality of life (CNS status, end stage malignancy, risk of systemic bleeding with anticoagulation);
  3) age and size of patient;
  4) futility: patients who are too sick, have been on conventional therapy too long, or have a fatal diagnosis.
- Parental refusal
- Patients with disease states with a high probability of a poor prognosis may require in-depth discussion as to the risks of the procedure vs. the potential benefits. There will, however, be situations where time does not allow for a complete evaluation of the full prognosis. In these cases, discussions should occur shortly after cannulation. If ECLS support is NOT in the patient's best interest, it should be discontinued.

ECLS SPECIALISTS

Staff and Training Competency:

The ECLS specialist is an RN who has received mandatory clinical and didactic ECLS training and has passed a written ECLS exam. Training and current competency must meet standards established by ELSO (Extracorporeal Life Support Organization). Refer to: *Extracorporeal Life Support: The ELSO Red Book (5th edition).*

ECLS specialist performance standards are described in Administration and Organization: Policy Statements of the Extracorporeal Membrane Oxygenation Program.

In addition, ongoing staff training and competency is required and includes the following:

- Participation in the annual ECLS Update Class that contains both didactic and skills as well as review of procedures for ECLS emergencies. In addition, an annual ACT competency is performed by each ECLS specialist at this time using visual confirmation technique. Refer to the Individual Education Log for documentation of participation.
- Review of the pump, circuit components and practice responding to alarm situations with a water filled circuit if pump experience interval exceeds 3 months. *Refer to ECLS pump time tracking log located in the nurse manager's office.*
- Participation in education related to changes in procedures, protocols and equipment as needed.
- Participation in precepted pump experience with another ECLS specialist if pump experience interval exceeds 6 months (due to leave of absence or other circumstances).

ECLS Specialist Shift Responsibilities:

BEGINNING OF SHIFT:

a) Check entire circuit for air and tie strap security.
b) Check cannula site
c) Check water heater temperature.
d) Check water heater level (fill with sterile water PRN).
e) Check air and oxygen tank levels (should be > 1000 PSA).
f) Bubble check: circuit
g) Clot check: circuit
h) Measure cannula length(s)
i) Count circuit clamps (6- 3/8" tubing, 3 pigtail, 2-1/4" circuit clamps)
j) Verify pressure alarms
k) Document circuit pressures (internal, arterial, venous and delta P)
l) Verify MODE - CARDIOHELP should be in Heart/Lung mode.
m) Check low flow alarm. CARDIOHELP should have low flow alarm set at 0.1 LPM in neonates and 0.5 LPM in pediatrics.
n) Check sweep gas flow, FiO2
o) Sigh oxygenator by increasing sweep gas flow for one minute according to patient's orders.
p) Confirm with blood bank that emergency units (2) of blood are available.
q) Obtain update on patient's condition from bedside nurse.

EVERY HOUR

a) Record vital signs and ventilator settings
b) Record internal (pre-oxygenator), arterial (post-oxygenator) and venous circuit pressures
c) Record temperature of water heater
d) Record pump flow
e) Record pump speed (RPMs)
f) Record ECLS sweep gas flow, FiO2
g) Record mixed venous saturatio
h) Record IV infusion levels (for infusions running through circuit)
i) Perform an ACT using Signature Elite cuvette (every 2-4 hrs)
j) Record heparin dose (units/kg/hr)
k) Record hemofilter output, if applicable
l) Perform circuit bubble and clot check

CardioHelp data will be automatically uploaded to EPIC

EVERY 6-12 HOURS

a) Obtain CBC with Platelet count
b) Obtain unfractionated Anti-Factor Xa level with corresponding ACT (bleeding patients may require more frequent monitoring)
c) Check and restock ECLS cart

EVERY 24 HOURS

a) Obtain Post-oxygenator blood gas (AM)
b) Obtain mixed venous blood gas
c) Change ACT sample site stopcock prn and every other day when drawing blood culture (during day shift in the presence of ECLS physician or ECLS coordinator/Superuser RN).
d) Change heparin infusion every 96 hours
e) Obtain Anti-Thrombin III (AT III) level
f) Obtain Plasma free Hgb level
g) Obtain Coagulation studies (PT, PTT, INR, fibrinogen) - Q12-24hrs

AT THE END OF THE SHIFT

a) Sign off on EPIC
b) Prepare syringes and flush for the next shift.
c) Clean ECLS equipment.
d) Restock any needed supplies.

ENTRY CRITERIA

Neonatal Criteria:

After meeting basic requirements listed, a patient must meet at least one of the criteria listed below prior to beginning ECLS:

Oxygen Index = MAP X $Fi0_2$ X 100/ PaO_2

Aa gradient= 713 – $PaC0_2$– PaO_2/FiO_2

- Oxygen index greater than 40 for 0.5- 6 hours
- AaDO2 >605-620 mm Hg for 4-12 hours
- Pa02 < 40 mmHg for > 2 hours
- Acute deterioration despite maximal therapy
- Failure to respond to maximal therapy
- Acidosis and shock with pH < 7.25 for > 2 hours or with hypotension
- Failure to improve after 5 – 7 days of maximal supportive therapy
- Congenital diaphragmatic hernia: Extreme lability in gas exchange with OI >30 or PaO2 < 45 on MAP>15 cm H2O

The route of perfusion used will be veno-venous or veno-arterial. In neonatal patients, the venous catheter will be inserted via the internal jugular vein and the tip threaded into the right atrium. The arterial catheter will be inserted into the common carotid artery and threaded to the aortic arch. In pediatric patients, catheters may be placed in the neck, groin or chest. The blood is drained from the right atrium or femoral vein, oxygenated outside the body, and returned to the systemic circulation.

Prior to beginning ECLS, the neonatal patient will have a neuro-ultrasound done to rule out intraventricular hemorrhage.

- Grade I bleed: the patient is still eligible for ECLS.
- Grade II bleed: cases will be considered on an individual basis.
- Grade III or grade IV bleed: ECLS is no longer a treatment choice.

The neonatal patient on ECLS will have frequent NUS to rule out IVH. If at any time a grade II or high bleed is diagnosed, the ECLS procedure may be terminated and conventional treatment resumed.

Prior to beginning ECLS, the patient will have an echocardiogram done to rule out structural heart disease.

Pediatric Criteria:

Any one of the following criteria qualifies the patient for ECLS:

Any one of the below signs of hypoperfusion or severe cardiac dysfunction, following appropriate volume resuscitation (≥ 60 mL/kg and/or CVP > 10) and inotropic/vasopressor support:

- Plasma lactate > 45 mM/L and not improving for > 30 minutes
- $SV0_2$ < 55% (estimated Cardiac Index < 2) for > 1 hour
- Rapidly deteriorating or severe ventricular dysfunction
- Intractable arrhythmia with poor perfusion
- Failure to wean from cardiac bypass
- Need for CPR
- Inotropic equivalent (IE) > 50 for 1 hour, > 45 for 8 hours

For patients with acute myocarditis or post cardiotomy, IE > 40.
IE= Dopamine(mcg/kg/min) + Dobutamine(mcg/kg/min) + Epinephrine(100Xs mcg/kg/min) + Norepinephrine(100Xs mcg/kg/min) + Isoproterenol(100Xs mcg/kg/min) + Milrinone(15Xsmcg/kg/min).

Any one of the following signs of severe respiratory failure with predicted high mortality rate; all values assume an attempt to optimize mechanical ventilation. **Additional indications: CO_2 removal for asthmatics, support of the tracheal bronchial tree, mediastinal masses, pulmonary embolism.**

- Oxygenation Index (OI = MAP x FiO_2 x 100 divided by PaO_2
  - OI > 45 for 6 hours on Conventional Ventilation and/or HFOV
  - OI > 35 for > 12 hours

- Aa gradient
  - Aa gradient= FiO_2 713 – $PaCO_2$- (PaO_2/FiO_2). Historically used in neonatal respiratory failure, an $AaDO_2$ > 610 for 8 hours correlated with an 80% mortality. Pediatric patients $AaDO_2$ > 470, was noted in some studies to have 80% mortality.

  - Exceeding recommended maximal ventilator settings of: Conventional PIP of > 35 for 8 hours or HFOV Amplitude of > 55 for 8 hours.

Any one of the following underlying imminently fatal or irreversible disease states may exclude the patient from ECLS:

- Severe CNS injury or asphyxia
- Persistent plasma lactate > 225 mg/dl (is highly predictive of death); (Note: > 135 mg/dl is highly predictive of adverse neurologic sequel in neonates)
- Base deficit > 30 on 2 ABG's
- Severe neurological exam persistent after respiratory and metabolic resuscitation
- End-stage malignancies or advanced AIDS
- Severe acquired or congenital immunodeficiency
- Major burn
- Advanced liver failure
- Evidence of ongoing uncontrolled bleeding (a potentially correctable coagulopathy is not exclusion).
- Severe fibrosis on lung biopsy
- Severe pulmonary disease ventilated aggressively for > 10 days
- Lethal condition incompatible with long life, including trisomy 13 and 18
- If concern about CNS prognosis during off-hours, consider portable head CT scan, followed by official reading by on-call radiologist.

CIRCUIT ASSEMBLEY AND PRIMING

Assembling and Priming the CardioHelp ECLS Circuit:

PURPOSE:
To outline the responsibilities involved when priming the ECLS circuit.

SUPPORTIVE DATA:
The ECLS circuit will be primed by an ECLS Physician, the ECLS Coordinator(s) or a perfusionist/ECLS superuser RN - any of whom having had specific training in the priming procedure. The ECLS circuit will be primed once the decision has been made to place the patient on ECLS.

EQUIPMENT LIST:
- CardioHelp HLS module pack
  - 5.0 HLS should be used standardly
  - 7.0 HLS for large patient expected to require flow of >5 LPM
- 3 units PRBCs and 20ml/kg pheresed platelets (neo) or 1 unit platelets (pediatric)
- Assembled circuit on ECLS Cart
- Pediatric custom pack
- Priming medications:
  - 500 ml bags plasmalyte (2-3 bags Neo; 3 bags Pedi)
  - 50 ml 25% albumin
  - Heparin (400 units)
  - Calcium chloride (400 mg)
  - 50 ml vial sodium bicarbonate 1 mEq/ml
- ECLS supply cart – contains tie gun and tie bands
- Circuit clamps (3/8 inch, 1/4 inch, and pigtail clamps)

Protocols for assembly and priming: Priming protocols are available for review in the ECLS storeroom and laminated copies are on the individual sprinter carts. ***DO NOT FORGET TO HUDDLE WITH CHARGE NURSE WHEN DECISION IS MADE FOR ECLS.***

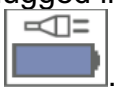
Extra Supplies: All miscellaneous and emergency supplies necessary for ECLS are stocked on the ECLS supply carts or in the ECLS storeroom.

****The end connector from a 23 gauge femoral cannula measures ½ inch. In order to connect to the 3/8 inch pediatric cannula connector, adapt a segment of ½ inch tubing: Connect the femoral cannula to the ½ inch tubing, then connect a ½ inch x 3/8 inch straight connector as a bridge to the cannula connector.***

Assembly of CardioHelp Circuit:

All patients will use a 5.0 HLS module with 3/8" tubing

1. Locate and open the sterile packaging for the **5.0 HLS set** and the Pedi supplemental pack.
2. Open the safety guard and confirm that the cable of the venous probe is plugged into the CardioHelp console, and that the venous probe is seated CORRECTLY on the safety bar. (Venous probe label MUST match console label i.e. ECMO 1= ECMO1)
3. Attach the HLS module to the CardioHelp drive. Make sure that the HLS module is correctly inserted and fastened in the locking mechanism (1 o'clock - 12 o'clock position).
4. Plug the cable for the integrated sensors into the sensor port of the HLS module (red dot towards red module).
5. Place the yellow cap on the de-airing port on the anterior aspect of the oxygenator.
6. Remove the dipstick from the pre-oxygenator luer, and place a 12" pigtail, ***high-flow*** 3-way stopcock and 10 ml syringe on the pre-oxygenator luer – confirm that all connections are secure. **Place a non-venting cap on the remaining luer.**
7. Place a 6" pigtail, 2-way stopcock and 10 ml syringe on the de-airing luer on the superior, posterior aspect of the oxygenator - confirm that all connections are secure.
8. Place a 3" pigtail, ***high-flow*** 3-way stopcock, and 10 ml syringe on the post-oxygenator luer at the base of the oxygenator – confirm that all connections are secure. **Place a non-venting cap on the remaining luer.**
9. Cut the 3/8" circuit ~6 inches from the protective spiral plastic. Attach a 3/8 x 3/8 leur to the arterial limb of the HLS module – do the same for the venous limb. **Tie band NEW connections.**
10. Place the bridge between the venous and arterial luers using ***high-flow*** 3-way stop-cocks. **Place non-venting caps on the remaining luers.** Turn the stopcocks **off to the circuit.**
11. Close the safety guard.
12. Place the table tray (clam shell) on the Cardiohelp handle and push securely into place.
13. Attach the CardioHelp arterial flow/bubble sensor on the arterial side close to the blood outlet and before the bridge. **Make sure that the device is placed with the arrow faced toward the direction of flow!**
14. Attach the venous bubble sensor on the venous side close to the blood inlet of HLS module.
15. Connect the green gas tubing to the gas filter and to the gas blender on the sprinter cart. (Tubing may need to be trimmed.)

16. Connect the water heater hoses to the water connections on the bottom of the HLS module (hoses can connect to either water connection on the HLS module).
17. Place the priming bag on the IV pole – hang with the end holes, not the center hole.
18. Close both 2-way stopcocks at the top of the priming bag.
19. Connect the red tube line (arterial) of the priming bag to the red tube line (arterial) of the table set by removing the quick-action couplings. It is best to remove quick-action couplings by placing your thumb on the side with the white button, and pressing down.
20. Connect the blue tube line (venous) of the priming bag to the blue tube line (venous) of the table set by removing the quick-action couplings.
21. Confirm that the (4) white clamps on the red and blue lines are open.
22. Place all items for rapid air removal in the pouch hanging on the right side of sprinter cart – include: 500ml bag of plasmalyte, spring loaded air removal line from HLS pack, and pre-packaged sterile empty 500ml bag attached to 12 inch tubing line with male connector.
23. Place all unused items in sterile bags in proper bin in ECLS storeroom for later use.
24. Confirm that the CardioHelp console in plugged into power source, and make sure that the batteries are charged  .

STOP HERE IF ONLY ASSEMBLY OF CIRCUIT REQUIRED!

Priming a CardioHelp Circuit:

Part 1: PRE-Priming 3/8" Circuit with 5.0 HLS Module

1. Check circuit to ensure proper assembly and secure connections.
2. **Remove yellow de-airing cap!**
3. Turn on Cardiohelp console and activate "global override". (While holding down the safety button, press global override button  .)
4. Open the Intervention screen on CardioHelp console and **zero the 3 pressure transducers** (Pven, Part, Pint) by pressing the oval icon, then pressing -0- icon, then confirming. The circuit should be dry to zero the pressure transducers!
5. Close the large white clamp on the blue (venous) line of the priming bag (two hand technique). Keep 2 red (arterial) clamps open.
6. Fill the priming bag with **1.5-2L of plasmalyte** via the spike of the quick priming line. Close the clamp on the quick priming line.
7. Make sure there is at least 2-3 feet in height between the upper protective frame of the CardioHelp and the lower edge of the priming bag.
8. Confirm **bridge is closed** – stopcocks OFF to the circuit.
9. Open the clamps on the blue line (venous) to allow for gravity prime.
10. When the flow stops, turn up your **RPMs to 3000 for 2 FULL MINUTES.** Set timer in CardioHelp.
11. After 2 minutes, turn RPMs to zero for 5 seconds, then up to **4000 for 1 FULL MINUTE**. Set timer in CardioHelp. If "air" sound can be heard, repeat steps 10-11.
12. Decrease **RPMs to zero.**
13. Take the table tray off the top of the CardioHelp console. **De-air 3 pigtails**: 1. front of oxygenator 2. posterior/superior oxygenator and 3. post-oxy arterial outlet.
14. Prime bridge and venous luer pigtail together: Attach empty 10ml syringe to pigtail on venous luer. Open the bridge on arterial side and open to syringe on venous side. Remove air with syringe. Turn stopcock off to bridge and de-air venous side. Turn stopcock off to pigtail to open bridge. Small bubbles remaining from bridge are ok.
15. Turn **flow back to 1000 RPMs** to move any remaining air through the oxygenator.
16. When no further air can be heard or seen, reset the bubble alarms by opening the intervention screen , pressing the oval venous bubble  and arterial bubble  icons, pressing reset, and then confirming.
17. Close bridge – stopcocks OFF to the circuit.
18. Turn pump **flow back to zero** and visually inspect the circuit to make sure the system has been completely de-aired. The most common place to see air would be the top of the oxygenator.

19. Isolate the flow sensor by clamping the red line (arterial) before and after the flow/bubble sensor with (2) metal 3/8” clamps. **Be careful not to clamp the bubble sensor cables.**
20. Press  and zero the arterial flow sensor, **then remove the 2 arterial clamps**.
21. Replace the yellow cap on the de-airing port *loosely* to allow air to escape.
22. Turn off Cardiohelp and cover with plastic sheet. Note the date of prime on white board.

Part 2: Priming 3/8" 5.0 HLS Module. CRYSTALLOID AND BLOOD PRIMING

1. **Remove yellow de-airing cap!**
2. Turn on CardioHelp console and activate "global override". (While holding down the safety button, press global override  .)
3. Open the clamp on the quick priming line and drain off excess prime back into plasmalyte bag – **do not drain below demarcation line on bottom LEFT of priming bag**. Re-clamp quick priming line.
4. Turn **pump to 1000 RPM**s (flow approximately 1LPM).
5. Add **50 ml of 25% albumin** to the priming reservoir via either 2-way stopcock at the top of the priming bag and circulate for a few minutes.
6. Fill CardioQuip water heater with **4L of sterile water** (waterline needs to be well above mesh). Ensure that both the lid AND the body of the heater are plugged in.
7. Turn on and prime the water heater: ***SEE CARDIOQUIP GUIDELINE***. Verify flow and make sure there are no leaks and that you do NOT see water entering the oxygenator!
8. Confirm that the sweep gas line is connected to the oxygenator and blender.
9. Turn **pump to ZERO RPMs.**
10. Clamp venous line out of priming reservoir using 2 white large clamps (2-thumb technique), and confirm clamp is closed to the priming line.
11. Clamp the arterial line immediately above the 1-way valve using a 3/8" metal clamp.
12. Add 3 units of PRBCs to priming reservoir via the spike on the quick priming line or via the 2-way stopcock at top of priming bag – **make sure to run blood through a pall filter**.
13. Add **400 units of Heparin** to the priming reservoir and mix manually.
14. Add **400 mg CaCl** to the priming reservoir and mix manually.
15. Place ¼" metal clamp (yellow) and a 1L waste bag on the quick priming line to collect the crystalloid prime as it is displaced by the blood.
16. Move the 3/8" clamp on the arterial line from above the 1-way valve to the arterial tubing immediately as it exits the priming bag (above the "Y" connection to quick prime line).
17. With ¼" metal clamp in place, open the white clamp on quick prime line.
18. Open the white venous clamps and allow circuit to blood prime via gravity – modulate the speed of the blood prime by slowly opening and closing the metal clamp on the waste bag line.
19. **Continue to watch the priming bag closely. Do not allow it to empty below the demarcation line.**
20. Once most of the plasmalyte returns to waste bag and blood has made its way to at least the "Y" of the waste bag, clamp off the waste bag. If time

permits, let it run until blood gets down to the demarcation line of priming bag.

21. To limit blood spillage, move the 4 white clamps on the red and blue lines close to the quick-action couplings and close all (4) white large clamps (two hand technique).
22. Separate the priming bag from the table set bowl by disconnecting the quick-action couplings. **Using airless technique, connect the red line to the blue line of the table set (clam shell).** Also connect the red and blue lines of the priming bag together.
23. **De-activate the "Global Override" mode**  **, and unclamp the 2 white clamps on the arterial and venous lines of the table set**.
24. Turn up **RPMs to 1000**.
25. Turn on the sweep gas to **0.3L, 21%.**
26. Add **15 mEq NaHCO3** to the pre-oxygenator pigtail port.
27. *Caution: adding and removing fluid from closed circuit will affect pressures. If P-art and P-int are too high (>350), remove some blood from the circuit until pressures are <350. If P-ven is too negative, add some fluid back to the circuit.*
28. Draw an ACT, ABG with lytes and iCa from the post-oxygenator pigtail. Add additional NaHCO3 and Ca as needed.
29. Turn the **sweep gas off** after any final adjustments made to circuit meds. (Turn on again prior to patient going on).
30. **The set is now ready for connecting to the cannulas**
31. When surgeon is *ABSOLUTELY* ready, **clamp the venous inlet tubing and arterial outlet tubing** with 3/8" metal clamps on the clamp symbols near the HLS module. *At this point, the circuit is clamped resulting in **blood stasis**, therefore the cannula connection process needs to proceed efficiently!*
32. Open the table set bowl (clam shell) and have the surgeon clamp the red and blue lines before and after the quick-action couplings or on the clamp symbols using **4 sterile 3/8" clamps**.
33. The surgeon will then separate quick connects and place sterile tubing onto sterile field – you will discard remainder of table set (clam shell).
34. The surgeon will make cannula connections by cutting off quick connect ends (if present) and attaching circuit to the cannula connectors airlessly (arterial to red line; venous to blue line)
35. Ask the surgeons to remove the clamps on their end.
36. Adjust the sweep gas to half of anticipated ECMO flow rate and 80% FiO2.
37. **You are now ready to go on ECMO - increase RPMs to 1500**
38. When confirmed with the surgeon, remove the venous clamp above the bridge and then slowly remove the arterial clamp above the bridge – making sure no air is seen.
39. **Increase flows to achieve 100-150 ml/kg.**
40. Sweep gas flow should be changed to match blood flow 0.5-1:1

41. Once the patient is on ECMO, connect the venous probe correctly to the venous shelf on the HLS module. **Please DO NOT force probe onto shelf, since this may break off connecting pin**.
42. **Transfuse 20 ml/kg (if patient < 15kg) or 1 unit (if patient > 15kg) of platelets to the patient**.
43. Confirm that you are **NOT on Global Override**.
44. **Confirm ALARMS**: venous pressure -60; Arterial pressure > 350; Delta P pressure ≥ 25; Low flow alarm at 500 ml/min;
45. **Confirm Interventions are on**: ARTERIAL BUBBLE SENSOR – **pump stops**, venous pressure >100 – pump slows down
46. Confirm the water heater is on and set to 37 degrees and running in **low power mode**.
47. Obtain cannula placement CXR/ECHO as needed. If cannulas are in good position, secure the ECMO cannulas to the bed.
48. After cannulas are sutured in place, secure to christmas tree with paper tape. **Tie-band ALL new connections**.
49. Obtain ACT, first round of gases and labs (CBC, coags), correlating with SVO2 monitor.
50. Begin **heparin infusion at 25 units/kg/hr when ACT < 350.**
51. For post-op Cardiac patients, determine with CT surgeon whether or not heparin will be immediately started.
52. For adult sized pediatric patients:
53. ***Max initial heparin bolus is 5000 units***
54. ***Max starting heparin drip is 1000 units/hr***.
55. Adjust sweep gas FiO2 to achieve post-oxygenator PaO2 200-300.
56. **Replace the yellow cap on the de-airing port *loosely* to allow air to escape**.

Part 2: Priming 3/8" Circuit with 5.0 HLS Module- CRYSTALLOID ONLY

1. **Remove yellow de-airing cap!**
2. Turn on Cardiohelp console and activate "global override". (While holding down the safety button, press global override button  .)
3. Turn **pump to 1000 RPMs** (flow approximately 1 LPM)
4. Add **50 ml of 25% albumin** to the priming reservoir via either 2-way stopcock at the top of the priming bag and circulate for a few minutes.
5. Fill CardioQuip with **4L of sterile water** (waterline needs to be well above mesh). Ensure that both the lid AND the body of the heater are plugged in and turned on. Check that you are in Low Power Mode.
6. Prime the water heater: **SEE CARDIOQUIP GUIDELINE**. Verify flow and make sure there are no leaks and that you do NOT see water entering the oxygenator!
7. Confirm that the sweep gas line is connected to the oxygenator and blender.
8. Turn **pump to ZERO RPMs.**
9. Move the 4 white clamps on the red and blue lines close to the quick-action couplings and close all (4) white large clamps (two hand technique). Moving clamps helps to limit the amount of spillage.
10. Separate the priming bag from the table set bowl by disconnecting the quick-action couplings. **Using airless technique, connect the red and blue lines of the table set (clam shell)**. Also, connect the red and blue lines of the priming bag together.
11. **De-activate the "Global Override" mode**  **, and unclamp the 2 white clamps on the arterial and venous lines of the table set**.
12. Turn up RPMs to 1000.
13. Turn on the sweep gas to 0.3L, 21%.
14. **The set is now ready for connecting to the cannulas** – when the surgeon is ready, clamp the venous tubing and arterial tubing above the bridge.
15. Open the table set bowl (clam shell) and have the surgeon clamp the red and blue lines before and after the quick-action couplings or on the clamp symbols using **4 sterile 3/8" clamps**.
16. The surgeon will then separate quick connects and place sterile tubing onto sterile field – you will discard remainder of table set (clam shell).
17. The surgeon will make cannula connections by cutting off quick connect ends (if present) and attaching circuit to the cannula connectors airlessly (arterial to red line; venous to blue line)
18. Ask the surgeons to remove the clamps on their end.
19. Adjust the sweep gas to half of anticipated ECMO flow rate and 80% FiO2.
20. **You are now ready to go on ECMO - increase RPMs to 1500**

21. When confirmed with the surgeon, remove the venous clamp above the bridge and then slowly remove the arterial clamp above the bridge – making sure no air is seen.
22. **Increase flows to achieve 100-150 ml/kg.**
23. Sweep gas flow should be changed to match blood flow 0.5-1:1
24. Once the patient is on ECMO, connect the venous probe correctly to the venous shelf on the HLS module. **Please DO NOT force probe onto shelf, since this may break off connecting pin**.
25. **Transfuse 20 ml/kg (if patient < 15kg) or 1 unit (if patient > 15kg) of platelets to the patient**.
26. Confirm that you are **NOT on Global Override**.
27. **Confirm ALARMS**: venous pressure -60; Arterial pressure > 350; Delta P pressure ≥ 25; Low flow alarm at 500 ml/min;
28. **Confirm Interventions are on**: ARTERIAL BUBBLE SENSOR – **pump stops**, venous pressure >100 – pump slows down
29. Confirm the water heater is on and set to 37 degrees and running in **low power mode**.
30. Obtain cannula placement CXR/ECHO as needed. If cannulas are in good position, secure the ECMO cannulas to the bed.
31. After cannulas are sutured in place, secure to christmas tree with paper tape. **Tie-band ALL new connections**.
32. Obtain ACT, first round of gases and labs (CBC, coags), correlating with SVO2 monitor.
33. Begin **heparin infusion at 25 units/kg/hr when ACT < 350.**
34. For post-op Cardiac patients, determine with CT surgeon whether or not heparin will be immediately started.
35. For adult sized pediatric patients:
36. ***Max initial heparin bolus is 5000 units***
37. ***Max starting heparin drip is 1000 units/hr***.
38. Adjust sweep gas FiO2 to achieve post-oxygenator PaO2 200-300.
39. **Replace the yellow cap on the de-airing port *loosely* to allow air to escape**.

Physician Pre-ECLS Checklist:

Discuss patient needs and eligibility:
- ☐ Include: ECMO TEAM, PICU TEAM, Cardiology, Surgery as needed
- ☐ Consider weight, duration of ventilation/CPR, surgical availability, comorbidities, patient access
- ☐ Consider type of ECMO (VA/VV), size/type of cannulas

Activate ECMO team:
- ☐ Charge nurse, ECMO specialist/coordinator
- ☐ ECMO physicians: ECMO BU, Community MD, PICU MD **(2848)**
- ☐ Huddle to delineate tasks.
- ☐ Notify Cardiology for ECHO, Radiology for HUS/neck US, and Surgical team.

Obtain/verify parental consents:
- ☐ ECMO consent (surgeons to obtain surgical consent separately). Print from EPIC forms.
- ☐ Blood products - if possible, delegate to PICU

Pre-ECMO Order Set:
- ☐ Labs, studies, blood, priming meds, heparin infusion
- ☐ **Order blood and CALL BLOOD BANK (3528):**
    - <4mo: Type-specific, leuko-reduced, irradiated, sickle negative, washed
    - >4mo: All of the above + cross-matched
    - NEONATAL: 3 units PRBC, 20 ml/kg platelets
    - PEDIATRIC: 3 units PRBC, 1 unit platelets
- ☐ For **emergency cannulation, use emergency release O negative blood** or consider going on with crystalloid prime
- ☐ Verify that **nurse "RELEASES" blood**
- ☐ Order heparin infusion bag (can take a while to make)
- ☐ Order code meds and epinephrine/dopamine drips.

Discuss ventilation plan with RT:
- ☐ Transition to conventional ventilation if on HFOV/HFJV.
- ☐ Discuss plan for rest settings

Initial prep of Cardiohelp circuit (storeroom To Do's):
- ☐ Check for proper assembly of 5.0 HLS module with 3/8" tubing and bridge in place
- ☐ Complete circuit crystalloid prime.
- ☐ Use priming guidelines in ECMO storeroom and on sprinter carts.

Final prep of Cardiohelp circuit (at bedside):

- ☐ Bring circuit, bedside drawers (RN), appropriately sized cannulas, and cannula connectors to bedside.
- ☐ **Blood prime at bedside for all patients.**
- ☐ If going on with crystalloid prime only, add priming meds at bedside.
- ☐ Plug circuit in
- ☐ Attaching gas hoses to wall outlet
- ☐ Turn sweep gas to 1L, 21%
- ☐ Confirm heater on

Obtain circuit gas and patient/circuit ACT

- ☐ Adjust circuit, electrolytes as needed

Final prep for cannulation:

- ☐ **De-activate the "Global Override" mode**  **, and silence the low-flow alarm.**
- ☐ Close all 4 large white clamps and separate priming bag from clam shell
- ☐ Turn up RPMs to 1000 for 1 minute to de-air the circuit, then back to ZERO.
- ☐ Clamp the blue line (venous) on the clamp symbol on the blood inlet side and the red line (arterial) on the outlet using metal 3/8" clamps.
- ☐ Confirm heater on
- ☐ Turn sweep gas up to 0.3L (Neo) or 1L (Pedi), 80%
- ☐ Heparin bolus to be given upon exposure of vessels. Wait 3 min. Repeat if >30 min passes.
- ☐ **Heparin bolus 100 units/kg (1000 units/ml).**
    - **Max initial heparin bolus is 5000 units**
    - **Max starting heparin drip is 1000 units/hour**
- ☐ Once on ECMO, slowly increase flows to achieve 100-120ml/kg
- ☐ Transfuse platelets (and PRBCs if crystallid prime)
- ☐ Place probe, check alarms, order stat gas and CBC. Complete ECMO Therapy order-set.
- ☐ Start Heparin drip when ACT<350

Ordering Blood Products:

Both PRBCs and platelets should be ordered immediately when preparing a patient for ECLS cannulation. A blood specimen should be sent immediately to the blood bank for type, screen, and ABO Rh blood type confirmation. ***Blood bank must have (2) separate patient specimens, newborn workup (type and Coombs) and ABO- Rh confirmation to begin the process.***

PRBC requirements for ECLS:

- babies less than 4 months old: type specific, leukoreduced, irradiated, sickle screen negative, washed
- babies greater than 4 months old: the blood must be cross matched in addition to all requirements listed above

Platelet requirements for ECLS:
Donor plasma compatible with recipient ABO group, leukoreduced, irradiated

If you are aware that there is a high possibility that a patient may require ECLS, please let the blood bank know ASAP (before the patient arrives) and they will begin the process by ordering FRESH UNITS from the supplier.

If you have the ABORh of the patient from the referral hospital, give this info to the blood bank and either type specific or type O fresh units will be ordered.

It is always better to request the fresh units, which can be used for other patients if not needed.

In extreme emergencies, O negative emergency blood can be released from blood bank. The O negative blood is not irradiated or washed. Please see following table for expected times of preparation.

These instructions will be kept in the blood bank and do not need to be specified by the ordering physicians.

Turnaround time from the blood bank (depending on availability of fresh blood and if the work-up has been completed) can take up to **2 hours.**

Patient Blood Type	Compatible **RED BLOOD CELLS**	Compatible **PLATELETS**	Compatible **PLASMA**	Compatible **CRYO**
O positive	O positive/negative	O, A, B, AB positive/negative	O, A, B, AB positive/negative	O, A, B, AB positive/negative
A positive	A, O positive/negative	A, AB positive/negative	A, AB positive/negative	A, AB positive/negative
B positive	B, O positive/negative	B, AB positive/negative	B, AB positive/negative	B, AB positive/negative
AB positive	AB, A, B, O positive/negative	AB positive/negative	AB positive/negative	AB positive/negative
O negative	O negative	O, A, B, AB negative	O, A, B, AB positive/negative	O, A, B, AB positive/negative
A negative	A, O negative	A, AB negative	A, AB positive/negative	A, AB positive/negative
B negative	B, O negative	B, AB negative	B, AB positive/negative	B, AB positive/negative
AB negative	AB, A, B, O negative	AB negative	AB positive/negative	AB positive/negative

TIME NECESSARY FOR BLOOD PREPARATION		
TIME	NO TYPE & SCREEN (send specimen ASAP)	TYPE & SCREEN & ABO CONFIRMATION AVAILABLE AND CURRENT
NOW	O NEG	O NEG OR TYPED/NONCROSSMATCHED BLOOD
15 MIN	O NEG	TYPED/CROSSMATCHED BLOOD
1HR (after receipt of specimen	TYPED/CROSSMATCHED BLOOD	TYPED/CROSSMATCHED BLOOD
ADDL TIME NEEDED	IRRADIATION 30 MIN	WASHING 60 MIN

Nursing Preparation for ECLS:

PURPOSE:

To outline the nursing responsibilities in assisting the ECLS team members in preparing to provide ECLS to a patient:

ECLS Bedside Preparation
Patient Preparation

SUPPORTIVE DATA:

Pre-ECLS patients are critically ill and unstable. As much preparation, as possible should be performed in advance once a patient has been identified as needing ECLS. In the ICN, bed spaces A4-A5, A7-A8 and A2-A3 are designated as ECLS beds. Bed spaces in room B may be used as ECLS beds when necessary if an empty bed spot is available next to the ECLS bed site. Bed spaces in the PICU are determined by availability. All surgical instrument trays and supplies related to ECLS cannulation and decannulation will be prepared by the OR staff.

ECLS BEDSIDE PREPARATION:

Equipment List:

- Radiant warmer table. NON-GEL MATTRESS (NICU)
- Standard bedside resuscitation equipment.
- Standard admission set up.
- Mayo stand (1).
- Cardiorespiratory monitor with dual pressure capability.
- Pump for heparin infusion.
- Syringe pump for mediations thru Trifuse site.
- 1 large sharps container.
- ECLS equipment cart.
- ECLS bedside cart with complete inventory.
- Surgical lamp.
- X-ray plate
- Computer on wheels.
- Masks and caps, shoe covers.
- Step stools.

Steps:

1. Admit patient to ECLS bed spot if it is anticipated that patient may require ECLS.
2. Place patient on radiant warmer table (NICU) in designated space after EVS has cleaned area thoroughly.
3. Adjust table to optimum surgical height.
4. Place exam light near bedside.
5. Place masks, hats and shoe covers on cart and place at entrance to room where cannulation is being performed
6. Place stocked ECLS syringe box at ECLS bedside
7. Place ECLS bedside drawers on wall next to ECLS cart
8. Place ECLS supply cart next to ECLS bedside drawers
9. Post bedside signs
10. Place ECLS case box on ECLS bedside drawers
11. Place ECLS signs on door to hall outside Room A, B or PICU

PATIENT PREPARATION:

Equipment List:

- Appropriate size Foley catheter and urine collection chamber.
- Appropriate size NG tube.
- X-ray plate.

Steps:

- Obtain and document baseline data: record weight, length and head circumference.
- Obtain lab work STAT as ordered per ECLS attending.
- Obtain order for 2-3 units of PRBC's and 20 ml/kg platelets for neonates or 3 units of PRBC's and 1 unit of platelets for pediatric patients.
- Verify that signed ECLS and cannulation consents have been obtained.
- Place x-ray plate under patient.
- Insert NG tube to gravity drainage.
- Insert bladder drainage catheter and connect to collection chamber.
- Obtain standardized heparin drip and hang at ECLS bedside.
- Obtain morphine drip (neonates) per ECLS attending and place at ECLS bedside.
- Administer muscle relaxants per ECLS attending/Anesthesiologist.
- Administer anesthesia per ECLS attending/Anesthesiologist.
- Obtain heparin bolus dose for cannulation and place at bedside.
- Have prepared at bedside: medications and blood products for treatment of hypovolemia, bradycardia, acidosis and cardiac arrest.
- See cannulation procedure.

DOCUMENTATION:

Record on nursing flow sheet in EPIC:

1. Labs drawn
2. Date/time medications administered to patient
3. Baseline data pre-ECLS

CANNULA SELECTION

VV BYPASS:

Drainage: JUGULAR
Return: JUGULAR
advantage: single site; Avalon double lumen catheter decreases recirculation, is wire reinforced, and allows patient repositioning
disadvantage: use of guidewire for Avalon cannula insertion requires ECHO or flouro guidance. Greatest risk is vessel or atrial perforation

Drainage: FEMORAL VEIN extending to infra-hepatic vena cava *preferred method when unable to insert VV cannula (patients >20kg and/or 3+ years of age)
Return: JUGULAR
advantage: minimizes recirculation
disadvantage: need large enough femoral cannula for adequate venous return

Drainage: JUGULAR VEIN
Return: FEMORAL VEIN
advantage: easier for venous return
disadvantage: significant recirculation

VA BYPASS:

Drainage: JUGULAR VEIN
Return: CAROTID ARTERY
advantage: known, common technique
disadvantage: increased risk of cerebral infarcts, especially in older patients

Drainage: JUGULAR VEIN
Return: FEMORAL ARTERY
advantage: saves carotid
disadvantages: decreased perfusion of aortic arch, coronaries, carotid; risk of ischemia to leg
options: placement of distal perfusion cannula into superficial femoral artery. Monitor pressures from post. tibial artery; if < 50 mmHg, attach perfusion catheter and run at rate of 1-200 ml/min

Drainage: FEMORAL VEIN
Return: FEMORAL ARTERY
advantage: saves carotid
disadvantages: need large femoral cannula for adequate venous return; decreased perfusion of aortic arch, coronaries, carotid; risk of decreased perfusion to leg, foot

Drainage: FEMORAL VEIN
Return: small cannula in FEMORAL ARTERY supplemented with return to JUGULAR VEIN VA (V)
advantage: provides arterial blood to lungs, aortic arch, upper body
disadvantage: Used for older pediatric patients, near adults

*** Univ of Michigan DOES NOT recommend femoral cannulation for < 20kg or 3 yr of age**

CANNULATION PROCEDURE

Cannulation:

PURPOSE:

To outline the ECLS team responsibilities during the ECLS cannulation procedure.

SUPPORTIVE DATA:

The cannulation procedure is an urgent procedure in an unstable patient, performed at the bedside. The patient must be carefully monitored during the procedure. The Pediatric surgeon or CT surgeon will perform the procedure, the ECLS neonatologist, pediatric intensivist or anesthesiologist will administer the anesthesia, and the circuit will be connected by the Primer. The scrub nurse and circulator will be OR personnel.

EQUIPMENT LIST:

- OR equipment including Bovie.
- ECLS cannulae, 8-23 Fr venous and 8-23 Fr arterial for VA or 13 (Origen), (13, 16, 19, 23, 26, 27, 31) Avalon/Origen for double lumen VV
- ECLS cannulae connectors
- Heparin.
- Fentanyl.
- Rocuronium.
- PRBCs, platelets.
- Surgical light from PICU storeroom.
- Eye and mucus membrane protection masks.
- Suction canister exclusive for OR staff.
- EPIC conscious sedation flow sheet

STEPS:

- Turn up audio signal on cardiac monitor.
- Remove all unnecessary equipment and machinery from the bedside
- Once OR packs are opened, caps and masks to be worn by personnel.
- Position the patient with head to the left.
- Place x-ray plate under patient, including the head, neck and chest.
- Give Rocuronium, ensuring muscle paralysis and to block vagal response from the Fentanyl.
- Give Fentanyl 10 mcg/kg slowly over 1-2 minutes.
- Obtain baseline ACT on patient before heparin is administered.
- When the vessels are exposed give 100 units/kg heparin and wait 2 minutes before inserting cannula.

- If patient is not on ECLS within 30 minutes of initial heparin bolus, an additional bolus of heparin 25-50 units/kg may be needed. Patient's ACT will help determine this.
- With the insertion of venous cannula, pressure may be applied to the liver to promote venous return and cannula filling.

DOCUMENTATION:
Record on EPIC Nursing Flow Sheet all procedures performed on patient, all medications and blood products given to patient and all other pertinent patient data. Record on ECLS Flow Sheet the time of cannulation, size of catheters inserted, patient tolerance of the procedure, date/time of all medications given to circuit, lab work obtained from the circuit and the time ECLS was initiated.

Connecting to ECLS and Initiating ECLS:

PURPOSE:

To outline the ECLS team responsibilities during the patient connection to and initiation of ECLS.

SUPPORTIVE DATA:

The ECLS circuit will already be primed according to “Priming the ECLS Circuit” procedure. The neonatologist, intensivist, or anesthesiologist will provide procedural sedation. The connection of cannulae to the ECLS circuit will be done by the surgeon and ECLS primer. Tie straps will be applied to the cannula-circuit junction connection by the surgeon, ECLS Physician or ECLS Primer. Once ECLS is initiated, the cannula connecting lines are secured to a “Christmas tree” or carefully to the patient’s bed to prevent dislodgement of the cannulae.

EQUIPMENT LIST:

- 1 primed ECLS circuit.
- Tie strap gun.
- Cable ties.

STEPS:

1. Observe cannulae being connected to ECLS circuit.
   CARDIOHELP – Remove the venous inlet clamp, then slowly remove the arterial clamp as you increase RPMs
2. Slowly increase RPMs while observing pump pressures, SVO2 and patient vitals.
3. Increase RPMs to achieve maximum flow over 15 minutes or according to physician orders to 80% of cardiac output (estimated at 120 ml/kg/min).
4. Give volume per ECLS Physician according to Administration of Blood Products into the ECLS circuit procedure.
5. After patient is stabilized on desired ECLS RPMs, infuse platelets to the patient over 5-10 minutes as ordered.
6. Provide tie strap gun and cable ties to ECLS Physician or Primer.
7. Observe tie strapping of circuit and cannula.

The following patient conditions may occur with the initiation of ECLS:

1. Hypovolemia:

Patients may become hypotensive secondary to hypovolemia during the initiation of ECLS. Hypovolemia can result from adjustment to prime, bleeding, hemodilution and patient vascular dilatation. The hypovolemic patient will not have sufficient right atrial volume to support full flow. Giving blood and/or crystalloid (10-20 mL/kg) may correct hypovolemia. However, it is important to determine if the patient is truly hypovolemic prior to volume administration. Observe heart rate, blood pressure, CVP, and LA pressure. Other causes of inadequate venous return may also include:

- Inadequate venous cannula diameter
- Improper cannula position
- Kink of cannula or ECLS tubing

Fluid boluses should only be given after other causes of insufficient venous return, particularly those related to the venous cannula, have been eliminated.

2. Hypertension:

Patients may also become hypertensive secondary to the vasopressor they were on prior to ECLS. Hypertension may also be the result of inadequate pain control/sedation as the ECLS circuit will quickly decrease the circulating levels of these medications. Increased frequency and larger doses of sedation are often required for the ECLS patient. Ensure adequate sedation/pain control have been achieved prior to weaning vasopressors. In the presence of adequate sedation/pain control, without vasopressor support, hypertension should be treated by vasodilator therapy ie. Nitroprusside, Nitroglycerin, Nicardipine, etc.

3. Arrhythmias

These may occur during the placement of the venous cannula or at the initiation of ECLS. These are often the result of stimulation of the SA node by the cannula or from electrolyte imbalances, particularly Ca and K. Corrections may include cannulae reposition and/or electrolyte treatment.

Arrhythmias may occur with crystalloid initiation, in which case the initiation should proceed more slowly allowing better mixing of the crystalloid prime and patient blood. *Immediate PRBC administration should be considered.*

4. Ventilation

When the patient stabilizes on VA ECLS the ventilator settings may be decreased to “rest” settings. Cardiac patients should remain on reasonable vent settings, and should not have their ventilator set to rest settings.

On VV ECLS, the ventilator FiO2 will be weaned over several hours. Moderate levels of ventilatory support may be required throughout the ECLS run to achieve the desired level of patient support.

Emergency ventilator settings should be a written order within the patient's medical record.

5. Full Flow

Inotropes are weaned and usually discontinued on VA ECLS. On VV ECLS inotropes are weaned slowly. Some VV patients may require inotropes throughout the entire run.

On VA ECLS the arterial tracing must be watched closely as the pump flow is increased. The tracing should begin to dampen as 100-150 ml/kg/min of flow is achieved. **Monitoring of SvO2, base excess, serum lactate and cerebral oximetry may be used as a guide for blood flow adequacy.**

Once the patient has been on ECLS for 5 minutes, an ACT should be checked. The heparin infusion is started when the ACT drops to <350 seconds. The initial rate should be 25 units/kg/hr. The initial ACT may be high and can drop quickly. The ACT should be monitored every 30 minutes until stable within the desired range. Titrate heparin according to ECLS Heparin Management protocol. A full set of laboratory samples including coagulation tests, should be drawn once the patient has reached the target flow.

The circuit tubing should be securely anchored to the bed, after ty-banding all tubing connections.

Complete the ECLS initiation note in the patient's medical record.

DOCUMENTATION:

Document on ECLS EPIC Flow sheet:

1. The time of connection of the patient to ECLS and by whom.
2. The time that ECLS flow to patient was started and how tolerated.
3. Amount, type and product number of any volume boluses given to ECLS circuit.
4. Size of cannulae inserted, depth of insertion.

GENERAL ECLS OPERATIONS

Heparin Therapy:

PURPOSE:

To outline the ECLS team responsibilities when caring for ECLS patient on heparin therapy.

SUPPORTIVE DATA:
Heparin is administered continuously into the ECLS circuit to avoid clotting anywhere inside the tubing surface. A baseline activated clotting time (ACT) should always be obtained before any additional heparin is administered. The desired range for ACTs while a patient is on ECMO will vary from 160 to 260 seconds, unless otherwise ordered. *Once a patient is heparinized there should be no IM medication administration, heel sticks, urinary catheter insertion, nasal suctioning with a catheter or venipunctures.* Heparin boluses should be given to the patient to prevent heparin contamination of the ACT sample site. The heparin infusion is begun when the patient is connected to the ECLS circuit and ACTs are <350 seconds. A standardized heparin concentration will be used which is 100 units/ml. Routine heparin maintenance begins at 25 units/kg/hr and is then titrated to meet the desired Anti-Xa levels (0.3-0.7). Heparin infusion volumes will be read off the infusion pump. Factors that may increase the amount of heparin needed are frequent administration of blood products and increased urine output.

Anti-Xa: Anti-Xa activity is the most accurate measurement of heparin effect. Standard anti-Xa range is 0.3-0.7. The range is tightened in the bleeding patient to 0.3-0.5. Heparin drip orders will be written by the ECLS MD.

If there is a significant difference between the anti-Xa activity and ACT, notify the ECLS physician. Generally significant differences between the two are due to platelet or clotting factor deficiencies and will improve as these issues are addressed. ***If a heparin rate change or bolus has been given, wait a minimum of three hours before checking the anti-Xa level.***

Heparin dosing:

- Unfractionated anti-Xa levels are checked routinely every 6-8 hours to determine heparinization. A correlating ACT level is done simultaneously to determine the appropriate ACT goal range.
- Heparin dose will be adjusted by 2.5-5 units/kg/hr for small changes in the Anti-Xa levels.
- Heparin dose will be adjusted by 5-10 units/kg/hr for large changes in the Anti-Xa levels

- A bolus may be indicated if the ACT falls below 180 seconds, or Anti-Xa levels remain below range despite increased heparin infusion rates.

The ECLS physician should be notified if:

- If the ACT falls <180 seconds and/or Anti-Xa is below 0.3, assuming normal ranges
- Heparin dose falls below 10 units/kg/hr or is greater than 75 units/kg/hr

Never stop the heparin infusion unless directed by ECLS attending.

Response to Anti-factor Xa Activities PTT and ACT values

Anti-factor Xa (0.3-0.8 u/ml)	PTT	ACT	Response
normal	↑	↑	1. Repeat anti-Factor Xa, PTT, ACT 2. Consider FDP/FSP to rule out DIC 3. Check pt. temperature 4. Rule out hemodilution 5. If at upper end of Anti-Xa range, consider decreasing Heparin drip rate by 5-10%.
normal	↓	↓	1. Consider checking ATIII and Fibrinogen level 2. Administer FFP 20ml/Kg or ATIII, then repeat anti-Factor Xa level 3. Increase heparin drip rate by 10%
normal	↑	↓	1. Consider checking ATIII level 2. Repeat anti-factor Xa, PTT and ACT at this time 3. If at upper end of Anti-Xa range, consider decreasing Heparin drip rate by 5-10%.
↑	↑	↑	1. Decrease heparin drip rate by 10%
↑	↓	↓	1. Consider checking ATIII level 2. Administer FFP/ATIII (preferably ATIII) 3. **Decrease** heparin drip rate by 5-10%
↓	↓	↓	1. Consider Heparin Bolus 2. Increase heparin drip rate by 10%
↓	↑	↑	1. **Consider Heparin bolus** 2. Consider FDP/FSP to rule out DIC 3. **Increase** Heparin drip rate by 5%

Administration of Heparin Boluses:

SUPPORTIVE DATA:

A heparin bolus may be indicated when the ACT falls <180 seconds or drops rapidly, or Anti-Xa levels are below desired range despite increased heparin infusion rate. **A bolus of Heparin is 12.5 units/kg, and will ordered by the ECLS MD.** Judgment is necessary to avoid a roller coaster effect. The previous hourly heparin requirements, the coagulation studies, the rate of ACT decrease, last blood transfusion and urine output should all be taken into consideration. It is rare that the Heparin requirement changes by more than 30 units/kg in one hour. **The Heparin bolus is administered directly to the patient.**

EQUIPMENT:

- Standardized heparin infusion bag (100 units/ml)
  OR Heparin 1000units/ml, 2ml vial
- TB syringe with needle.
- Medication label.

Steps:

- Determine amount of Heparin bolus required
- Calculate Heparin bolus and draw up medication from standardized heparin bag for neonates.
- A bolus required for a large pediatric patient may necessitate ordering a vial of heparin from the pharmacy (1000 units/ml, 2ml vial) and will require a physician's pharmacy order
- Double check calculation and medication with another RN
- Clearly label syringe as a Heparin bolus
- Administer Heparin bolus into the patient over a few seconds
- Obtain an ACT 15 minutes after administering the Heparin bolus. Continue to monitor every ½ hour until stable. Repeat Anti-Xa level 3 hours after Heparin bolus.

DOCUMENTATION:

Document Heparin bolus administration in the medication section of the nurses' notes (MAR in computer) and in EPIC ECLS notes. Document ACT values on ECLS flow sheet.

Activated Clotting Times (ACT):

PURPOSE:

To outline the ECLS team responsibilities while obtaining and running ACTs

SUPPORTIVE DATA:

ACTs will be obtained and run every 2 hours and prn. ACTs will be obtained and run within 30 minutes after every change made in the IV heparin rate or after a heparin bolus.

EQUIPMENT LIST:

- Signature Elite ACT LR cuvette
- Signature Elite ACT device
- Sterile non-heparinized TB syringe and 5 ml syringe
- Flush solution in 10 ml syringe

STEPS:

ECLS SIGNATURE ELITE ACT-LR Testing Guide

- Follow steps below in sequence. Do not deviate.
- Hold down the green *Start* button to turn the device on.
- Electronic QC (EQC) will automatically run every 8 hours. EQC takes about 5 minutes to complete. Press "QC" then the #1 to force an EQC run at any time.
- If EQC passes press the *Cancel* button to return to the main screen for patient testing.
- If EQC fails, repeat test by pressing the *QC* button then *#1* to repeat EQC. If EQC fails again, replace device and call X 2746 to request service.
- To begin patient testing insert a cuvette into the black slot on the right side of the device.
- Scan OID = Operator ID (your badge).
- Scan the PID = patient's ID (Barcoded DP #).
- A 5 minute countdown will start.
- Draw 5 mls to clear the pigtail prior to collecting a sample.
- Draw patient specimen – 0.2 mL. Check the syringe for clots and/or air
- bubbles.
- Roll the syringe briefly to mix the sample.
- Expel one drop from the syringe onto a paper towel then immediately add one drop to the cuvette well.
- IMMEDIATELY Press the green *Start* Button.

- To send all patient data from the device plug the grey cable into the Ethernet Port on the side of the device. Press “Data Base”, then #6 ITC >> COM to send. **THIS CAN BE DONE ON THE NIGHT SHIFT.**
- Additional cuvettes may be obtained from the Lab.
- *** Make sure to take only ECLS ACT (LR) cuvettes!!
- Label the box with the new expiration date (3 months after opening). Let cuvettes come to room temp prior to testing.

For Troubleshooting please call Kellie Graham (x2746) or page X0013 for assistance.

DOCUMENTATION:
Record ACT obtained and results on EPIC ECLS flow sheet. Record any changes made to the heparin infusion or any heparin boluses administered.

Administration of Blood Products to the Circuit:

PURPOSE:

To outline the ECLS team responsibilities when administering blood products into the ECLS circuit.

SUPPORTIVE DATA:

Physician's order for blood products will be acknowledged in the patient order section of EPIC. EPIC and Soft lab will be used to communicate the preparing and dispensing of blood products with the blood bank. Products will be checked and documented according to BCHO protocol and EPIC procedure.
For neonatal and pediatric patients, **the preferred method of administration of blood products will be directly to the patient.** If necessary, PRBC's can be transfused through the circuit at the ACT sampling site. **Platelets and FFP can be given via the post-oxygenator pigtail only if there is no possible option of administering them to the patient directly.**

EQUIPMENT LIST:

- Blood product from blood bank.
- Flush solution in 3 ml syringe.
- Platelet filter set if platelets.

STEPS:

1. Scan patient and blood product and begin EPIC documentation.

2. If a pediatric patient is receiving an entire unit of blood: Prime filter and IV tubing with blood. Place tubing into infusion pump and set delivery of volume and time as ordered by physician. Find port for administration and confirm that it is clamped to circuit. Remove Curos from port (if applicable) and place IV tubing into port. Unclamp port to circuit and begin administration of blood. Documentation on patients in the PICU will be coordinated with the bedside PICU nurse.

3. If a pediatric or neonatal patient is receiving blood that has been dispensed by blood bank in a syringe: PRBC's that have been dispensed in a syringe may be administered through the circuit on a medication infusion pump or in aliquots.

4. If using a medication infusion pump, prime tubing with blood and place in pump. Set delivery of volume and time as ordered by physician. Find port for administration and confirm that it is clamped to circuit. Remove Curos

from port and place tubing into port. Unclamp trifuse port to circuit and begin administration of blood.

5. If blood is to be given in aliquots divide total volume into pushes that will be given over ordered amount of time. Attach a stopcock to blood syringe. Draw off volume to be given into syringe. Aliquots of blood may be given at the ACT sampling site, flushing after each push of blood. After flushing, turn stopcock off to circuit and place Curos on stopcock.

6. If platelets or FFP must be given through the circuit, they are given at the post oxygenator pigtail in pushes only. You are entering the high-pressure side of the circuit, be prepared for considerable back pressure. Divide total volume to be given into aliquots. Remove Curos (if present) from post oxygenator pigtail and attach syringe. Turn stopcock on to syringe while carefully holding syringe to prevent backflow from circuit. Administer product, turn stopcock off to circuit. Attach flush, turn stopcock on to syringe again carefully holding syringe to prevent backflow. Flush pigtail and turn stopcock off to circuit. Place Curos on stopcock.

7. ***NOTE: PUSH BLOOD PRODUCTS VERY SLOWLY BECAUSE TURBULENCE IN THIS PART OF THE CIRCUIT CAN ACTIVATE ARTERIAL BUBBLE SENSOR AND SHUT OFF PUMP.***

DOCUMENTATION:
Recording of vital signs and transfusion volume will be done per BCHO policy and EPIC documentation. This will be coordinated with the patient's bedside nurse.

Administration of IV Medications to the ECLS Circuit:

PURPOSE:
To outline the ECLS team responsibilities while administering IV medications into the ECLS Circuit.

SUPPORTIVE DATA:
All IV medications require a physician's order. All IV medications will be prepared by the ECLS RN or the ECLS Specialist in NICU or bedside RN in PICU. IV medication administration will be charted by the bedside RN in MAR for computer charting. All IV medications will be administered to the patient if able. If IV meds need to be administered to the ECLS circuit due to lack of patient IV access, the medications will be administered via the ACT sampling stopcock. The line will be flushed before and after medication administration with flush solution. All continuous infusions into the circuit require luer connections and may be given via a trifuse attached to ACT sampling site.

EQUIPMENT LIST:

- Medication and diluent if necessary.
- Syringes to draw up diluent and medication.
- Needles to draw up diluent and medication.
- Flush solution in 3 ml syringe.

STEPS:

- Prepare and draw up the correct dosage of medication according to physician's order and the drug administration policy per ICN or PICU policy and procedure.
- Remove flush syringe and discard.
- Insert syringe with medication into infusion stopcock, twisting securely into place.
- Turn stopcock open to syringe and pigtail
- Aspirate slightly to remove any air at connection.
- Inject medication according to ICN policy on specific drug administration
- Turn stopcock off to pigtail when medication infused.
- Remove syringe and discard.
- Insert 3 ml syringe with flush solution into stopcock, twisting securely
- Turn stopcock open to syringe and pigtail.
- Aspirate slightly to remove any air at connection.
- Flush stopcock and pigtail with 1-2 ml's of flush solution.
- Turn stopcock off to pigtail and leave flush syringe in place.

DOCUMENTATION:
Record drug, dose, route, time and patient response on EPIC flowsheet.

Blood Sampling from the ECLS Circuit:

PURPOSE:
To outline the ECLS team responsibilities while obtaining blood samples from the ECLS circuit.

SUPPORTIVE DATA:

All lab work and blood tests that cannot be drawn on the patient, will be drawn from the ACT sample site using a regular syringe (non-blood gas syringe—non-heparinized), with the exception of post-oxygenator blood gases which will be drawn from the post-oxygenator pigtail (CardioHelp). When accessing the positive pressure site of the ECLS circuit (from pump to patient), eye and mucus membrane protection must be worn.

EQUIPMENT LIST:

- 1 sterile 5 ml syringe.
- 1 sterile syringe of adequate size and type to aspirate necessary amount of blood.
- Proper container for blood (blood tubes for labs, blood gas syringes for gases).
- Patient labels and appropriate laboratory slips.
- Flush solution in 5 ml syringe.

STEPS:

- Gather necessary equipment.
- Attach 5 ml syringe, open stopcock and aspirate enough blood to clear pigtail into attached syringe.
- Cap and set aside syringe to be returned later.
- Place sterile syringe of adequate size into stopcock port.
- Turn stopcock open to syringe.
- Aspirate required amount of blood.
- Close stopcock to circuit.
- Remove syringe with blood from stopcock.
- Return all “cleared” blood through ACT site.
- Flush pigtail with flush solution. Leave syringe in place.
- May hand syringe with blood in it to bedside RN or lab personnel for remaining steps.
- Place appropriate amount of blood in proper receptacles.
- Place patient label on blood tubes and write date, time, labs to be run, initials of person drawing blood and “ECMO circuit” on label.
- Send specimens to lab.

Hemofilration on ECLS:

PURPOSE:

To outline the ECLS team responsibilities when priming and installing the hemofilter.

SUPPORTIVE DATA:

The Hemofilter will be installed to regulate fluid balance in the ECLS patient with acute renal failure when diuretics alone are insufficient. During **hemofiltration**, plasma water and non-protein bound plasma solutes are removed from the blood by ultrafiltration, while cellular elements and proteins are returned to the patient. The plasma water and solutes removed from the blood are called ultrafiltrate (UF).

Priming the hemofilter unit to remove all air is required prior to use. The Hemofilter is placed between the venous access luer and the pre-oxygenator luer on the CardioHelp.

Flow through hemofilter = approximately 15% of pump flow.
Installation and priming of the hemofilter will be done by the ECLS primers.

Eye and mucus membrane protection must be worn when accessing the positive pressure side of the circuit.

EQUIPMENT LIST:

- Hemofilter – minifilter plus
- Hemofilter Kit (found in hemofilter bin in ECLS storeroom; comes in NEO supplemental pack when circuit is initially assembled)
    - (2) 24-inch pigtails
    - Filtrate line
- (2) 500 ml Normal Saline bags, each containing 2500 units Heparin for mini-filter plus **(5 units heparin/ml) - must order from pharmacy**
- (2) Baxter spike infusion sets:
    - secondary medication set - used to spike the priming bag;
    - Continue Flo solution set which attaches to the hemofilter and subsequently the pump.
- (3) pigtail clamps.
- Grey Collection basin.
- Urine collection system **– stocked in NICU.**
- Baxter infusion pump – nurses will have at ECLS bedside.
- ¼” male luer connector.
- (2) 3-way stopcocks.

- Rubber reflex mallet

ASSEMBLY:

- Remove hemofilter from package.
- Attach filtrate line (with white clamp) to uncapped filtrate port at **VENOUS** end of hemofilter. Clamp filtrate line with white clamp.
- The ultrafiltrate port proximal to the ARTERIAL end (labeled) is used only when hemodiafiltration is desired. **DO NOT** remove the white luer cap. Be sure the white luer cap is screwed securely in place.
- Attach distal end of filtrate line to Baxter infusion set using the spike.
- Attach other end of Baxter tubing to the urine drainage set using a 3-way stopcock and the ¼" male luer connector.
- Attach (1) 24-inch pigtail to both the arterial and venous ports of hemofilter.
- Attach a 3-way stopcock to the 24-inch pigtail on the arterial side of the hemofilter.
- Spike the NS bag with the second spike infusion set and prime the tubing. Clamp using a pigtail clamp.
- Attach the distal end of the primed spike infusion set to stopcock on arterial side of hemofilter.
- Invert hemofilter **(arterial port down)** and mount to suitable surface temporarily with tape.
- Open pigtail clamp on the spiked NS bag, allowing fluid to flow through the hemofilter and out the VENOUS pigtail. Make sure the end of the venous pigtail is in the grey collection basin.
- After 500 ml, clamp the VENOUS pigtail and unclamp the filtrate line, allowing fluid to flow through the filtrate line. It may be necessary to turn the hemofilter from side to side to de-bubble.
- After 200 ml, clamp the filtrate line and unclamp the VENOUS pigtail, allowing the remaining 300 ml of fluid to flow through the filter.
- De-bubble the filter during this last 300 ml of fluid using a rubber reflex mallet.
- Clamp both VENOUS and ARTERIAL pigtails with pigtail clamps.
- Remove infusion set and 3-way stopcock from ARTERIAL pigtail.
- Bring primed hemofilter and filtrate (urine) collection bag to ECLS bedside.
- Attach the ARTERIAL side pigtail of the hemofilter to the pre-oxygenator pigtail stopcock.
- Attach the VENOUS side pigtail of the hemofilter to the venous luer stopcock.
- Mount the hemofilter in vertical position onto the hemofilter clamp apparatus with **ARTERIAL side up**.
- Confirm that Transonic flowmeter is in place on the arterial limb of the ECLS circuit and record flow prior to beginning hemofiltration.
- Have ECLS Specialist place Baxter tubing into Baxter pump. Set pump rate, but do not turn on pump.

- Place the ultrafiltrate collector (urine bag) below the hemofilter.
- Remove the yellow cap from the de-airing port
- To begin filtration, unclamp the **ARTERIAL** pigtail, and then unclamp the **VENOUS** pigtail.
- Increase ECLS pump flow until Transonic flowmeter (flow to the patient) is at the same flow rate as before the hemofilter was installed.
- After 3-5 minutes of blood flow through the hemofilter, unclamp the filtrate line, turn on Baxter pump at desired ultrafiltration rate and begin ultrafiltration.
- Replace yellow cap loosely

CAUTION: A significant drop in the ultrafiltration rate may signify clotting in the system. The appearance of red blood cells in the ultrafiltrate signifies a fiber leak. Remove the hemofilter and ultrafiltrate line and replace with a newly primed system.

DOCUMENTATION:
A procedure note in the Progress section of the medical record is made by the individual who primed and installed the hemofilter. Hemofilter inspection and hourly filtrate output is recorded by the ECMO Specialist. The ECMO bedside nurse is informed of hourly totals.

PrismaFlex Dialysis on ECLS:

PURPOSE:

To outline the nursing/physician responsibilities when initiating PrismaFlex dialysis on ECLS.

SUPPORTIVE DATA:

PrismaFlex dialysis is indicated for the treatment of ECLS patients who are in catabolic acute renal failure with hypervolemia and uremia requiring high solute clearance not achievable with standard hemofiltration.

EQUIPMENT LIST:

- Primed PrismaFlex machine
- 2 high-flow 3-way stopcocks
- 2 pigtail clamps.

STEPS:

- Confirm that the PrismaFlex machine is fully primed and ready to use
- Remove the yellow cap from the de-airing port
- Clamp off the pre-oxygenator pigtail and replace stopcock with a 3-way high-flow stopcock, and prime new stopcock
- Clamp off superior post-oxygenator pigtail and replace 2-way stopcock with a **high-flow** stopcock, and prime new stopcock
- When PrismaFlex machine is ready for connection, attach the **inlet** side of the PrismaFlex tubing (red) to the superior post-oxygenator high-flow stopcock – make sure the PrismaFlex tubing is clamped
- Attach the **outlet** side of the PrismaFlex tubing (blue) to the pre-oxygenator high-flow stopcock – make sure the PrismaFlex tubing is clamped
- When ready to begin dialysis, unclamp the post-oxygenator pigtail, followed by the inlet (red) tubing of the PrismaFlex circuit, followed by the outlet (blue) tubing of the PrismaFlex circuit, followed by the pre-oxygenator pigtail.
- PICU team will advance the PrismaFlex flow until desired degree of dialysis is obtained.
- Monitor ECLS pressures and circuit for air as dialysis is established.
- Loosely replace yellow de-airing cap.
- Label inlet and outlet pigtails to PrismaFlex circuit.

DOCUMENTATION:
Document time that PrismaFlex dialysis was started and hourly volume changes in EMR.

CardioHelp Alarm and Intervention Settings:

PURPOSE:

To identify the venous and arterial pressures in relationship to pump flow and to identify any potential clotting problems within the oxygenator.

SUPPORTIVE DATA:

As preload decreases and venous pressure reaches a threshold, CardioHelp pump flows will begin to readjust and slow themselves down. At high negative pressures, there may be evidence of line chatter and increasing hemolysis. Venous pressure alarm will be set at -60mm Hg on CardioHelp, and the pump will slow down to not allow pressures greater than -100.

The post-oxygenator arterial pressure alarm limit is set at: 350 mmHg for neonatal and pediatric circuits. As the afterload increases and arterial pressure reaches a threshold, the flow may readjust and slow down. At high positive pressures, there may be evidence of increasing hemolysis.

The pre-oxygenator arterial pressure (internal) is set at: 350 mmHg for neonatal and pediatric circuits. The pre-oxygenator (internal) arterial pressure reflects the pressure necessary to drive blood through the oxygenator. **An increase in pre-oxygenator pressure and delta P may reflect clotting through the oxygenator.**

DOCUMENTATION:
Record venous, arterial, and internal pressures hourly in the ECLS Flow Sheet in EPIC. CardioHelp also documents delta P, which is the difference between the Pre-oxygenator pressure (Pint) and Post-oxygenator pressure (Part), and is an indicator of oxygenator health.

Transonic Flow Meter Operation:

PURPOSE:

To outline ECLS team responsibilities when operating the HT110 Bypass Flowmeter.

SUPPORTIVE DATA:

The transonic flow meter will be installed on the ECLS circuit if a hemofilter is in place or we have flow through a shunt. Immediate volume flow measurements (ml/min or L/min) are provided using clamp-on tubing sensors. For extended ECLS runs, pump flows may be altered by changes in membrane pressure or pump occlusion. The flow meter enhances patient safety by ensuring delivery of pump flow and provides a rapid method of checking pump occlusion.

EQUIPMENT LIST:

- Transonic flowmeter and clamp-on probe (1/4”or 3/8”).
- Petroleum jelly.

STEPS:

- If Transonics flow measurement is needed, place the probe after the shunt for accurate ECLS flow to the patient.
- Connect flow-sensor to connector on front panel.
- Lubricate the tubing with petroleum jelly.
- Clamp the probe onto tubing.
- Turn on Transonics machine.
- Check ultrasound signal quality on SET-UP Display; should be > 75%.
- If the patient is receiving hemofiltration, increase the pump flow accordingly. Transonic flow will reflect the actual volume flow delivered to the patient.
- Wipe surface of flow-sensor with alcohol after use to remove petroleum jelly.

DOCUMENTATION:

Record date and time transonic flow meter was placed in operation in the Progress Notes. Transonic flow will be recorded hourly by the ECLS specialist.

Surgical Procedures on ECLS:

Background:

ECLS patients may require surgical interventions prior to and during ECLS. Blood loss can be minimized by minimizing systemic anticoagulation: discontinuation of heparin to promote clot formation and use of the antifibrinolytic agent, tranexamic acid (TXA) to prevent clot breakdown. These steps are done in conjunction with providing optimal platelets and clotting factors to the patient and should be incorporated prior to, during, and following the surgical procedure.

Procedure:

- Use a new Bioline coated ECLS circuit (< 1 week old) when possible. Consider changing the circuit prior to discontinuation of heparin if necessary.
- Discontinue heparin for 4-6 hours prior to the procedure to minimize bleeding.
- Give a loading dose of TXA 10 mg/kg 1 hour prior to surgical start time. If not given before the procedure, then start as soon as possible. Then begin a continuous TXA infusion of 1 mg/kg/hr.
- Monitor the circuit closely for clot formation.
- Low dose heparin (5 units/kg/hr) should be restarted post procedure when there is minimal or no surgical site bleeding or when the patient has been off of heparin for 8 hours. Titrate heparin to keep the anti-Xa level between 0.1-0.2. If the bleeding risk is extremely high due to the extent of the procedure, then anticoagulation may be withheld for 12 -24 hours.
- The TXA infusion should continue for 72-96 hours post procedure depending on the difficulty in achieving hemostasis versus the extent of circuit clotting.
- Keep platelets > 150k and fibrinogen > 200.
- When transfusing large volumes of PRBCs for bleeding > 10ml/kg/hr, keep the transfusion ratio of PRBC:FFP:platelets 1:1:0.5
- A saline primed circuit should be immediately available should it become emergently necessary to change the circuit.

Converting of VV to VA ECLS on CardioHelp:

PURPOSE:

To outline the ECLS team's responsibilities when converting from VV to VA ECLS.

SUPPORTIVE DATA:

Successful management of the patient on VV ECLS depends on the adequate provision of cardiac output and oxygen content. If the optimal cardiac output or oxygen content cannot be maintained with maximal pump flow, increased ventilator FiO2, repositioning the VV cannula, or maintaining the hemoglobin greater than 15, converting to VA ECLS must be considered.

EQUIPMENT LIST:

- Sterile 12" cannula connector line of appropriate size
- Arterial cannula (8,10,12 or 14 Fr).
- MALE luer connector.
- 4 circuit clamps of appropriate size.
- IV solution and tubing to infuse into old arterial re-infusion line.
- Eye and mucus membrane protection, gloves.

STEPS:

- Give sterile 12" cannula connector line and appropriate sized arterial cannula to surgical circulating nurse to hand to scrub nurse. The connector line and arterial cannula are primed and inserted by the surgeon.
- Double clamp the arterial limb of V-V cannula after the luer from the original cannula connector.
- Sterilize the tubing between the clamps with alcohol and cut arterial limb tubing.
- Connect the new arterial cannula to arterial side of the circuit, priming the connection with flush solution. May remove any residual air via the luer.
- Remove the clamps to establish arterial flow through the new cannula and clamp old arterial cannula connecting line. ECLS flow is now through new arterial line.
- Double clamp old arterial cannula connecting line as close as possible to the VV cannula (high) and cut between the clamps.
- Attach male straight luer connector to the end of the old arterial cannula. Infuse with heparinized saline ½ NS with 1 unit heparin/ml at 5ml/hr.

DOCUMENTATION: Record time, date, and indication for conversion to VA ECLS on the ECLS flowsheet.

An alternative would be to continue to use arterial limb of VV cannula for arterial blood return in addition to new arterial cannula in carotid artery. This would continue to supply oxygenated blood to the lungs and coronary arteries. To do this, you would need a ⅜ or ¼ inch Y luer connector (depending on size of the circuit.

- Double clamp on both sides of the luer on the cannula connector of the arterial limb of the VV cannula
- Clean between the clamps with alcohol, then cut out the luer of the cannula connector.
- Connect the 2 ends of the arterial limb to the ⅜ or ¼ “Y” luer connector of the new arterial cannula airlessly
- Remove any residual air by using the luer connector.
- Remove all clamps slowly to establish arterial flow
- Turn up circuit flow to achieve adequate patient support

DOCUMENTATION: Record time, date, and indication for conversion to VA ECLS on the ECLS flowsheet.

Transporting Patients on ECLS:

PURPOSE:

To outline the ECLS team responsibilities when moving a patient on ECLS.

SUPPORTIVE DATA:

The ECLS patient will be moved when requiring surgical procedures in the OR, non-portable diagnostic studies, etc. An ECLS Physician must accompany the patient when being moved. The patient must also be accompanied by a respiratory care practitioner and an ECLS Specialist. Once the move is completed, plug the ECLS cart into an electric plug as soon as possible, as the water bath for the heat exchanger will not be circulating, and the blood will cool. The ECLS supply cart must accompany the ECLS patient during the move.

EQUIPMENT LIST:

- Complete ECLS set-up on cannulated patient.
- ECLS supply Cart.
- Portable respiratory gas tanks.

STEPS:

- **Simulate move and determine optimal position that the patient will need to occupy in various places prior to and at the destination point.**
- **Choose the smallest gurney which fits the patient, can be raised upward, and fits through the doors of the PICU.**
- When moving the ECLS patient to the Cath Lab or radiology, it is easiest to first place the child onto the white board which is kept in the ECLS Storeroom. Place padding on white board. The ECLS cannulas and tubing should be secured firmly to the board and moved carefully to the gurney which fits into the elevator. (The service elevator across from the NICU nursing lounge measures 9 feet deep by 5 feet, 3 inches wide and is the largest elevator on the third floor of the hospital. The elevator closest to the PICU measures 8 feet deep by 4 feet, 11 inches wide).
- Lower the patient's bed to the highest level of gurney and assure that flows are stable.
- Move the patient from the bed to the gurney. Lift child and backboard up, roll bed out, and roll gurney in.
- If patient is too heavy to lift, try bringing the bed next to the patient's left side and sliding the patient onto the gurney.
- Lower the IV poles on the ECLS cart to provide doorway clearance.
- Lower the bed to provide doorway clearance.
- Obtain baseline ABG from patient.

- Move patient EKG monitor and pulse oximeter to the bed.
- **Minimize pumps and remove meds which are not critical to the patient during move.**
- Add extension tubing length to critical IV lines.
- Mount all IV pumps on IV poles of ECLS cart or on the bed. The IV pole will be positioned at patient's left side near the head of the bed in the elevator.
- Secure all circuit lines, cables, and hoses away from wheels or other potential areas that could become entangled or stepped on.
- Unplug power to cart, and check that battery display indicator is lit on the console
- **Check that the yellow cap is ON the de-airing port of the oxygenator during transport – it should also be tightened**.
- Open air and oxygen tanks on ECLS cart (turn to left). Confirm there are appropriate levels of gas in the tanks (minimum 100 psi).
- Unplug gas lines of ECLS cart from the wall.
- Remove ventilator and begin hand bagging at same settings. The anesthesiologist stands near the head of the bed at the patient's left side.
- **Alert security to help with clearing traffic from the hallways and placing the elevator on hold.**
- **Move patient to destination positioned such that patient's head and IV pole are leading and the ECLS pump is at the end.**
- The gurney will be positioned in the back of the elevator against the left/back wall, IV pole to left of head, and pump at foot of bed.

<u>At destination:</u>

- Plug cart power into wall power at destination.
- Plug air and O2 lines into wall. Turn off tanks.
- If using, readjust Transonics as if turning on, it does not need to be re-zeroed.
- When ready to leave, repeat same procedure.

<u>If moving to or from the O.R.</u>

- ECLS cart ultimately must lie next to CPB cart on patient's LEFT side while in the OR.
- To plug into the OR electrical supply, do the following steps: Plug into the OR power supply. Because the power cord from the Blue Electrical box on the cart is too short to reach, remove the Blue electrical power box from the ECLS cart while keeping all cords plugged into it. It will be necessary to stretch the cords on the floor to allow the ECLS cart to move closer towards the OR bed. Tape over the cords using masking tape for safety.
- Turn on portable O2 and air tanks prior to switching from CPB to ECLS.
- When on ECLS and off CPB, connect ECLS gas lines to OR source

- Verify ECLS supply cart has accompanied patient.
- Before moving patient on ECLS back to PICU, it is necessary to move ECLS cart to patient's RIGHT side.
- Bring patient bed between ECLS cart and OR table.
- Transfer patient to bed.
- Move patient out of room (feet first)

DOCUMENTATION:
Document on the Bedside Nurses Notes how the patient tolerated the move including vital signs, pulse oximeter readings, color, amount of support needed, etc. Document on ECLS flowsheet why and where patient was moved to and any other pertinent details regarding the move.

WEANING AND DECANNULATION

Weaning ECLS:

PURPOSE:

To gradually reduce ECLS support to the patient over a period of time until the patient is on “idle” flow.

The decision to reduce ECLS flow should be made by the ECLS physician after reviewing the:

- Patient’s most recent CXR
- Patient’s overall clinical course
- Patient’s current ventilator settings including oxygen requirement
- Patient’s cardiac function as verified by cardiac ECHO
- Patient’s blood gases

The patient should not remain on “idle” flow for more than **two hours** before a trial off ECLS is conducted.

Idle is defined as:

20 ml/kg/min or 100 ml/min (whichever is greater)

STEPS:

- Determine new ventilator settings and FiO2.
- Decrease RPMs and reduce pump flow by determined ml/hr.
- The sweep gas will need to be decreased as pump flow drops.
- Increase ACT parameters as flow decreases to minimum of 200-240 or higher if clotting is present in the circuit. If clotting is present, use higher flows and a shunt through the bridge if present, or place bridge.
- Monitor patient’s blood gases and lactate.
- Monitor SVO2.
- Monitor blood pressure.
- **Minimum flow through the oxygenator should be maintained**
- Create a shunt through the bridge to wean flow to the patient while allowing adequate flow through the oxygenator.
- Place Transonics flow probe above bridge and adjust pump flow until the flow meter is reading the desired patient blood flow rate.
- Chart the new pump flow rate, RPMs, and transonics flow rate on EPIC ECLS flow sheet.

Trial Off of VA ECLS:

PURPOSE:

To outline the ECLS team responsibility during trial off VA ECLS.

SUPPORTIVE DATA:

Before decannulation, the patient will be taken off bypass by circulating through the patient bridge for one hour and observing lung function. Heater is left at 37 degrees C to prevent blood from over cooling causing potential problems if the patient requires re-institution of bypass. Ideally, FiO2 should be weaned to at least 40% before decannulation. Trial off for VA ECLS should not last longer than one hour.

BEFORE TRIAL OFF:
- Obtain CXR to verify ETT placement. Increase ventilator settings in preparation for coming off ECLS
- Obtain baseline ABG from the patient
- Obtain baseline echocardiogram. Consider starting or increasing pressors. Check pacer (if applicable)
- Switch all IV fluids and medications, including heparin infusion, over to patient at least one hour prior to trial off
- Apply Transonics flow sensor to arterial line, distal to bridge
- Make plan for trial off: use of bridge versus trial on nominal flow with bridge closed for larger patients

DURING TRIAL OFF:
- Continue patient anticoagulation
- Keep CardioQuip heater ON
- Turn OFF sweep gas flow
- Decrease flow to nominal amount (<20ml/kg/min) OR clamp off flow to patient and circulate through bridge
- If running through bridge: Flash cannula every 10 min
- Obtain ABG every 30-60 min during trial off
- Follow SVO2, CO2, and lactate
- Obtain ACT levels per standard
- Keep off for no more than 1 hour

AFTER TRIAL OFF:
- Turn on sweep gas and return to ECLS support
- Saline prime bridge if not using
- Alert surgeon
- Order blood and decannulation medications

Trial Off of VV ECLS:

PURPOSE:

To outline the ECLS team responsibility during trial off VV ECLS.

SUPPORTIVE DATA:
During a trial off VV ECLS support, the patient will remain on ECLS flow but with removal of all ECLS gas exchange by discontinuation of sweep gas flow to the circuit. Circuit flow should remain at adequate level to prevent clot formation. Patient should remain on trial off of VV for a minimum of 1 hour but may continue for hours.

BEFORE TRIAL OFF:
- Obtain CXR to verify ETT placement. Increase ventilator settings in preparation for coming off ECLS
- Obtain baseline ABG from the patient
- Switch all IV fluids and medications, including heparin infusion, over to patient at least one hour prior to trial off

DURING TRIAL OFF:
- Continue patient anticoagulation
- Keep CardioQuip heater ON
- Turn OFF sweep gas flow and clamp green gas tubing
- Obtain ABG every 30-60 min during trial off
- Follow oxygen saturations and CO2
- Obtain ACT per standard protocol
- Keep off for a minimum of 1 hour, may continue off for hours

AFTER TRIAL OFF:
- Return to ECLS support
- Alert surgeon
- Order blood and decannulation medications

DOCUMENTATION: Document patient tolerance of the procedure on Bedside Nurses Notes. Document time trial off was initiated and ACT values on the ECLS Flow Sheet.

Decannulation:

PURPOSE:

To outline the nursing responsibilities during decannulation from ECLS.

SUPPORTIVE DATA:

Decannulation will occur at the end of the ECLS run. The procedure will be performed by the Pediatric General or Cardiovascular Surgeon and will occur at the bedside or the Operating Room. The patient will receive muscular blockade during the actual removal of the venous cannula to avoid inspiration and subsequent air entry. The scrub nurse and circulator will be Operating Room personnel. The neonatologist will provide procedural sedation in the NICU.

EQUIPMENT LIST:

- Decannulation Equipment from O.R.
- Fentanyl.
- Rocuronium.
- ECLS emergency unit of PRBC's from O.R. (ask O.R. team to bring).
- Surgical light
- Eye and mucus membrane protective wear.

PROCEDURE:

- Take the patient off ECLS and cut-away ECLS circuit.
- The surgeon will prep and drape the patient.
- Before muscle blockade, increase ventilator settings.
- The ECLS MD will order decannulation medications, which will be drawn up and available at the bedside.
- The ECLS MD will monitor the patient throughout the procedure and keep a Sedation Monitoring Record.
- All meds are administered directly to the patient including heparin.
- Obtain ABG after the cannulas are removed.
- Wean patient rapidly after muscle paralysis wears off, usually within 2-3 hours.

STEPS:

- Obtain back up unit of PRBC's from O.R. and place on ice in cooler at ECLS bedside.
- Position patient's head slightly to the left.
- Switch all IV solutions over to the patient including heparin.
- Before administration of decannulation meds, increase ventilator settings per MD order.

- Administer Rocuronium 0.5 mg/kg IV for required neuromuscular blockade.
- Administer Fentanyl, 10 mcq/kg IV (usual dose) for required anesthesia.
- After decannulation:
    1. Discontinue heparin infusion.
    2. Obtain ABG.
    3. Obtain CXR.
- Wean ventilator settings rapidly after paralysis wears off, usually within 2-3 hours.
- Return backup unit blood to blood bank.
- Notify blood bank that the patient is off ECLS and that blood products no longer need to be held for this patient.
- Score for Opiate withdrawal q 4hr using the Opiate Weaning Flowsheet. Continue scoring until off all Opiates for 72 hrs. Follow ICN Opiate Weaning Protocol.

DOCUMENTATION:
Document administration of meds and patient tolerance of the procedure on the Bedside Nurses Notes. Document the time of cannulae removal on the EPIC ECLS Flow Sheet. Place the completed Sedation Monitoring Record in the patient's chart.

Cannula Stenting Procedure:

PURPOSE:

To maintain patency of both the arterial and venous cannulas in the event the patient needs to be returned to ECLS support.

To maintain patency of the arterial limb of a VV cannula after a patient is converted from VV to VA ECLS.

EQUIPMENT:

- Luered perfusion adaptor (available in 1/4” and 3/8” only)
- Tubing clamps (4)
- Sterile sheers
- 0.45% normal saline with heparin 2units/ml

STEPS:

- Bring pump to idle flow.
- Remove patient from ECLS support.
- Double clamp arterial and venous lines.
- Cleanse the area between the clamps on each limb of the circuit using alcohol.
- Using sterile sheers, cut in between the two clamps on each line.
- Insert ¼ or ⅜ inch straight connector into circuit side of arterial and venous circuit tubing and connect circuit tubing together.
- Remove all tubing clamps.
- Re-circulate pump at flow of 500 ml/min.
- Disconnect gas from oxygenator.
- Check ACT to confirm over 200.

Cleaning Up and Putting Away ECLS Equipment:

PURPOSE:

To outline the ECLS team responsibilities when cleaning up ECLS equipment.

SUPPORTIVE DATA:

The entire ECLS cart and equipment needs to be cleaned thoroughly after each ECLS run and before being placed in storage. No unit stock supply items should be placed in the ECLS storage room after an ECLS run.

EQUIPMENT LIST:

- Towels.
- Red biohazard bags - at least two.

STEPS:

- Turn off power at pump console and unplug cart from power source.
- Disconnect any infusions.
- Unplug ECMO cart from power source at wall.
- Unhook gas lines from wall.
- Remove venous probe and replace back into housing on CardioHelp safety bar.
- Remove venous and arterial bubble sensors.
- Remove gas line from back of flow meter.
- Turn off CardioQuip heater and unplug both the body of the heater AND the lid. Disconnect the heater from CardioHelp oxygenator. Drain water from main tub as well as from heater hoses.
- Place clamped off circuit into a double-bagged biohazard bag. Be careful not to discard any clamps. Dispose of it in infectious (yellow) waste barrel.
- Wipe down and restock ECLS supply cart and bedside drawers. Clean syringe holder box and discard any open syringes.
- Return ECLS case box to store room if not already done so.
- After cleaning, return to ECLS storage:
- ECLS supply cart and bedside drawers
- Step stools, hats and shoe covers
- Syringe holder box and “Christmas Tree”
- Any other miscellaneous ECLS related items at the bedside
- Wipe down the ECLS cart using the “grey” sanitizer wipes and deliver the ECLS cart to the ECLS store room.
- Wash ALL clamps. Send ECLS shears to CPD for re-sterilization.

DOCUMENTATION: Document on EPIC ECLS Flow Sheet time clean up procedure was performed.

Rapid Deairing Procedure for CardioHelp:

PURPOSE:
To re-prime HLS pump-head in a severe air entrainment incident where ECLS flow/RPMs goes to zero.

EQUIPMENT LIST:
- Rapid de-airing line
- 0.5-1L Plasmalyte
- Waste Bag
- Large bore 12” pigtail

PROCEDURE:
- Remove yellow cap from de-airing port
- Turn RPMs to zero.
- Take patient off ECMO – clamp arterial outlet tubing at clamp symbol near HLS module and venous inlet tubing behind 3/8x3/8 luer.
- Attach 12” pigtail with waste bag and male connector to stopcock on luer on venous inlet tubing.
- Attach 0.5-1 L plasmalyte to rapid de-airing line via spike and prime – close white clamp on de-airing line.
- Attach other end of rapid de-airing line to oxygenator on HLS unit at the spring port – remove cap.
- Open white clamp on rapid de-airing line and rapidly push ~0.5-1L plasmalyte through the oxygenator and out the venous limb to waste bag to re-prime pump. **Make sure stopcock on venous luer is open to the waste bag!**
- Once majority of air is removed, turn stopcock off to the waste bag.
- Remove venous cannula clamp.
- Turn up RPMs as you release the arterial cannula clamp.
- Reset venous bubble alarm.
- Remove emergency rapid de-airing line and replace spring cap.
- Remove the waste bag apparatus from the venous luer and replace 6” pigtail and 3 ml syringe.
- **Replace yellow cap on the de-airing port.**

Hand Crank Procedure for CardioHelp:

PURPOSE:
Hand cranking is intended for emergency situations only (mechanical pump failure, electrical failure, or wall/internal battery failure). ***Hand cranking should never be performed when the pump has stopped due to air in the circuit.***

EQUIPMENT:
CardioHelp emergency drive

PROCEDURE: In the event of equipment power failure:

- Place hand crank on top of CardioHelp console in slot on handle
- Turn down RPMs to zero
- Clamp arterial outlet tubing
- Open safety guard on CardioHelp console
- Remove integrated sensor from HLS module
- Remove venous probe from inlet tubing and place in venous probe holder on CardioHelp safety guard
- Tighten yellow cap on de-airing port
- Remove HLS module from CardioHelp console and place in hand crank
- Remove arterial clamp as you begin to hand crank
- Loosen yellow cap on de-airing port

Going back on to CardioHelp:
- Tighten yellow cap on de-airing port
- Clamp arterial outlet tubing
- Remove HLS module from hand crank and replace in CardioHelp console
- Replace integrated sensor onto HLS module
- Turn up RPMs as you remove arterial clamp
- Loosen yellow cap on de-airing port
- Replace venous probe onto inlet tubing
- Close safety guard
- Remove hand crank from CardioHelp console

DOCUMENTATION:
- Time off and on ECLS.
- Time START and STOP hand cranking.
- Procedure performed
- Reason for hand cranking
- Patient response
- Any complications

BLEEDING AND HEMOLYSIS

Hemolysis:

BACKGROUND:

Hemolysis may be clinically suspected due to the presence of hematuria, hyperkalemia, anemia, renal failure, or jaundice. An elevated plasma free Hgb or any elevated reading associated with clinical evidence of intravascular hemolysis or circuit malfunction should be acted upon immediately and should be reported to the ECLS attending.

CAUSES OF HEMOLYSIS:

- Clot within the circuit, oxygenator, or cannulae causing fibrinolysis
- Inappropriate pump speed (RPM) settings
- Inadequate venous return. Venous access insufficiency occurs when flow into the circuit from the patient is inadequate for the pump speed (RPM). Poor venous return and high negative pressures may be related to patient position, cannula size, cannula position, or obstruction near the venous cannula. Blood flow into the circuit fluctuates with wide pressure swings which may result in damage to red blood cells. The venous line leading away from the patient may visibly shake or “chatter”.
- Mechanical shunts created across the ECLS bridge or with hemofiltration
- Blood group incompatibility

MANAGEMENT OF HEMOLYSIS:

If venous pressure exceeds -60mm Hg, turn down the RPM and determine the cause.

- Increase intravascular volume.
- Ensure that the cannula is not obstructed, kinked, or malpositioned
- If clots are present and there are signs of circuit DIC (thrombocytopenia, hemolysis, poor oxygenator function, low flow), consider changing the circuit.
- Check a blood type and screen to rule out an antibody reaction.
- Reset anticoagulation target.

If the arterial pressure exceeds +350, turn down the RPM and determine the cause of the high pressure.

- Ensure that the arterial cannula is not obstructed, kinked, or malpositioned

PREVENTION OF HEMOLYSIS:
Avoid high negative pressures by limiting RPM to 3000-3500. Use of a predetermined RPM is then a function of venous volume and resistance of the venous cannula.

Bleeding Management:

Obtaining Emergency Blood from the Blood Bank:

SUPPORTIVE DATA:
One unit of emergency PRBCs and platelets should be available for the ECLS patient in the blood bank at all times, and is ordered when the patient goes on ECLS.

Emergency blood specifications:

- ABORH typed & cross-matched
- Not washed
- Not irradiated
- (if more than one unit is needed, the blood bank will immediately issue more based on what is available and possible (crossmatched or uncrossmatched, type specific or not type specific). **O negative or typed/non-crossmatched blood is available immediately.**

STEPS:

- The nurses will acknowledge the "dispense" order and then go to blood bank to pick up the blood.
- The order has already been sent and EPIC will show that the product has been "selected".
- Order only if you need additional units.
- You should order and call if you need more than the one (1) unit in an emergency.

Bleeding Protocol:

IVH or bleeding greater than **5ml/kg/hr** will trigger the Level I portion of this protocol. Maintenance of the parameters listed may require transfusing multiple blood products simultaneously into the patient and ECLS circuit. It is preferable to transfuse products into the patient when possible.

Level I (5-10ml/kg/hr)		
Management	Frequency	Range
Heparin		10-60 units/kg/hr
Platelet count	Q 6-8hrs	>100,000
PT	Q 6-8hrs	≤15secs
PTT	Q 6-8hrs	50-70 secs
INR	Q 6-8hrs	<1.5
Hct	Q 6-8hrs	>35%
Fibrinogen	Q 6-8hrs	>150 mg/dL
ACT	qhr	170-190 sec
antiXa	Q 6-8hrs	0.3-0.5 units/mL
ATIII	Q am	>80%
D dimer	prn	

Bleeding 5-10ml/kg/hr:

Platelet count- Assessed every 6-8 hours. The platelet goal is 100,000. Platelets should be administered in quantities of 15-20 ml/kg for patients from 2-20kg. Patients > 20kg may require 1 or more units of platelets for replacement. Transfusions should always be given directly to the patient or when necessary at the platelet infusion site post oxygenator on the circuit. Recheck platelet count 15 minutes post transfusion.

Hct- The venous probe will be used to trend the patient's Hct. The venous probe must be calibrated. The Hct goal is ≥ 35%.

Fibrinogen- Assessed every 6-8 hrs. The fibrinogen should be maintained > 150 mg/dL. If less than 150mg/dL, treat with one unit of cryoprecipitate. If less than 100 mg/dL, treat with two units of cryoprecipitate.

Anti-factor Xa- Assessed every 6-8 hrs. This is the most accurate measurement of heparin effect. Titrate heparin to maintain range set by the ECLS physician. Standard anti factor Xa range is 0.3-0.7. The range should be tightened in the bleeding patient to 0.3-0.5. If there is a significant difference between the anti-factor Xa level and ACT, notify the ECLS physician. Generally significant differences between the two are due to platelet or clotting factor deficiencies and will improve as these issues are addressed. *If a heparin rate change or bolus*

has been given, wait a minimum of three hours before checking the anti-factor Xa level.

Antithrombin III- Assessed daily. Replace AT-III if level < 80%. Monitor ACTs every 30 minutes during infusion. A vial of AT-III is ~500 units. Approximate dosing is 1vial/8kg.

PT/INR- Assessed every 8-24 hrs. The PT should be ≤ 15 seconds, INR< 1.5. The PT can be prolonged in DIC, liver disease, vitamin K deficiency, deficiency of clotting factors, polycythemia or with use of argatroban. While treatment with heparin does not normally prolong the PT, the PT may be transiently elevated following a bolus of heparin. If greater than 15 seconds, treated with FFP (20ml/kg for patients < 10 kg or 1 or more units for patients > 10kg).

PTT- Assessed every 8-24 hrs. If the PTT is prolonged, consider decreasing the heparin rate. *If a heparin rate change or heparin bolus has been given, wait a minimum of three hours before checking PTT.* If unresponsive to decreasing heparin or there are signs of DIC, consider transfusion of cryoprecipitate or FFP.

D-dimer- Elevated D-dimer levels, reflecting degradation of cross-linked fibrin, are the most common abnormal parameter in patients with DIC. However, this finding is not specific for DIC, as there are multiple other causes for an elevated D-dimer level. Treatment for elevated D-dimer is correction of the underlying cause. In the ECMO patient with bleeding and DIC, clotting factors can be replaced by either FFP or cryoprecipitate. FFP provides both procoagulant and anticoagulant proteins. Cryoprecipitate has higher concentrations of factor VIII and fibrinogen, and can be used to correct hypofibrinogenemia.

Level II (>10ml/kg/hr)		
Management	Frequency	Range
Heparin		0-60 units/kg/hr
Platelet count	Q 4hrs	>150,000 >100,000 (cardiac patient)
PT	Q 4hrs	≤ 15 sec
PTT	Q 4hrs	45-60 secs
Hct	Q 4hrs	>35%
Fibrinogen	Q 4hrs	>200 mg/dL
ACT	Q 1hr	160-180 secs
Anti Factor Xa	Q 6hrs	0.3-0.4 units/mL

Bleeding > 10ml/kg/hr:

Heparin- Heparin should remain at rate necessary to attain Anti Factor Xa at a low range of 0.3-0.4. Consider turning the heparin off if the circuit is < 48hrs old. Keep pump flows high through the oxygenator and create a shunt through the bridge to reduce flows to the patient.

Platelets- The platelet goal is increased to 150,000. In a post-op cardiac patient, check platelet parameters with the CV surgeon.

PT-The PT should remain < 15 secs. Treat with FFP if necessary.

PTT- If the PTT is prolonged, consider decreasing the heparin rate. Transfuse with FFP if necessary. If a heparin rate change or heparin bolus has been given, wait a minimum of three hours before checking the PTT.

Hct- The Hct goal is > 35%.

Fibrinogen- The fibrinogen should be maintained > 200mg/dL. If less than 200 mg/dL, treat with one unit of cryoprecipitate. If less than 150 mg/dL, treat with two units of cryoprecipitate.

ACT- The ACT range should be adjusted according to anti Factor Xa levels (goal 0.3-0.4).

With the ECLS patient that is bleeding > 10ml/kg/hr, blood product administration should be provided at a 1:1:0.5 ratio (PRBC: FFP: platelets). This concurrent therapy more closely replaces the whole blood that is being lost. With large transfusions of blood or FFP preserved in CPD, calcium chloride may be needed in a ratio of 0.5mg calcium chloride to every 1 ml of blood product administered. Ionized calcium levels should be quantified by iSTAT.

Monitoring ECLS Patient Off Heparin:

This protocol is intended for use in circuits < 48 hours old and heparin bonded.

- Heparin is initiated or discontinued under the direction of the ECLS physician.
- Notify ECLS physician when ACTs fall to < 160 or by 6 hours off heparin, whichever occurs first.
- Re-initiate heparin drip at 10 units/kg/hr.
- Monitor anti Xa, CBC, coags, and fibrinogen within an hour of initiating ECLS and then q 4hrs.
- Replace platelets and coagulation factors as indicated below:
    - Platelets > 100,000
    - INR < 1.5
    - PTT 50-70
    - Fibrinogen > 150
- Monitor ACTs hourly
- After eight hours on heparin of 10 units/kg/hr, if bleeding has decreased significantly or stopped, increase heparin to 15 units/kg/hr and titrate to maintain anti Xa 0.3-0.5.
- Monitor bleeding for another eight hours with these anticoagulation goals. If there is not an increase in bleeding, convert to the non-bleeding patient protocol.
- At the start of a platelet or cryoprecipitate infusion, bolus with 10 units/kg of heparin if ACT is < 150. Monitor ACTs q 30 minutes throughout the infusion. Re-bolus every 30 minutes during infusion if ACT is < 150.
- Monitor AT-III levels q am. Replace AT-III if level < 80%. Monitor ACTs q 30 minutes during infusion. Consider monitoring q 12 hours if unable to reach levels >80%.
- A vial of AT-III is ~500 units; Approximate dosing is 1vial/8kg, though we typically use a full vile even in neonates.

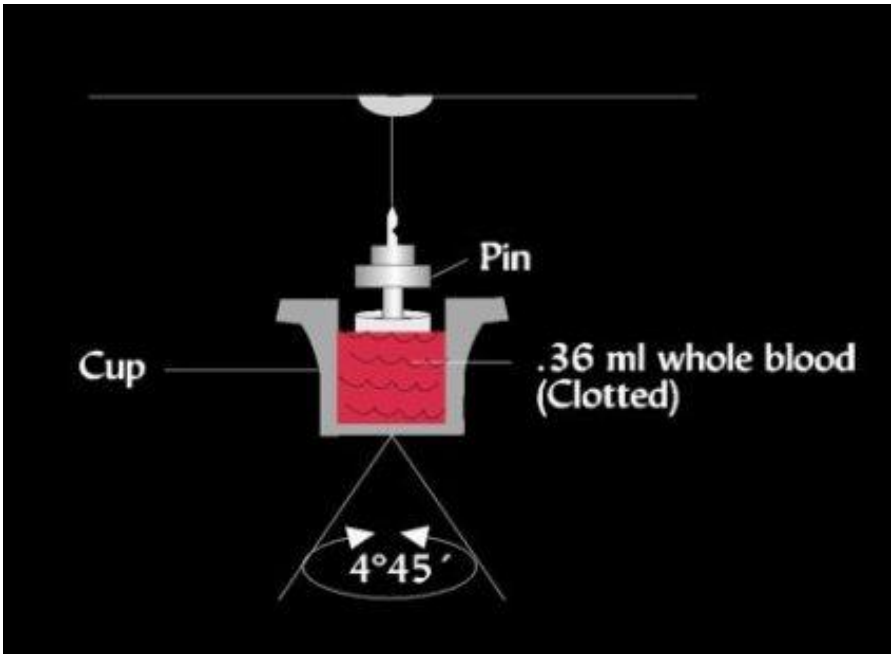
Thromboelastography (TEG):

OVERVIEW

- TEG is a viscoelastic hemostatic assay that measures the global visco-elastic properties of whole blood clot formation under low shear stress
- TEG shows the interaction of platelets with the coagulation cascade (aggregation, clot strengthening, fibrin cross linking and fibrinolysis)
- TEG does not necessarily correlate with blood tests such as INR, APTT and platelet count (which are often poorer predictors of bleeding and thrombosis)

METHOD

- TEG® measures the physical properties of the clot in whole blood via a pin suspended in a cup (heated to 37C) from a torsion wire connected with a mechanical–electrical transducer
- The elasticity and strength of the developing clot changes the rotation of the pin, which is converted into electrical signals that a computer uses to create graphical and numerical output
- TEG is a point of care test (quick, takes around 30min)
- TEG can be repeated easily and compared and contrasted
- TEG requires calibration 2-3 times daily
- TEG should be performed by trained personnel
- TEG is susceptible to technical variations

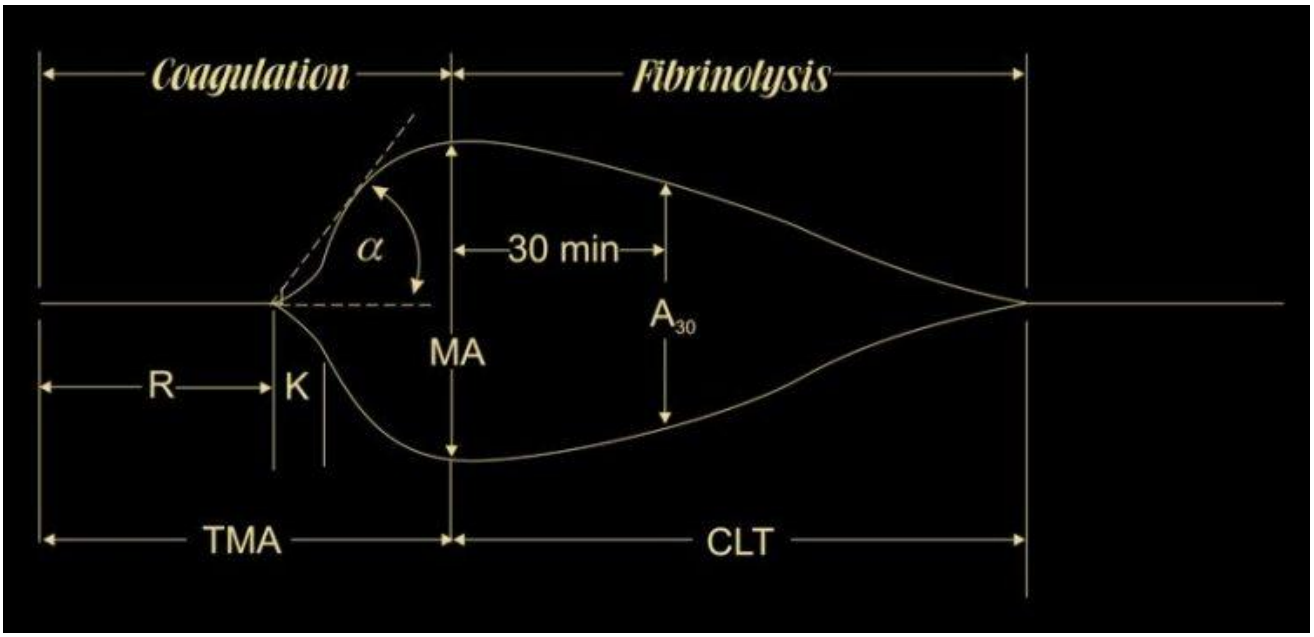


USE

Indications

- prediction of need for blood product transfusion
- guide anticoagulation strategy

NORMAL TEG



Specific parameters represent the 3 phases of the cell-based model of hemostasis: initiation, amplification, and propagation

- R value = reaction time; time of latency from start of test to initial fibrin formation (amplitude of 2mm); i.e. initiation
- K = kinetics; time taken to achieve a certain level of clot strength (amplitude of 20mm); i.e. amplification
- alpha = angle (slope between R and K); measures the speed at which fibrin build up and cross linking takes place, hence assesses the rate of clot formation; i.e. thrombin burst
- TMA = time to maximum amplitude(s)
- MA = maximum amplitude (mm); represents the ultimate strength of the fibrin clot; i.e. overall stability of the clot
- A30 or LY30 = amplitude at 30 minutes; percentage decrease in amplitude at 30 minutes post-MA and gives measure of degree of fibrinolysis
- CLT = clot lysis time (s)

IMPORTANT PATTERNS

Normal
R;K;MA;Angle = Normal

Anticoagulants/hemophilia
Factor Deficiency
R;K = Prolonged;
MA;Angle = Decreased

Platelet Blockers
Thrombocytopenia/
Thrombocytopathy
R ~ Normal; K = Prolonged;
MA = Decreased

Fibrinolysis (UK, SK, or t-PA)
Presence of t-PA
R ~ Normal;
MA = Continuous decrease
LY30 > 7.5%; WBCLI30 < 97.5%;
Ly60 > 15.0%; WBCLI60 < 85%

Hypercoagulation
R;K = Decreased;
MA;Angle = Increased

D.I.C
Stage 1
Hypercoagulable state with
secondary fibrinolysis

Stage 2
Hypocoagulable state

TEG AS A GUIDE TO TREATMENT

- Increased R time (5-10 min reference range) => FFP

- Decreased angle or increased K; (K 1-3 min reference range, Angle 53-72 degrees reference range) => cryopreciptate
- Decreased MA (50-70 reference range) => platelets
- Fibrinolysis (LY30: 0-8% reference range) => tranexamic acid (TXA)

VALUE	Clinical cause	Treatment Considerations
R > 10 minutes (nl 5-10 min)	Factor deficiency, hemodilution, anti-coagulation	FFP – amount to be transfused dependent of how significantly R is prolonged
R < 5 minutes	Hypercoaguability	Consider increase anticoagulation
K > 3 minutes (nl 1-3 sec); angle <53 (nl 53-72)	Hyperfibrinogenemia and/or poor platelet function	Consider cryoprecipitate
MA < 50 mm (nl 50-70)	Poor platelet function, thrombocytopenia, low fibrin	Consider platelet transfusion
LY30 > 8%	Fibrinolysis	Consider TXA

CHANGING OUT CARDIOHELP CIRCUIT COMPONENTS

Changing Pigtails:

PURPOSE:

To outline the ECLS team responsibilities when changing ECLS circuit pigtails.

SUPPORTIVE DATA:

Pigtail tubing will be changed when damaged or when blood clotting has occurred inside the tubing. The pigtail may be clamped first, and then changed non-emergently.

EQUIPMENT LIST:

- One sterile pigtail; 6 or 12 inch.
- One 3 ml syringe.
- One sterile 2-way stopcock or 3-way luer lock stopcock.
- Flush solution.
- Small padded hemostat.
- 2 large tubing clamps.
- Eye and mucus membranes protection.
- Gloves.

STEPS:

- Identify damaged or clotted pigtail tubing.
- Clamp small padded hemostat on old pigtail tubing.
- Gather necessary equipment.
- Draw up flush solution in 3 ml syringe
- Connect a new stopcock to new pigtail tubing and flush with flush solution to clear stopcock and tubing of air. Leave 3 ml syringe in place.
- Place patient on ventilator settings necessary for support off ECLS and notify neonatologist or intensivist immediately for additional care that patient may require until procedure completed.
- Take the patient off ECLS.
- Turn pump flow to zero.
- Clamp circuit tubing above and below the pigtail to be changed, using tubing clamps. NOTE: ONLY PIGTAIL THAT CAN BE CHANGED ON CARDIOHELP IS THE PIGTAIL ON THE VENOUS LUER.
- Put on protective face wear and gloves
- Remove the damaged pigtail and discard appropriately after removing the hemostat.
- Twist new pigtail into place.

- Remove tubing clamps.
- Aspirate back on the stopcock to remove any air, using the 3 ml syringe, flush.
- Turn the stopcock off to the pigtail.
- Remove yellow de-airing cap
- Place patient back on ECMO
- Turn up pump flow and allow any remaining bubbles to be removed by the oxygenator.
- Reset venous bubble alarm if needed
- Re-establish previous ECLS flow rate.
- Wean ventilator to previous ECLS support settings.

DOCUMENTATION:
Document on the Bedside Nurses Notes how the patient tolerated coming off ECLS, including vital signs, pulse oximeter reading color, amount of support needed, etc. Document on ECLS Flowsheet reason for changing pigtail, length of time off ECLS, and who performed the procedure.

Changing Circuit Connectors:

PURPOSE:

To outline the ECLS team responsibilities when changing circuit connectors.

SUPPORTIVE DATA:

Connectors in the circuit will be changed when damaged or leaking. If the procedure is delayed for any reasons: switch the heparin infusion over to the patient at the same rate and transfer maintenance IV fluids/HA to patient to prevent hypoglycemia and hypovolemia.

EQUIPMENT LIST:

- Appropriate size and type of connector.
- Povidone iodine swabs.
- Tubing shears – sterile.
- 4 tubing clamps.
- Tie gun.
- Cable ties.
- 60 ml syringe and large jelco.
- Flush solution.
- Eye and mucus membrane protection.
- Sterile gloves.

STEPS:

- Identify damaged circuit connector.
- Remove yellow de-airing cap
- Turn pump flow to zero.
- Place patient on appropriate ventilator settings for support off ECLS and immediately notify neonatologist or intensivist to provide any necessary additional care to patient until procedure is completed
- Take the patient off ECLS
- Gather necessary equipment.
- Draw up flush solution in 60 ml syringe.
- Clamp circuit with 2 clamps 1½ inches above and 2 clamps 1 ½ inches below the connector to be changed using tubing clamps. Leave enough tubing between damaged connector and clamp to allow for insertion of new connector.
- Cleanse tubing around old connector with alcohol solution and allow to dry.
- Put on protective face wear and sterile gloves.
- Cut between clamps above and below damaged connector, and remove damaged connector.

- Place new connector in one end of tubing. Slide tubing up to the second notch on the connector.
- Back fill connector with flush making sure there are no bubbles.
- Drip flush solution over connector and tubing as second new connection is made.
- Remove circuit clamps.
- Place Patient back on ECMO.
- Turn up pump flow and allow any bubbles to be removed by the oxygenator. Reset venous bubble detector as needed.
- Reduce ventilator settings gradually to “rest” settings as ECLS flow is gradually increased to previous flow rate.
- Tie band new connector at both ends.

DOCUMENTATION:
Document on the Bedside Notes how the patient tolerated coming off ECLS including vital signs pulse oximeter reading, color, amount of support needed, etc. Document on EPIC ECLS flow sheet reason connector change, length of time off ECLS, and who performed the procedure.

Changing a Trifuse:

PURPOSE:

To outline the ECLS team responsibilities when changing the IV trifuse on the ECLS circuit (if present). Eye and mucus membrane protection is advisable when accessing the circuit.

SUPPORTIVE DATA:

The IV trifuse on the ECLS circuit shall be changed if necessary due to evidence of a clot or leak.

EQUIPMENT:

- Sterile trifuse device.
- 3 ml syringe.
- Flush solution.
- Small padded hemostat.
- 2 – way stopcock for trifuse.

STEPS:

- Gather necessary equipment.
- Draw up flush in 3 ml syringe.
- Flush sterile trifuse with flush, expelling all air from all ports.
- Remove old trifuse, twisting off at luer lock connection.
- Twist on new device, remove any air bubbles.
- Connect IV tubing to trifuse
- Unclamp tubing, check all connections for leaks or blood backflow.

DOCUMENTATION:
Document date and time of trifuse change in narrative section on ECLS flowsheet as well as the ECLS circuit maintenance log.

Changing ECLS Stopcocks:

PURPOSE:

To outline the ECLS team responsibilities when changing ECLS circuit stopcocks.

SUPPORTIVE DATA:

ECLS ACT sample site stopcocks must be changed every 48 hours or prn during day shift. Only luer-lock stopcocks found in the ECLS bedside cart will be used. Other stopcocks can be changed after discussion with the ECLS Attending. Eye and mucus membrane protection must be worn when accessing the positive pressure side of the circuit (from pump to patient).

EQUIPMENT LIST:

- One sterile luer lock 2 or 3-way stopcock depending on location of circuit.
- Small padded hemostat.
- 1 male/female luer lock adapter caps (for 3-way stopcock change only).
- Flush solution in 3 ml syringe.

STEPS:

- Gather necessary equipment
- Draw up flush solution in 3 ml syringe
- Prepare new stopcock by flushing with flush solution, expelling all air from all parts of the stopcock. Leave 3 ml syringe in place.
- Cap any remaining open ports with non-venting caps.
- Clamp the pigtail with a small padded hemostat only. Tubing clamps are non-occlusive on such small diameter tubing.
- Unscrew stopcock to be changed and discard in proper receptacle.
- Screw new stop-cock into the tubing securely and leave 3 ml syringe in place.
- Remove the hemostat from pigtail.
- Aspirate slightly with 3 ml syringe to remove any air bubbles.
- Turn stopcock off to pigtail and leave flush syringe in place.

DOCUMENTATION:
Document time and site of stopcock change on the ECLS flowsheet and the ECLS circuit maintenance log.

Changing CardioHelp Circuit:

PURPOSE:

To outline the ECLS team responsibilities when switching circuits while a patient is on ECLS.

SUPPORTIVE DATA:

This procedure allows switching of the ECLS patient from an existing CardioHelp circuit to a newly primed circuit. Changing the ECLS circuit during an ECLS run may be indicated in the following incidences:

- Clots
- Circuit wear
- Oxygenator failure
- Elevated plasma free Hgb and evidence of circuit DIC

EQUIPMENT:

- Newly blood primed CardioHelp circuit and cart. May be only crystalloid primed for larger pediatric patients
- 4 circuit clamps of appropriate size
- Sterile ECLS circuit shears (2)
- Sterile 3/8" or ¼" straight connectors (2)
- Alcohol swabs
- Large syringe of flush solution (2) with Jelcos
- Eye and mucus membrane protection
- Gloves
- Ty-gun and bands
- Sterile end caps (3/8"or ¼").

STEPS:

- Follow CardioHelp crystalloid and blood priming guidelines.
- Bring the newly primed CardioHelp ECLS circuit and cart into place in front of the old CardioHelp ECLS circuit and cart.
- Remove yellow de-airing cap from the de-airing port on the newly primed circuit
- On the newly primed circuit, open the clamshell using **sterile technique** and place (2) 3/8" or ¼" clamps on both the venous and arterial lines.

Separate new circuit from clamshell using the quick-action couplings (if present) or by cutting between the clamps.

- Using sterile shears, cut away the quick-action couplings on both the A and V lines (if present), and place 3/8 x ⅜ or ¼ x ¼ straight connectors on both A and V lines. Fill ends with flush solution.
- Take patient off ECLS by turning flow to zero and clamping both the arterial and venous lines near the CardioHelp console.
- Place two circuit clamps approximately 2 inches apart **above the cannula connector luers of the old circuit** on both A and V lines. Swab in between areas of both lines with alcohol and allow to dry.
- With protective face-wear on, cut the A and V tubing in the middle of the clamped areas.
- Airlessly, connect the newly primed venous ECLS line to the old venous ECLS line and remove clamps.
- Airlessly, connect the newly primed arterial ECLS line to the old arterial ECLS line and remove clamps.
- Place patient back on ECMO by removing the venous clamp on the new CardioHelp circuit, and then slowly removing the arterial clamp on the new circuit as you increase ECLS flow back to previous level.
- **Be prepared to straight transfuse 1-2 units of PRBCs immediately to maintain adequate Hgb if new ECLS circuit was not blood primed.** May need to also consider exchange transfusion technique if volume overload is a concern. If exchange transfusion is required, remove equal volumes of blood from ECLS circuit via pre-oxygenator port as PRBCs are transfused into the patient.
- Place ty-bands on all new connections.

DOCUMENTATION:
Document on ECLS Flow Sheet time and reason for circuit change and who performed the procedure. Document procedure in medical progress notes.

Off-Bypass Procedures:

PURPOSE:

To outline the ECLS team responsibilities when a patient is taken off ECLS.

SUPPORTIVE DATA:

Patients will be taken off ECLS in the event of emergencies that require adjustments in the circuit. Coming off ECLS, even briefly, can produce untoward effects such as acidosis, hypoxemia, bradycardia, or respiratory deterioration and should only be done in the event of an emergency or according to ECLS policy. ***A physician should be called to the bedside whenever a patient is taken off ECLS***.

EQUIPMENT LIST:

- Tubing clamps
- Necessary supplies to correct identified problem in the ECLS circuit.

STEPS:

Taking a patient off bypass:

- Increase ventilator settings and pressors (if patient will be off ECLS for significant time)
- Clamp patient off bypass:
    - Clamp Arterial line on clamp symbol near HLS module
    - Clamp Venous line on clamp symbol near HLS module

Returning a patient to bypass:

- Remove clamp on venous line
- Slowly turn up RPMs as you slowly remove clamp on arterial line

Additional steps if patient is off bypass for more than 15 minutes:

- Turn off gas flow to membrane oxygenator to prevent super saturation and the formation of microbubbles.
- Turn off water heater.
- Transfer all infusions, including heparin to patient.
- Check a patient ACT. IF ACT is below set parameters, start the heparin infusion into a patient line at the same rate it was infusing into the ECLS circuit.
- If ACT is extremely low, a heparin bolus to the patient may be indicated. See ECLS Procedure: Heparin Therapy.

DOCUMENTATION:
Document on the Bedside Nurses notes how the patient tolerated coming off ECLS, including vital signs, pulse oximeter, color, amount of support needed etc.
Document indication for coming off ECLS on ECLS flowsheet.

MEDICAL CONSIDERATIONS FOR THE ECLS PATIENT

- **Myocardial Stun:** Acute loss of preload and sudden increase in afterload following ECLS initiation can lead to worsened cardiac function and cause minimal to no pulse pressure. Expected time to recovery is 3-7 days.

- **Ventricular distension:** If the left ventricular function is inadequate to open the aortic valve, left ventricular diastolic pressure and left atrial pressure will gradually increase, as the left side of the heart fills with bronchial venous flow. When the left atrial pressure reaches 25-30 mmHg, pulmonary edema will ensue. This process takes 4-8 hours in most cases. Additionally, increased intracavitary pressure may decrease myocardial perfusion pressure and cause subendocardial ischemia. Decompression should be considered, via a left ventricular vent or catheter based creation and/or dilation of an atrial communication (e.g. septostomy).

- **Cardiac cannulas:** Cardiac cannulas are supplied by the CV surgical team/perfusionists. For certain cardiac cannulas, a 3/16" x ¼" straight connector needs to be used to attach the cardiac cannula to the ECLS circuit via the cannula connector. These straight connectors are stored in the bedside ECLS cart.

Cardiovascular assessment and monitoring
Rhythm and Heart rate

- Dysrhythmia resulting in no cardiac ejection, can lead to ventricular distension and its complications.
- Conversion to sinus rhythm/ atrioventricular synchrony generally reduces myocardial demands and promotes ventricular recovery.

Blood pressure

- The patient's blood pressure is determined by two modifiable factors; blood flow (pump flow plus native cardiac output), and vascular resistance.
- Due to narrow pulse pressure, the mean systemic arterial pressure will be lower than normal mean arterial pressure.
- Adequacy of support is determined by assessment of standard clinical parameters of cardiac output and oxygen delivery: capillary refill, warmth and color of extremities, urine output and neurological status.
- Exact ideal blood pressure targets are not known, but initial targets can be based on predicted mean values for age and size, premorbid mean blood pressure (if known) and anatomical and physiological factors, which would then be titrated to surrogate markers of adequate oxygen delivery (lactate, NIRS).

- Blood flow is managed to maintain the venous saturation 70-80%.
- Pulse pressure: In order to maintain some flow through the heart and lungs and prevent intracardiac and pulmonary thrombosis and LAH, flow is maintained around 80% of venous return, this is reflected by a pulse contour of about 10mmHg.
- Changes in arterial waveform can reflect myocardial recovery, or an acute complication (circuit dysfunction, reduced preload, increased afterload).

Inotrope/ Vasoactive Medications: The requirement for vasoactive agents is almost universal in patients about to undergo extracorporeal support. After ECMO initiation, some patients will require ongoing vasoactive support, albeit at lower levels, to support cardiac function and end-organ perfusion.

- Enhancement of contractility in a patient severe cardiac dysfunction, in order to facilitate aortic valve opening and prevent stasis of blood in the systemic ventricle and aortic root (Epinephrine, Dobutamine).
- Peripheral vasoconstriction in a patient on VA ECMO for septic shock, on maximal circuit blood flow with inadequate systemic perfusion (Norepinephrine, vasopressin).
- Peripheral vasodilation to reduce afterload and improve circuit blood flow and systemic perfusion (Phentolamine, nitroprusside).

Central venous pressure and fluid management

The CVP trend is a simple method of estimating intravascular volume status. CVP combined with circuit characteristics and function (increasingly negative venous pressure, low flow, circuit “chatter”) will assist with guiding fluid management.

- A low CVP coupled with impaired device flow is generally a signal to replace intravascular volume.
- A high CVP with impaired flow should prompt a search for conditions such as pericardial tamponade.
- A high CVP with preserved flow indicates hypervolemia and diuretics and/or hemofiltration should be considered.

However, these generalizations must also be qualified by recognizing the limitation of CVP- as it reflects not only volume status, but is also affected by cardiac and vascular compliance, and studies have noted poor correlation between CVP and actual cardiac filling volume. Volume repletion may improve circuit function, but the patient and circuit should be reassessed for potential causes of impaired venous flow such as tamponade or cannula obstruction.

Ventilation management

The primary objective is to minimize lung injury and optimize lung function in order to allow separation from ECLS once cardiac recovery has occurred.

- Suggested protective lung strategy: Pressure limited ventilation, elevated levels of positive end expiratory pressure (PEEP 10cm02), maximum tidal volume 6-8mls/kg, peak inspiratory pressures 18-20cm H20, with low rate (generally 10bpm). Meticulous pulmonary hygiene is essential.
- No single ventilation strategy is universally practiced, and the suggested target may be inappropriate in patients with an open sternum, poor lung compliance, pulmonary hemorrhage or intrathoracic hematoma.
- It may be appropriate to allow spontaneous breathing or extubate in the absence of lung pathology if a patient is cannulated peripherally (particularly for an adult size patient with femoral cannulation).
- Adjuncts to mechanical ventilation include bronchoscopy and prone positioning.
- If there is a major pulmonary air leak or interstitial emphysema, the ventilator pressure can be reduced or turned off altogether for hours or days until the leak seals. This will lead to significant atelectasis in addition to the primary lung disease. If the patient develops a pneumothorax, placement of a chest tube is not an automatic response. Even placing a small tube may result in significant bleeding ultimately requiring thoracotomy. A small pneumothorax (less than 20%) with no hemodynamic compromise is best treated by waiting for absorption. An enlarging pneumothorax or a pneumothorax causing hemodynamic compromise requires external drainage.

Managing gas exchange with the ECLS circuit

On VA ECLS, arterial blood gases reflect mixing of returning circuit blood flow with the native cardiac ejection in the aorta. The returning circuit blood is typically PCO2 40 mmHg, PO2 300mmHg, saturation 100%. The ratio of returning circuit blood flow to native cardiac blood flow is typically 8:1 (near total bypass).

Anticoagulation and bleeding

- Bleeding is a common problem and associated with increased mortality risk.
- Bleeding can impair circuit function due to inadequate preload due to hypovolemia or tamponade physiology.
- Risk factors include mediastinal exploration prior to ECLS, greater surgical complexity, early post-operative cannulation and longer bypass time. If intrathoracic bleeding occurs in a patient cannulated through the neck with a closed sternum, there should be a low threshold for opening the chest in

the ICU, re-exploring the operative sites, evacuating clot, and controlling bleeding as much as possible.

- Prevention of bleeding is important throughout the ECLS course. Care providers may forget that simple venipuncture, endotracheal suctioning, passage of a catheter through the nose or urethra, can lead to uncontrollable bleeding. Because of ample blood access there is very rarely any need for needle punctures in ECLS patients. Suctioning and passage of catheters should be done with caution, and only after assuring that the anticoagulation status is optimal (low ACT, adequate platelet counts). If invasive procedures are necessary, appropriate preparation is essential.

Management of bleeding

- Identify causes that are surgically correctable (e.g. a bleeding vessel at a cannulation site).
- Transfuse platelets to greater than 100,000
- Decrease level of anticoagulation; ACT target reduced to 160-180 seconds, or as low as 140-160 seconds.
- Antifibrinolytic therapy: reduces bleeding associated with activation and dysregulation of fibrinolysis in major surgery and trauma. At present, data to support routine use of antifibrinolytic therapy during ECLS is lacking, however as an adjunct to blood product and coagulation factor therapy may help reduce bleeding, particularly after surgery.
    - Tranexamic acid 100mg/kg bolus then 10mg/kg/hr.
    - Fresh frozen plasma or specific clotting factors may be indicated if deficiencies are demonstrated.
    - Recombinant factor VIIa (rFVIIa) has been used for torrential bleeding. Careful consideration must be given prior to rFVIIa administration, as the thromboembolic risk has not been established in the setting of ECLS and may be associated with acute circuit thrombosis.

If bleeding remains uncontrolled it is reasonable to stop anticoagulation altogether. This may stop the bleeding but may also result in clotting in the circuit, **so whenever anticoagulation is turned off a primed circuit should be available.**

Life threatening or uncontrollable bleeding may require the discontinuation of ECLS.

Specific sites of bleeding

- Cannulation site: This is the most common site of bleeding, particularly if access has been gained by direct cutdown. Bleeding at the cannulation site may be an indication that the cannula is loose or pulling out. The

possibility of decannulation should always be considered. Usually cannula site bleeding is slow oozing related to disruption of small vessels in the skin or subcutaneous tissue. Topical pressure will often control the bleeding. If bleeding persists after direct cutdown access, the wound should be re-explored.

- Chest drain site: Bleeding post chest tube placement: Bleeding is a common complication even if all appropriate steps are taken during tube placement. It may occur early or after days.
- Surgical site: The second most common site of bleeding is related to recent operations, particularly thoracotomy if the patient is on ECLS for postoperative cardiac failure. In this circumstance (particularly when going directly from CPB to ECLS) the first step is to place suction catheters in the operative site, seal the site with an occlusive plastic drape, and collect the blood to quantitate the rate of bleeding.
- When going directly from CPB to ECLS in the OR, it is reasonable to wait until the ACT is normal or bleeding stops before starting anticoagulation. When the platelet count, ACT, and other medications are optimal, the operative site should be re-explored for active bleeding. When an operative site is explored for bleeding it is best to leave the site open with active drainage and a plastic seal closure, rather than surgical closure of the skin.
- Gastrointestinal: Bleeding can occur from esophagitis, gastritis, duodenal ulcer, or other sources. It is important to determine the site of bleeding. If the site of bleeding can be reached by an endoscope or arterial catheter, local measures should be attempted. The decision to operate to control bleeding or excise the bleeding organ is the same as in any patient with GI bleeding and a systemic coagulopathy. The coagulopathy is corrected as much as possible, and then operation is indicated if uncontrolled bleeding persists.
- Neurological: Bleeding into the head or brain parenchyma is the most serious ECLS complication. It is usually extensive and fatal.

Neurologic Complications

- Neurologic complications may occur more commonly in the congenital heart disease patient population, and vigilance for neurological complications is essential.
- Screening cranial ultrasounds and more definitive neuroimaging (CT head) can detect intracranial haemorrhage or embolic events.
- Continuous EEG monitoring may be considered in patients who underwent neonatal cardiopulmonary bypass.

Analgesia and sedation

Analgesia and sedation strategies for ECLS patients are similar to strategies for

all critically ill children, with a major trend towards minimizing sedation, allowing spontaneous movement and ventilation, and facilitating neurological assessment. Dosing requirements may be elevated, as drugs may be absorbed into the circuit, tolerance can develop, and hemofiltration may remove administered drugs.

Fluids and renal replacement therapy

The balance between adequate intravascular volume for ECLS circuit function and the development of progressive interstitial edema is challenging. Excess interstitial edema leads to organ dysfunction, contributing to worsening cardiac, pulmonary, gastrointestinal and renal function, and prolongs time on ECLS.

Spontaneous or pharmacologic diuresis should be instituted, with the goal of resolution of edema and returning patients to their dry weight. If the response is inadequate or the patient develops renal failure, hemofiltration can be incorporated into the ECLS circuit.

Nutrition

- Adequate caloric and protein nutritional support, as with all critically ill patients, is essential.
- Enteral nutrition in patients receiving venoarterial ECLS is well tolerated, provides adequate nutrition, is cost effective, and has minimal risk.
- Initiation of enteral nutritional support should begin after resuscitation is complete and perfusion is restored (usually within 12-24 hours).
- Parenteral nutrition can be used when the enteral nutrition is contraindicated (e.g. mechanical obstruction, bowel ischemia).

Procedures

When a procedure is necessary, coagulation should be optimized (anticoagulation minimized). Even small operations like chest tube placement are done with extensive use of electrocautery. For the surgeon, the procedure is like operating on any coagulopathic patient.

Weaning, Trials off and Discontinuing Pediatric Cardiac ECLS

Separating from ECLS is a complex process that is affected by multiple patient, circuit and system factors, and requires careful planning and assessment starting from the time of ECLS initiation.

Successful ECLS weaning is generally defined as survival after discontinuation of ECLS without the need for re-initiation of mechanical support for the next 48 hours.

Timing of ECLS wean

- Local factors: determined by the ability of the ECLS team to care for the patient on ECLS support without contributing to the burden of complications.
- Length of support: Most myocardial recovery occurs in the first two weeks of support. Additional gains become less likely after this period and should prompt a discussion about length of support, and if transition to VAD is indicated as a bridge to recovery or cardiac transplantation.
- Indication for support: the clinical course of myocardial dysfunction is a major determinant of the expected timing of recovery and ultimate removal of ECLS.
- Primary myocardial dysfunction: recovery occurs over weeks to months, or not at all. ECLS may not be the best form of mechanical support beyond two weeks, if sufficient myocardial recovery has not occurred, and conversion to VAD should be considered.
- Recovery from myocardial dysfunction after cardiac surgery: Myocardial injury after cardiac surgery and cardiopulmonary bypass consists of inflammatory, ischemia-reperfusion, and surgical insults, and is thought to peak around 24 hours. Generally, the patient is supported for at least 48 hours with adequate tissue oxygen delivery, LV decompression, hemostasis, correction of metabolic disturbances and exclusion of residual lesions. Patients with pre-existing myocardial dysfunction prior to cardiac surgery may require a longer period of support to recover adequate cardiac function.

- Perception of prognosis: Cannulation onto ECLS often occurs rapidly without a full understanding of the cause for deterioration. It may become apparent that there is limited or no reasonable therapeutic options or likelihood of recovery. Perceptions of prognosis often differ between team members, and these decisions benefit from a team approach.
- Capacity to go back on support: If there is technical or logistical barriers to rapid return to ECLS support, such patients may require further optimization, and a greater certainty of successful weaning prior to decannulation.

Predictors of successful weaning

- A general approach is to assess for evidence of myocardial recovery and resolution of complicating factors (SIRS, pulmonary dysfunction). Evidence of myocardial recovery includes: increasing pulse pressure, increasing systolic pressure, and improving function on echocardiography.
- Echocardiography: Function measured by echocardiography while on full flow ECLS does not predict myocardial performance when loading conditions are altered on low flow or following decannulation.

- In patients whose support includes a left atrial vent or atrial septostomy the following can suggest left ventricular recovery.

  a) Lower left atrial vent flows,

  b) Drop in circuit mixed venous oxygen saturation

  c) Increased left ventricle native ejection when the atrial vent is clamped or removed.

Weaning Trial Optimization

For clinical parameters and echocardiography to accurately reflect adequate cardiac function off mechanical support, myocardial loading conditions must be optimized.

Specific echocardiographic physiological conditions prior to the wean should closely approximate those after decannulation. This process will often start several hours prior to the weaning trial.

- Low dose inotropes and vasopressors in-line with enough time to reach the patient.
- Confirm endotracheal tube position and function, resume conventional ventilation and ensure adequate recruitment and tidal volumes. In patients at risk of pulmonary hypertensive crises, inhaled nitric oxide should be initiated.
- Pacemaker wires should be tested and connected to the pacemaker box.
- Correction of all metabolic abnormalities, in particular potassium, magnesium, phosphate, calcium and glucose.
- Anticoagulation should be titrated to minimize the likelihood of thrombus formation at lower flows. Thrombocytopenia and hypofibrinogenemia should be corrected prior to surgical manipulation.

Weaning trial

There are various strategies to reduce the contribution of the ECLS circuit to assess suitability for decannulation. For either strategy, adequacy of ventricular function is assessed by echocardiography, cardiac output, oxygenation and ventilation.

- Clamping of the cannula proximal to the patient and circulating the circuit slowly through the AV bridge. This allows complete separation from support for briefs periods, however bridges can increase the risk of circuit clots by being sites of low and turbulent flow. A variation of this can

involve flushing the cannula with crystalloid, and then instilling them with heparin to prevent thrombosis, allowing longer periods of complete separation.

- Incremental reduction of flow with administration of fluid and titration of ventilation and inotrope/vasopressor support. With this strategy, flows should not be reduced to below 200ml/min to minimize risk of clot formation.
- For patients whose systemic to pulmonary shunts have been partially or completely occluded as part of their ECLS strategy, readiness to wean must be judged without reduction in flows, as this will lead to desaturation.

Decannulation:

Preparation prior to decannulation is vital. Personnel, equipment, medications and blood products are organized for the decannulation procedure.

- There should be anticipation and an established plan for complications such as low cardiac output, pulmonary hypertension, bleeding, arrhythmias and the need to rapidly re-initiate ECLS.
- All patients should have a defined plan in the event of deterioration after discontinuation of ECLS, including whether re-initiation of ECLS is indicated.
- Patients should not be weaned off ECLS on maximal inotropic and vasopressor support (unless in the case of a “one-way” decannulation), as patients often require increased hemodynamic support in the hours following decannulation.

Sample decannulation checklist

Decannulation Checklist
Inotropes and vasopressors in line
Anesthetic and resuscitation drugs prepared
Temporary pacemaker attached to wires and checked
Euvolemic state, volume expanders drawn up
Packed red blood cells available
Endotracheal tube checked
Adequate pulmonary recruitment
Normal electrolytes
Established plan if decannulation fails. Cannula of the same size in the room. Spare ECMO circuit prepared.

Surgical perspectives:

- When the same circuit will be used to re-cannulate for ECLS if required, the tubing beyond the connector attached to the cannula should be prepped and placed in the operative field.
- Tissue and fluid from the cannulation site, particularly if central cannulation was utilized, can be taken for gram stain and culture.
- Manipulation of the heart, extensive dissection and undue bleeding may destabilize the patient and should be avoided.
- The cannulas can be removed whenever the patient is ready, but ideally after the heparin has been turned off for 30 to 60 minutes.
- Venous and arterial cannula placed by percutaneous access can be removed directly and bleeding controlled by topical pressure. When removing a venous cannula, air can enter the venous blood through the side holes if the patient is breathing spontaneously. Short-term pharmacological paralysis is recommended when removing the venous cannula.
- For central cannulation, chest closure can be considered if ventricular function has improved significantly. Otherwise, the chest should remain open, and the purse strings for cannulation should be snared and left in the chest.
- If a patient has been supported centrally for more than 2-3 days the edges of the wound may not be viable. Debridement should be postponed until the time of wound closure to minimize risk of bleeding.

Failure to wean from ECLS support:

- Children that do not follow an anticipated trajectory and are unable to wean from ECLS support require early and aggressive approach to investigation and management of residual lesions, inadequate hemodynamic or pulmonary support, infection and pulmonary disease.
- Echocardiography, chest ultrasound, CT angiography, cardiac catheterization and electrophysiology studies may reveal residual lesions amenable to surgical or interventional correction.
- Many hemodynamically significant residual lesions may only be detected by cardiac catheterization and not by echocardiography. Early detection of residual lesions within 3 days of ECLS support is associated with a higher rate of successful decannulation and better survival to hospital discharge.

Risk factors for mortality:

- Risk factors for increased mortality in ECLS patients include renal failure, lactatemia and acidosis at 24 hours of support, bleeding, and initiation of ECLS in ICU vs directly from cardiopulmonary bypass.

- In patients with primary myocardial dysfunction (myocarditis, cardiomyopathy) who fail to demonstrate adequate recovery, VAD support should be considered within 10 days.
- In the setting of recovered myocardial function with persistent severe pulmonary disease, conversion to VV-ECLS should be considered.

Discontinuation of support

- The possibility of stopping for futility should be explained to the family before ECLS is begun. In each case, a reasonable deadline for organ recovery or replacement should be set early in the course.
- For cardiac failure, three to five days of no cardiac function in a patient who is not a VAD or transplant candidate is considered futile in most centers.

Special considerations

A. Myocarditis

Patients with myocarditis can be well supported, and many pediatric patients will have full cardiac recovery. Current survival to recovery is 60% in this population, and exceeds 80% in selected reports. Evidence of low cardiac output, with escalating inotropic support is an indication for ECMO. As always, careful monitoring to insure ongoing LV ejection is necessary. Left atrial and pulmonary venous hypertension can be addressed by septostomy or LV venting.

B. Single Ventricle Palliation

1. Stage 1 palliative surgery (Norwood operation): ECLS support after neonatal stage 1 palliation for hypoplastic left heart syndrome is now the most frequent post-operative indication for ECLS. In patients with an arterial shunt, effective use of ECLS necessitates management of the shunt to ensure restricted pulmonary blood flow during support. Higher ECLS flows in the range of 150-200ml/kg/min may be associated with better outcomes, however, if cardiac output remains insufficient on higher ECLS flows, then constriction of the shunt to limit pulmonary blood flow and promote systemic blood flow and tissue oxygen delivery may be necessary.

2. Stage 2 and 3 palliative surgery: Infants and children after surgical palliation with cavopulmonary anastomoses (Glenn or Hemi-Fontan and Fontan circulations) represent a complex physiological group, in whom stable support

with ECLS can be difficult to establish. Establishing adequate flow in a patient with a Bidirectional Glenn or Hemi-Fontan may be challenging given the separation of systemic venous return. Nevertheless, ECLS can provide stable support if a reversible process is present. In general, cannulation of the systemic venous return in the right atrium will provide stable flow in the immediate postoperative setting.

3. Patients with Fontan physiology and new cardiac or respiratory failure can be supported with ECLS in the perioperative setting, or if they present with potentially respiratory or cardiac failure later in life. Fixed pulmonary hypertension in a patient with respiratory failure after several weeks of support on VV-ECLS may also be an indication of futility, or at least an indication to convert to VA access.

Cardiac catheterization and surgical procedures

Diagnostic and interventional cardiac catheterization, can be performed on ECLS support. In pediatric patients, the most common indication for catheterization on ECLS is evaluation for residual lesions following corrective surgery. Early correction of residual lesions is associated with shorter duration of support and improved survival on ECLS, so interventional diagnostic procedures should be considered when noninvasive studies are non-diagnostic.

The use of ECLS support during cardiac catheterization procedures, when the procedure may precipitate hemodynamic instability, is an evolving, but established use of ECLS support (for example trans catheter valve replacement and endovascular stent deployment).

Complex airway surgery may also be facilitated by the use of ECLS, without the need for the full anticoagulation and hemodilution of CPB. The details of cannulation and support (location, timing, duration of support following procedure) vary depending upon location.

ECPR

While outcomes for ECPR (ECLS initiation following initiation of CPR and PALS support) are worse than those for “elective” VA ECLS initiation, survival can be achieved. The outcomes for patients who arrest due to an underlying cardiac pathology are better than for patients who have a non-cardiac (i.e., respiratory or metabolic) etiology of arrest. Out of hospital cardiac arrest portends a grave prognosis, and ECPR should not be considered in these patients.