Anticoagulation (Unfractionated Heparin) for Short-term (48 hours) Extracorporeal Membrane Oxygenation (ECMO) Clinical Pathway
Johns Hopkins All Children’s Hospital

Anticoagulation (Unfractionated Heparin) for Short-term (48 hours) Veno-Arterial (VA) Extracorporeal Membrane Oxygenation (ECMO) Clinical Pathway

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Updated: June 2022

Owners: Awais Ashfaq, MD, MBBS; Jessica Daniels, MD; Amy Kiskaddon, PharmD

This pathway is intended as a guide for physicians, physician assistants, nurse practitioners and other healthcare providers. It should be adapted to the care of specific patients based on the patient’s individualized circumstances and the practitioner’s professional judgment.
Anticoagulation (Unfractionated Heparin) for short-term (48 hours) Veno-arterial (VA) Extracorporeal Membrane Oxygenation (ECMO) Clinical Pathway

Rationale:
This clinical pathway was developed by a consensus group of JHACH physicians, advanced practice providers, nurses and pharmacists to standardize the management of unfractionated heparin (UFH) for short-term (48 hours) extracorporeal membrane oxygenation (ECMO) support in neonates and children requiring mechanical circulatory support post-cardiotomy.

This clinical pathway addresses the following clinical questions and problems:
- How to manage patients requiring short term ECMO support
- What laboratory tests to order or consider
- Dosing and titration of UFH heparin
- Interpretation and utilization of labs to guide decision making
- When to consider alternative anticoagulation strategies

Background:
ECMO is a form of Extracorporeal Life Support (ECLS) that is utilized in the pediatric and neonatal settings to support the respiratory and cardiac systems. In hospitals caring for children with congenital heart disease, ECMO is an essential part of modalities used to temporarily support patients when conventional therapies are inadequate. Patients may receive ECMO for support following cardiac surgery, or cardiac disease, such as cardiomyopathy, myocarditis, and/or arrhythmias. Management of ECMO requires use of systemic anticoagulation to prevent and circuit-based thrombosis, which can increase the risk of hemorrhage. The current standard for anticoagulation in ECMO is a continuous infusion of UFH, which aims to prevent both patient and circuit thrombosis.

UFH is a complex glycosaminoglycan, with activity dependent on antithrombin (AT), which results in a conformational change that enhances the inhibitory activity of AT, inactivating thrombin and preventing further thrombin generation. The UFH-AT complex inhibits the activity of thrombin, and may neutralize IXa, Xa, XIa, and XIIa. Upon entering the blood stream, heparin interacts and binds with other endogenous plasma proteins (Heparin Binding Proteins – HBP, platelet factor 4, and high molecular weight multimers of vWF, which reduce anticoagulation activity. The variability in plasma concentrations of HBPs and age-related variation are likely the cause of the unpredictability that is seen across patients in terms of the anticoagulation activity of heparin. Clearance of heparin occurs in two phases in a dose-dependent fashion, and driven
by a combination of rapid saturable phase clearance, followed by a slower phase involving renal clearance. The rapid saturable phase is largely due to heparin binding to endothelial cells and macrophages. The heparin molecules are then degraded in these cells. At higher doses of heparin, this saturable phase is overcome and the remainder of heparin is cleared by the kidneys. Therefore, the half-life of heparin is affected by the heparin dose and/or renal insufficiency.

As heparin can lead to significant bleeding complications, it is imperative to monitor its anticoagulant effect. There is limited evidence supporting the optimal therapeutic range and monitoring protocol in neonates or children. Most recommendations are extrapolated from adult guidelines or based on expert opinions only. Heparin therapeutic effects are commonly monitored with anti-Xa or activated partial thromboplastin time (aPTT) values. Both tests should be interpreted with caution given the lack of evidence as to the optimal therapeutic value, as well as inherent difficulties in interpretation of the results. Many neonates can have prolonged baseline aPTT values. In addition, aPTT values can be affected by significant illness, inflammation, or hepatic dysfunction. Furthermore, interpretation of the results of both aPTT and anti-Xa tests is complicated by the fact that the assays vary across different instruments, reagents, and institutions. The JHACH clinical pathway incorporates observations, recommendations, and expert opinion.

**Inclusion Criteria:**
Neonatal and pediatric patients requiring short term (48 hours) VA ECMO support
Anticoagulation with UFH

**Exclusion Criteria:**
ECMO anticoagulation with bivalirudin

**Initial Management on ECMO:**

*Baseline labs:*
- Complete blood count (CBC)
- Serum creatinine (SCr)
- Anti-Xa
- Prothrombin time (PT)
- International normalized ratio (INR)
- Fibrinogen
- Activated Partial Thromboplastin Clotting Time (aPTT)
- Antithrombin III (ATIII)
- Activated clotting time (ACT)
- Thromboelastography (TEG)
- Any abnormalities in the baseline studies including coagulopathy or thrombocytopenia should prompt correction with clotting factors or blood products.
Timing and dosing of initial UFH bolus and infusion:
- UFH bolus should be administered prior to cannulation at the discretion of the surgical ECMO team
  - Non-bleeding patient: 100 units/kg
  - Bleeding patients: 75 units/kg
- ACT should be obtained every 30 minutes after cannulation
- Initiate heparin infusion once ACT is less than 200 seconds
- Heparin infusion initial rate is dependent on the patient’s weight, and timing of initiation should be adjusted based on risk assessment of active or possible bleeding
  - Patients <10 kg: 28 units/kg/hr
  - Patients 10 to <50 kg: 20 units/kg/hr
  - Patients ≥50 kg: 10 units/kg/hr

Lab Monitoring and Adjustment of UFH infusion:
- Initial Monitoring
  - Within 1 hour of initiation of VA ECMO cannulation, obtain CBC, anti-Xa, PT/INR, aPTT, and fibrinogen
  - Goal anti-Xa 0.3-0.7 units/mL
  - Monitor PTT and anti-Xa 4 hours after initiation of the UFH infusion, and titrate as per table (Appendix)
- Dose adjustments
  - Check PTT and anti-Xa 4 hours after infusion dose is changed (regardless of previous timing of lab tests)
  - aPTT should also be monitored to assess coagulopathy (goal 60-85 seconds)
  - If two consecutive aPTT and/or anti-Xa are therapeutic (4 hours apart) then monitoring may be adjusted to every 8 hours
  - NOTE: Changes in doses should only be initiated by providers (attending or advanced practice provider)
- Labs Monitoring: obtain labs every 6-12 hours
  - Platelets <80 x 10^3/uL: Administer 10-20 mL/kg platelets
  - INR> 2: Administer 10-20 mL/kg FFP
  - Fibrinogen <150 mg/dL: Transfuse 5 ml/kg Cryoprecipitate
  - Hematocrit <30-35%: Transfuse 10-20 mL/kg pRBC (For single ventricle, use threshold of <45%)

Additional Considerations
- If anti-Xa is <0.1 for two consecutive values, consider heparin bolus (50 units/kg) with next dose adjustment
- Heparin infusion should not go below 10 units/kg/hr or above 40 units/kg/hr without discussion with the ECMO team
- In neonates ≤30 days, or patients with ATIII levels <50%, consider FFP or ATIII replacement instead of heparin bolus after discussion with ECMO team
Antithrombin III (ATIII)

- ATIII is a natural anticoagulant necessary for UFH activity
- ATIII may be repleated via administration of fresh frozen plasma (FFP) or AT-III concentrate (Thrombate®)
  - FFP contains approximately 1-2 units/mL of AT-III
  - 20 mL/kg FFP should raise AT-III value by approximately 30%
  - 50 units/kg AT-III concentrate should raise AT-III value by approximately 30%
- ATIII Replacement
  - <6 months of age: Consider replacement if AT level is <50%
  - >6 months of age: Consider replacement if AT level is <50% and anti-Xa is subtherapeutic
  - Dosing = 
    - \[ \text{[(desired AT level } \% \text{ - } \% \text{ baseline AT activity level)} \times \text{ patient weight (kg)}] \]
    - Example: Goal AT level 100, baseline AT level 35, patient weight 3 kg → 
      \[ [(100 - 35) \times (3 \text{ kg})] = 195 \text{ units} \]
  - Consider decreasing heparin infusion by 20% if replacing ATIII.
- AT-III Monitoring
  - Monitored every 12-24 hours or 4 hours after giving a dose
  - Anti-Xa and/or aPTT should also be evaluated following AT-III administration

Transition to prolonged ECMO (>48 hours)

- Check baseline ACT at the time of decision of converting to long-term ECMO anticoagulation with bivalirudin
- Stop heparin infusion
- Once ACT <200 seconds, initiate bivalirudin at the rate instructed in the “Bivalirudin ECMO protocol Clinical Pathway”: 0.16 mg/kg/hr (consider lower starting dose in patients with renal dysfunction or on renal replacement therapy)
- Additional daily labs: plasma free Hgb, LDH, D-dimer

Outcomes

- Bleeding requiring re-operation
- ECMO circuit change
- Thrombotic complications
- Recovery/Decannulation

Education

- Education to occur at Heart Institute Division Meetings
Anticoagulation (Unfractionated Heparin) for short-term (48 hours) Veno-arterial (VA) Extracorporeal Membrane Oxygenation (ECMO) Clinical Pathway

**Inclusion**
- Neonatal/pediatric patients requiring short term (48 hours) VA ECMO support
- Anticoagulation with UFH

**Exclusion**
- Anticoagulation with bivalirudin

**Obtain Baseline Labs**
- CBC, SCr, Anti-Xa, PT/INR, aPTT, Fibrinogen, ATIII, ACT, TEG

**Correct if abnormal**

- If normal → UFH bolus
  - 75 units/kg bleeding patients
  - 100 units/kg non-bleeding patients

**Draw ACT every 30 minutes following cannulation & initiate UFH infusion when ACT < 200**

**Heparin Infusion**
- Patient < 10 kg: 28 units/kg/hr
- Patient 10-49 kg: 20 units/kg/hr
- Patient ≥ 50 kg: 10 units/kg/hr
- Goal anti-Xa: 0.3 – 0.7 IU/mL
- Goal aPTT: 60 – 85 seconds
- Refer to Table 3 for titration

**Initial Laboratory Monitoring**
- Within 1 hour of VA-ECMO cannulation obtain:
  - CBC
  - PT/INR
  - Anti-Xa
  - aPTT
  - Fibrinogen

**Two consecutive therapeutic (4 hrs apart) aPTT and/or Xa**

**No**
- Continue checking every 4

**Yes**
- Adjust to check X every 8 hours
Additional Monitoring Considerations:
Anticoagulation with UFH for short-term VA ECMO

**Additional Laboratory Monitoring**
1. Anti-Xa < 0.1 for 2 consecutive values: consider heparin bolus (50 units/kg) with next dose adjustment
2. Platelets < 80 x 10^3/uL: Administer 10-20 ml/kg platelets
3. INR > 2: Administer 10-20 ml/kg FFP
4. Fibrinogen < 150 mg/dl: Transfuse 5 ml/kg Cryoprecipitate
5. Hematocrit <30-35%: Transfuse 10-20 ml/kg pRBC (For single ventricle, use threshold of < 45%)
6. AT-III
   1. < 6 months of age: Consider replacement if AT level is < 50%
   2. ≥ 6 months of age: Consider replacement if AT level is < 50% and anti-Xa is subtherapeutic
5. Dose (See Antithrombin III Section)
4. Monitor AT-III every 12 hours, and ≥ 4 hours following AT-III replacement dose

**ECMO > 48 Hours**
Consider transition to prolonged ECMO anticoagulation with bivalirudin
- ACT < 200 seconds, initiate bivalirudin
- Normal renal function: 0.15 mg/kg/hr
- Impaired renal function: discuss with Clinical Pharmacist dosing
- Additional daily labs:
  - Plasma free hemoglobin
  - LDH
  - D-Dimer
Table 1: Johns Hopkins Hospital - Anticoagulation Laboratory Assays

<table>
<thead>
<tr>
<th>Laboratory Assay</th>
<th>Definition</th>
<th>Goal Range</th>
</tr>
</thead>
<tbody>
<tr>
<td>Activated Clotting Time (ACT)</td>
<td>Point of care clotting test used to monitor UFH during invasive procedures</td>
<td>ECMO: 180 – 200 seconds or 200 – 220 seconds CPB: per perfusion</td>
</tr>
<tr>
<td>Activated partial thromboplastin time (aPTT)</td>
<td>Lab test that measures the time (seconds) that an activated sample of re-calcified plasma requires to clot. It is used to titrate doses of UFH when clinical situations may interfere with the obtaining reliable anti-Xa activity (e.g., elevated levels of plasma hemoglobin ≥ 100 mg/dL, bilirubin ≥ 6.6 mg/dL, or triglycerides ≥ 360 mg/dL).</td>
<td>50 – 80 seconds</td>
</tr>
<tr>
<td>AT-III Activity</td>
<td>Lab test that measures the level of antithrombin-III activity in the plasma. AT-III is a protease inhibitor that plays a central role in the body’s natural anticoagulant system. A value of 100% denotes there is 1 unit of AT-III per 1 mL of plasma.</td>
<td>Neonates: ≥ 50% Infants and children: ≥80%</td>
</tr>
<tr>
<td>UFH Anti-Xa (Anti-Xa)</td>
<td>Lab test used to measure the extent of the Factor Xa inhibition in the presence of UFH, and monitor/guide heparin therapy.</td>
<td>0.3 – 0.7 IU/mL</td>
</tr>
<tr>
<td>Internationalized Normalized Ratio (INR)</td>
<td>A ratio of a patient’s prothrombin time to a control sample, raised to the power of a standard value.</td>
<td>≤ 1.2 seconds</td>
</tr>
<tr>
<td>Fibrinogen</td>
<td>Soluble protein in the plasma that is broken down to fibrin by the enzyme thrombin to form clots.</td>
<td>&gt; 100 mg/dL or &gt; 150 mg/dL for 4 hours prior to surgical intervention or if ongoing hemorrhage</td>
</tr>
<tr>
<td>Platelets</td>
<td>Blood cells that form hemostatic plugs that bind to fibrin, creating a stable clot.</td>
<td>&gt; 100,000 mm³</td>
</tr>
<tr>
<td>Prothrombin Time (PT)</td>
<td>Lab test that measures the time in seconds for a citrated plasma sample to clot after the addition of thromboplastin and calcium.</td>
<td>≤ 12 seconds</td>
</tr>
</tbody>
</table>

Source: Johns Hopkins Hospital

Table 2: Johns Hopkins Hospital Considerations for Anticoagulation Monitoring

<table>
<thead>
<tr>
<th>Influences on Coagulation Monitoring</th>
<th>aPTT</th>
<th>Anti-Xa</th>
<th>ACT</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Pre-analytical</strong></td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>Improper blood sampling</td>
<td></td>
<td></td>
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<tr>
<td>Improper flushing prior to sample</td>
<td></td>
<td></td>
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<tr>
<td>Under-filled sample tubes</td>
<td>←→</td>
<td>←→</td>
<td></td>
</tr>
<tr>
<td>Delay in sample analysis</td>
<td>↓</td>
<td>↓</td>
<td>↓</td>
</tr>
<tr>
<td>Gross hemolysis of sample</td>
<td>↓</td>
<td>↓</td>
<td>↓</td>
</tr>
<tr>
<td><strong>Biologic</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Hypothermia therapy</td>
<td></td>
<td></td>
<td>←→</td>
</tr>
<tr>
<td>Elevated inflammatory marker levels</td>
<td></td>
<td>←→</td>
<td></td>
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<tr>
<td>Fibrinogen</td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>Factor VIII</td>
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<tr>
<td>Increased heparin binding proteins in presence of</td>
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<tr>
<td>Inflammation</td>
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<td></td>
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<tr>
<td>Infections</td>
<td></td>
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<td></td>
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<tr>
<td>Malignancy</td>
<td></td>
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<td></td>
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<tr>
<td>Thrombocytopenia (&lt; 50,000 cu/mm)</td>
<td>←→</td>
<td>←→</td>
<td></td>
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<tr>
<td>Anti-thrombin (AT-III) deficiency</td>
<td>↓</td>
<td>↓</td>
<td>↓</td>
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<tr>
<td>Consumption coagulopathy (e.g., DIC)</td>
<td></td>
<td>←→</td>
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</tr>
<tr>
<td>Impaired hepatic function</td>
<td></td>
<td></td>
<td>←→</td>
</tr>
<tr>
<td>Decreased clotting factor production</td>
<td></td>
<td></td>
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<tr>
<td>Impaired renal function</td>
<td></td>
<td></td>
<td>←→</td>
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<tr>
<td>Decreased elimination of anticoagulant</td>
<td></td>
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<tr>
<td>Clotting factor deficiency</td>
<td></td>
<td>←→</td>
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<tr>
<td>Lupus anticoagulant</td>
<td>←→</td>
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<tr>
<td>Elevated triglyceride (TG) level (≥ 360 mg/dL)</td>
<td>←→</td>
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<tr>
<td>Elevated total bilirubin level (≥ 6.6 mg/dL)</td>
<td>←→</td>
<td></td>
<td></td>
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<tr>
<td>Elevated plasma-free hemoglobin (≥ 100 mg/dL)</td>
<td>←→</td>
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</tr>
</tbody>
</table>

Source: Johns Hopkins Hospital
<table>
<thead>
<tr>
<th>UFH Anti-Xa</th>
<th>0.11-0.29</th>
<th>0.3-0.7</th>
<th>0.71-0.9</th>
<th>0.9-1.0</th>
<th>&gt;1.0</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>&lt; 60</strong></td>
<td>- Increase 20% + bolus one-hour worth of new rate</td>
<td>- Decrease 10%</td>
<td>- Decrease 10%</td>
<td>- Hold 1 hour, decrease 20%</td>
<td>- Hold 1 hour, recheck before initiation</td>
</tr>
<tr>
<td></td>
<td>- Recheck Anti-Xa 4 hours after dose change</td>
<td>- Recheck Anti-Xa 4 hours after dose change</td>
<td>- Recheck Anti-Xa 4 hours after dose change</td>
<td>- Recheck Anti-Xa 4 hours after dose change</td>
<td>- Discuss systemic inflammation/biological influence that may falsely elevate Anti-Xa</td>
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<tr>
<td></td>
<td>- Discuss FFP or AT-III administration</td>
<td>- Discuss Presence of systemic inflammation</td>
<td>- Discuss presence of systemic inflammation</td>
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<td>- Discuss systemic inflammation/biological influence that may falsely elevate Anti-Xa</td>
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<tr>
<td><strong>60-85</strong></td>
<td>- Increase 10% + bolus one-hour worth of new rate</td>
<td>- Increase 10%</td>
<td>- Decrease 10%</td>
<td>- Hold 1 hour, decrease 20%</td>
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</tr>
<tr>
<td></td>
<td>- Discuss DIC and/or hepatic dysfunction</td>
<td>- No change</td>
<td>- Decrease 10%</td>
<td>- Hold 1 hour, decrease 20%</td>
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<td><strong>86-105</strong></td>
<td>- Decrease 10%</td>
<td>- Decrease 10%</td>
<td>- Decrease 10%</td>
<td>- Hold 1 hour, decrease 20%</td>
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<td></td>
<td>- Consider labs: platelets, D-Dimer, Fibrinogen, AT-III, LFTs, INR, total bilirubin, plasma free hemoglobin</td>
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<td>- Hold for 1 hour, and decrease 20%</td>
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<td><strong>106-120</strong></td>
<td>- Decrease 10%</td>
<td>- Decrease 10%</td>
<td>- Decrease 10%</td>
<td>- Hold for 1 hour, and decrease 20%</td>
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<td><strong>&gt;120</strong></td>
<td>- Hold 1 hour, decrease 20%</td>
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Clinical Pathway Team
Anticoagulation (UFH) for short-term (48 hours) Extracorporeal Membrane Oxygenation (ECMO) Clinical Pathway

Johns Hopkins All Children’s Hospital

Owner(s): Awais Ashfaq, MD, MBBS; Jessica Daniels, MD; Amy Kiskaddon, PharmD

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Johns Hopkins Children’s Center Team:
Others: Heart Institute Clinical Practice Council

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Date Approved by Heart Institute Clinical Practice Council: August 23, 2021
Last Revised: June 20, 2022

Disclaimer

Clinical Pathways are intended to assist physicians, physician assistants, nurse practitioners and other health care providers in clinical decision-making by describing a range of generally acceptable approaches for the diagnosis, management, or prevention of specific diseases or conditions. The ultimate judgment regarding care of a particular patient must be made by the physician in light of the individual circumstances presented by the patient.

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