INTERNATIONAL SOCIETY FOR HEART AND LUNG TRANSPLANTATION
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Core Competency Document (CCD)

Core Competencies in Pediatric and Adult Congenital Heart Disease Ventricular Assist Device Support

(Working Title: Peds MCS CCD)

Supporting Councils: Pediatric Council, Mechanical Circulatory Support and Junior Faculty and Trainee Council

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Introduction:

This core competency document provides a practical and concise clinical review for medical professionals to develop understanding and management of ventricular assist devices (VADs) and the Total Artificial Heart (TAH) in children with and without congenital heart disease and adults with congenital heart disease.

The primary objective is to provide a compendium of topics for guided revision for the developing expert in the field. This document is a collaborative effort provided by the ISHLT Pediatric and Mechanical Circulatory Support Councils to use for future learning activity.

The field is experiencing rapid evolution and this manuscript will require further refinement over time. It should not be seen as a comprehensive textbook or substitute thereof. Feedback for the authors is encouraged.

The text is also designed to assist pediatric centers in the development of a comprehensive ventricular assist device support program. It does not replace professional training or credentialing and merely serves to guide professionals in their efforts to study the subspecialty content in their particular clinical setting. It is therefore meant to be a guide for expert development and serves as part of the educational curriculum of the ISHLT. It provides the basis for separate learning activities and self-directed study.

General Learning Objectives:

This document allows learners and participants to develop or improve competence and professional performance in their ability to:

1. Evaluate a patient for VAD implantation including preoperative assessment, planning and optimal timing of implantation
2. Determine the optimal VAD and support strategy for each unique patient.
3. Understand VAD/TAH implantation strategies and intraoperative strategies.
4. Understand, anticipate, recognize, and manage potential adverse events that may occur in pediatric VAD patients.
5. Understand the basic principles of anti-coagulation in this population.
6. Determine the optimal pump settings by using non-invasive monitoring and diagnostic testing, including echocardiography.
7. Evaluate a child for possible discharge on a VAD and prepare for the transition back into the community.
8. Understand the benefits of VAD support while awaiting transplantation in select cases.
9. Recognize the utility of palliative care, preparedness planning and end of life decision making in pediatric VAD patients.

10. Recognize the essential components and long term educational needs of a pediatric VAD program/team.

Table of Contents

Section I: Historical Overview of VAD Use in Pediatrics

Learning Objectives for VADS in pediatrics:

A. **Understand the historical perspective and evolving use of VADs in pediatric patients**
B. **Understand the history of clinical VAD trials in pediatrics**
C. **Appreciate the impact VAD support has had on heart transplant waitlist morbidity and mortality**

1. Historical perspective of pediatric VADs
    a. Early era
        i. Frequency and type of devices employed
            1. Temporary support
            2. Biventricular support
        ii. Patient characteristics and indications
        iii. Clinical outcomes
    b. Recent era
        i. Frequency and type of devices employed
            1. Temporary support
            2. Biventricular support
        ii. Patient characteristics and indications
        iii. Clinical outcomes
2. VAD approvals and clinical trials in pediatrics
    a. DeBakey VAD Child
    b. Berlin EXCOR trial
    c. The Pediatric Circulatory Support Program (PCSP) and PumpKIN trial
    d. Syncardia 50 cc trial
3. Historical perspective on waitlist and transplant outcomes with and without VADs
    a. European Experience
    b. Canadian Experience
    c. US Experience
    d. Asia Experience

Key References:
1-14

Section II: Patient Selection for Ventricular Assist Devices

Learning Objectives for selecting the right VAD patient:

- **A. Understand the indications and optimal timing of device placement, in particular the differences in outcomes between the different INTERMACS classes.**
- **B. Appreciate changes in markers of end-organ function that may drive earlier VAD placement.**
- **C. Define the importance of determining the intent of the device therapy.**
- **D. Understand the high-risk pediatric VAD populations that may be better bridged to transplant with medical management.**

1. Appreciate literature regarding optimal timing of implantation
    - a. Adult experience: INTERMACS I/II vs III/IV
    - b. Pediatric experience from the Berlin trials
2. End-organ function screening
    - a. Renal function
        - i. Cystatin C
        - ii. Nuclear GFR
    - b. Hepatic Function
        - i. INR
        - ii. Fibrosis
        - iii. Bilirubin
    - c. Respiratory
        - i. Positive Pressure Ventilation
    - d. Nutrition
        - i. Pre-albumin/ albumin
        - ii. Frailty – adult experience
    - e. Neurologic
3. Decision model for deciding to stabilize first on short term device (center specific)
    - a. End-organ recovery with ECMO/Short term device
    - b. Family consent and education regarding future options
4. Preoperative Planning: Determine degree of support needed
    - a. Left ventricular support
    - b. Biventricular
        - i. Adequacy of RV function
            1. RV scoring systems in adults
            2. Pediatric BiVAD experience
            3. Berlin heart experience
            4. Era effect
5. Define the indications for therapy
    - a. Inotrope dependent
        - i. Additional end-organ dysfunction
        - ii. Unable to maintain nutrition
    - b. Post-cardiotomy failure to wean from CPB
    - c. Unable to tolerate oral medications

    d. Uncontrollable Arrhythmias
    e. Tumor
    f. Restrictive cardiomyopathy unresponsive to medical therapy
6. Define the intent for therapy
    a. Bridge to Decision
    b. Bridge to Transplant
    c. Bridge to Recovery
    d. Bridge to a Bridge
    e. Chronic (destination) therapy
7. To discuss the unique populations that may be followed in a pediatric center
    a. ACHD (see also section VII)
        i. Fontan
        ii. Sennings/Mustards
        iii. ccTGA
        iv. Complex with residual lesions
        v. Other
    b. Neonatal/infant single ventricles
        i. Shunted
        ii. Glenn
    c. Muscular dystrophies
        i. The Duchene's muscular dystrophy experience
    d. Chemotherapy-induced cardiomyopathy
    e. Metabolic and genetic syndromes associated to heart failure
8. Ethics of determining which children will be destination vs. bridge to transplant
    a. DMD
    b. Recent chemotherapy
    c. Developmental delay
9. Literature review of complex populations: When may medical management be optimal when compared to VAD implantation as a bridge to transplant?
    a. Single ventricle patients
    b. Neonates
    c. Myocarditis
    d. Patients with contraindication to anti-coagulation
    e. Difficult social situations/non-adherence

Key References:

4, 15-24

Section III: Ventricular Assist Device Selection: Short-Term Devices

Learning objectives for Short-Term Devices:

- **A. Understand the indications and contraindications for the use of short-term mechanical circulatory support in pediatric patients.**
- **B. Understand the short-term MCS devices and their associated outcomes in pediatric patients.**
- **C. Understand the role of rapid resuscitation ECMO or "eCPR" after cardiopulmonary arrest and the clinical outcomes associated.**
- **D. Understand basic patient management for children supported on ECMO or short-term continuous flow mechanical circulatory support.**
- **E. Understand the process of weaning a patient from either ECMO or short-term continuous flow mechanical circulatory support.**
- **F. Understand the process of converting a patient from short-term MCS to more long-term VAD support.**

1. Indications for short-term support
   - a. Reversible etiology for cardiac dysfunction
     - i. Myocarditis
     - ii. Acute Heart Transplant Rejection
     - iii. Other
   - b. Inadequate RV function
   - c. Pulmonary disease and ECMO
   - d. Septic shock and ECMO
   - e. Intractable, malignant arrhythmias
   - f. Post-cardiotomy failure
   - g. Unknown candidacy for long term support
2. Contraindications for short term MCS support
   - a. Multi-organ failure
   - b. Refractory infections or severely immunosuppressed states
   - c. Untreatable conditions (e.g end-stage metastatic cancer or severe CNS injury)
   - d. Inability to obtain vascular access
   - e. Unable to accept blood products or tolerate anticoagulation
   - f. Progressive or severe neurological injury
3. ECMO outcomes
   - a. Congenital heart disease
   - b. Myocarditis
   - c. Cardiomyopathy
   - d. Post-cardiotomy failure
4. Current devices used for short term support
   - a. ECMO
     - i. Components
       1. Pump
       2. Heater
       3. Oxygenator
     - ii. Highlighting the differences in veno-venous (VV) ECMO versus veno-arterial (VA) ECMO
   - b. Pedimag/Centrimag centrifugal ventricular support
   - c. Rotaflow centrifugal ventricular support

    d. Impella
        i. 2.5
        ii. 5.0
        iii. RP
    e. Tandem Heart
    f. Intra-aortic balloon pump
    g. Other
5. Patient management
    a. Device selection
        i. Emergent
            1. eCPR
        ii. Acute
            1. ECMO: Peripheral cannulation vs central cannulation
                a. Strategies for peripheral cannulation
            2. Short term VAD
    b. Managing inotropic support on short term support
        i. Vasodilator therapy to optimize flow
        ii. Inotropic support as appropriate for right ventricular support
    c. Ventilator management
        i. Lung preserving settings
        ii. Preparing for support wean/decannulation
    d. Left atrial decompression (with ECMO)
        i. Diagnosing left atrial hypertension
            1. Echo
            2. Chest x-ray
        ii. Therapy
            1. Atrial septostomy
            2. Left atrial or ventricular vent (surgical)
            3. Left ventricular support
                a. Percutaneous short term support
            4. Surgical placement of VAD
    e. Anticoagulation (see also anticoagulation section)
        i. Heparin infusion
            1. Monitoring parameters
                a. ACT
                b. PTT
                c. Anti-Xa levels
                d. Thromboelastography
            2. Optimization
                a. Monitoring AT3 levels
                b. AT3 replacement
            3. Heparin induced thrombocytopenia
        ii. Balancing bleeding and clotting
            1. Starting heparin
            2. Risk of events and time since support initiation
        iii. Inflammation/Infection and anticoagulation
        iv. Monitoring the circuit for fibrin/thrombus
    f. Assessment myocardial function on support
        i. Invasive and non-invasive assessment of recovery
            1. Hemodynamic assessment

2. Echocardiography

ii. Staged wean of circuit flows

1. ECMO
2. LVAD

Key References:

1, 7, 8, 25-39

Section IV: Ventricular Assist Device Selection – Long-Term Devices

Learning objectives for Long-term Devices:

A. Understand various device selection algorithm for children of all sizes and ages (country and center-specific).
B. Know the relative indications and contraindications for the use of long-term support in pediatrics.
C. Understand the differences in the flow dynamics of currently available devices.
D. Recognize the long-term VAD support strategies and understand the various bridge therapies.
E. For US clinicians, Identify the FDA approved indications for all the commonly used devices.
F. Describe the pediatric experience of long-term continuous flow devices.
G. Recognize the various VADs available for children and adult patients with end stage congenital heart diseases (ACHD)
H. Recognize limitations and advantages of different VAD types (extra-corporeal vs. intra-corporeal)

1. Characteristics of currently available durable continuous flow devices
    a. Ages of children that can be implanted with currently available devices
    b. Industry recommends for size, in patients >1.5 m^2
    c. Devices approved for destination
    d. Common Devices
        i. HeartMate II (Thoratec)
            1. Axial flow
            2. Requires pump pocket
            3. Larger device, unlikely to fit in most children
            4. Pocket controller has back up battery, benefit to adolescents
        ii. HVAD (HeartWare)
            1. Centrifugal flow
            2. Pericardial device
            3. Smaller device, used in children as small as $0.7m^2$
        iii. Jarvik 2000
2. Characteristics of currently available durable pulsatile devices *
    a. Devices
        i. Berlin Heart EXCOR
            1. Only FDA approved device for children (US)
            2. Pneumatic
            3. Can be used as Bivad
            4. All sizes

5. Unable to discharge (US)

ii. TAH-t (Syncardia)

1. Two sizes (50cc and 70 cc)
2. FDA approved for adults (70 cc)
3. Trial underway for children
4. Must have BSA>1.7m^2 (70 cc)

iii. Other

1. P-VAD
2. Toyobo
3. Berlin InCOR
4. Reliant

4. Initiatives for miniaturizing of pumps
    a. Decreasing shear stress
    b. Need for minimal anti-coagulation
5. VADS that are soon to be available in Europe and North America to follow
    a. Syncardia 50 cc TAH
    b. Circulite (HeartWare)
    c. MVAD (HeartWare)
    d. HeartMate III (Thoratec)
    e. HeartMate X (Thoratec)
    f. Jarvik 2000 (PumpKIN trial)
    g. Other

Key References:

40-49

Section V: Surgical Implantation

Learning objectives for surgical implantation:

- **A. Understand VAD-type selection algorithm based on patients weight, anatomy, illness, bridge strategy (bridge to transplant, recovery, decision, long-term support) in the various countries.**
- **B. Learn relevant surgical techniques including children with congenital heart diseases (CHD) and grown-up/adults after palliation of CHD.**
- **C. Recognize new peri-operative diagnostic tools for VAD placement in children.**
- **D. Understand the pitfalls and perils of VAD implantation in the pediatric and ACHD population including pre-existing valve pathology.**
- **E. Appreciate improvements in device design, technology, peri-operative management and implantation technique.**

1. Surgical implantation (unique considerations in children)
    a. LVAD placement and cannulation techniques
    b. Continuous flow VAD in small patients
    c. Implantation in patients with failing surgically palliated CHD
    d. Management/placement of drivelines
2. Surgical cannulation techniques for RVAD
3. Special considerations in the uni-ventricular heart (see also below)
4. Concomitant Cardiac Surgery
    a. Aortic valve insufficiency
    b. Atrio-ventricular valve regurgitation
    c. Intracardiac and extracardiac shunts
    d. Artificial valves
5. Novel Diagnostic Procedures to Determine Device "fit"
    a. CT reconstrucution
    b. Virtual implantation
    c. Three dimensional models
6. Weaning form Cardiopulmonary Bypass
    a. Inotrope management
    b. De-airing
    c. Protecting the right ventricle
    d. Bleeding
    e. Chest Closure

Key References:

17, 50-58

Section VI: Support Strategies for the Single Ventricle Patient

Learning Objectives for Support strategies for the single ventricle:

A. **Review the different cardiac malformations leading to palliative single ventricle repair**
B. **Recognize the consequences of palliative single ventricle repair and critical time points of possible failure.**
C. **Understand anatomical and surgical challenges in patients after palliative single ventricle repair.**
D. **Learn different MCS and cannulation strategies at different time points for the staged palliative single ventricle repair.**
E. **Review new diagnostic tools including especially imaging methods for patients how underwent palliative sing ventricle repair.**
F. **Understand how to diagnose a `failing fontan`.**
G. **Recognize treatment options in patients suffering from end-stage heart failure with Fontan circulation.**

1. Anatomical variations and etiology of failure
    a. Cardiac malformations leading to palliative single ventricle repair
    b. Staged single-ventricle repair
        i. Norwood Stage I
        ii. Glenn
        iii. Fontan
    c. Physiology of a Fontan Circulation
    d. Issues in the growing child with the Fontan Circulation
2. Support and cannulation strategies for all stages
    a. Single-ventricle patients with circulatory failure following Norwood I procedure
    b. Single-ventricle patients with circulatory failure following superior cavopulmonary anastomosis (Glenn)
    c. Single-ventricle patients with circulatory failure following total cavo- pulmonary connection (Fontan)
    d. Recognizing the need for multicenter collaboration to assess MCS in single ventricle patients
3. Evaluation of the Failing Fontan patient
    a. Clinical and laboratory examination
    b. Echocardiographic Evaluation of palliated single-ventricle patients
    c. CT and MRI imaging in ACHD and Fontan Circulation
    d. Invasive measurements (including cardiac catheterization and invasive hemodynamic monitoring)
    e. Stages of the failing Fontan circulation
4. Treatment options for the Failing Fontan
    a. Medical optimization
    b. Surgical options (Including Fontan conversion, transplantation, TAH, Take-down, Fenestration, MCS)
    c. Palliative Care

Key References:
59-66

Section VII: Support Strategies for Adult Congenital Heart Disease Patients

Learning Objectives for adult congenital heart disease support:

- **A. Understand the dramatic differences between the VAD implantation rates of adults with CHD vs non-CHD adults waiting for transplant and how this effects their waitlist time and mortality.**
- **B. Understand VAD options at various centers for complex CHD including when a TAH may be the best option.**
- **C. Better appreciate the high rates of sensitization and end-organ dysfunction in this patient population and how this may effect support decision making.**
- **D. Understand the needs and differences in device selection between typical adult heart failure patients and children/adults with congenital heart disease.**

1. Increasing prevalence of adult congenital heart disease
2. Heart failure prevalence and outcomes in ACHD: defining areas of need for MCS
    - a. Evaluating heart failure symptoms in ACHD
    - b. Medical therapies
    - c. Electrophysiology and heart failure
        - i. Sinus node dysfunction
        - ii. Atrial dysrhythmias
        - iii. AV node dysfunction
        - iv. Dysynchrony/Resynchronization
    - d. Arrhythmias and sudden death
        - i. Atrial
        - ii. Ventricular
3. Causes of heart failure and MCS outcomes (if available) in specific lesions
    - a. Ventricular interaction
        - i. Tetralogy of Fallot
        - ii. Ebsteins
    - b. Transposition
        - i. Atrial switch patients
        - ii. cc-TGA patients with systemic ventricular failure
    - c. Single ventricle physiology
4. Sensitization with long term VAD support
    - a. Waitlist outcomes and sensitization
    - b. Post-transplant outcomes and the sensitized patient
    - c. Sensitization risk in congenital patients independent of VAD support
        - i. Understanding cytotoxic versus non-cytotoxic Sensitization
    - d. Available desensitization therapies

Key References:
50, 67-102

Section VIII: Post-operative ICU Care of the Ventricular Assist Device Patient

Learning Objectives for Routine Post-Operative Care of the VAD Patient:

A. Discuss the routine post-operative care for patients supported on continuous flow devices to prevent adverse events.
B. Discuss routine post-operative care for Berlin Heart patients to prevent adverse events.
C. Discuss the routine post-operative care for TAH patients to prevent adverse events.
D. Appreciate the importance of establishing hemostasis in the early post-operative period.

1. Device specific hemodynamic goals
    a. Continuous flow device hemodynamic goals
        i. Cardiac index goals
            1. Non-invasive indices adequate
            2. RPM and Watts within goal
        ii. Adequate blood pressure control to optimize flow
        iii. Careful fluid management
    b. Berlin Heart EXCOR hemodynamic goals
        i. Calculated CI by pump size and rate
            1. Non-invasive indices adequate
        ii. Blood pressure control not as essential
        iii. Full fill and full eject by visualization
    c. Total artificial heart
        i. Cardiac index adequate; as calculated by fill and rate
        ii. Adequate after-load control
        iii. Partial fill, full eject
2. Right heart support for LVAD
    a. Decrease PVR
        i. Obtain FRC with optimal ventilator settings
        ii. Consider iNO or PGE
        iii. Avoid acidosis
    b. Inotropes
    c. Slow gentle diuresis
    d. Careful management of heart rate
    e. Adjust LVAD settings to optimize RV
3. Antibiotics
    a. Prophylaxis approaches
        i. Drug resistant organisms
        ii. +/- anti-fungal prophylaxis
4. Hemostasis
    a. Avoidance of quick reversal of anti-coagulation
    b. Blood product use and potential avoidance
    c. Pump parameters consistent with tamponade
5. Physiology that may complicate post-operative care
    a. Intracardiac shunts
    b. Collaterals
    c. AV valve regurgitation

d. Contraction around inflow cannula

Section IX: Review of Post-Operative Adverse Events

Learning Objectives for Routine Post-Operative Care of the VAD Patient:

A. **Identify common adverse events encountered in pediatric patients on a VAD.**
B. **Identify treatment options for post-operative right heart failure.**
C. **To discuss the literature pertaining to device infections and ways to prevent them.**
D. **Appreciate the signs of pump thrombosis and the different treatment options for various devices.**
E. **Understand indications for pump exchange in the setting of thrombosis for both continuous flow and pulsatile VADs.**
F. **Assessment and management of hemorrhagic or thrombotic stroke in patients on MCS**
G. **Recognize interventions to improve long term neurological recovery.**

1. Right Heart Failure
    a. Current definitions for right heart failure
    b. Frequency of occurrence
    c. Assessment of right ventricular failure
        i. Clinical parameters
            1. CVP
            2. Edema
            3. Hepatomegaly
            4. Renal dysfunction
            5. Changes in flow and fill
        ii. Hemodynamics
        iii. Parameters from the LVAD
        iv. Imaging modalities: echocardiogram
            1. Septal shift
            2. Tricuspid regurgitation
    d. Incidence of right ventricular failure following left ventricular assist device (LVAD) insertion
        i. Adult data
        ii. Pediatric Data
    e. Risk factors for development of right ventricular failure post-LVAD implantation
        i. Etiology of heart disease more likely to present with biventricular failure
        ii. Markers pre-operatively that can predict failure, including adult scoring systems
        iii. Role of pre-operative pulmonary hypertension
    f. Outcomes of right ventricular failure following LVAD insertion
        i. Impact on mortality
        ii. Impact on end-organ function
        iii. Impact on LVAD functioning
    g. Intraoperative strategies for prevention of right ventricular failure
        i. Techniques for coming off bypass
        ii. Use of inhaled nitric oxide

    iii. Importance of minimization of bleeding
    iv. Use of continuous ultra filtration
    v. Role of inotropes and vasodilators
    vi. Role of LVAD
  h. Management of RV failure in the post-operative period including both medical and device strategies
    i. Medical strategies: nitric oxide, pulmonary vasodilators, inotropes
    ii. Mechanical ventilations strategies
    iii. Right ventricular assist devices (temporary)

2. Bleeding and Tamponade
  a. The definition of major bleeding
    i. Review InterMACs and PediMACS definitions
    ii. Frequency of occurrence
  b. The scope of the problem
    i. Berlin Heart EXCOR data
    ii. Adult continuous flow pump data
    iii. Early vs. Late bleeding
  c. Risk factors for post operative bleeding
    i. ECMO
    ii. Previous surgeries
    iii. Pre-op anticoagulation
  d. Clinical presentation of tamponade in a VAD patients (LVAD or BIVAD)
  e. Management strategies for major bleeding
    i. Alteration of anticoagulation (reversal or lowering)
    ii. Surgical interventions

3. Post-Operative Stroke
  a. Definition of device related stroke
  b. Frequency of this adverse event
  c. Management algorithm for cerebrovascular events
    i. Neurology service
    ii. Neuroimaging
    iii. Baseline assessment of hemostasis (anticoagulation and antiplatelet testing, TEG)
    iv. Available protocols for alterations in anticoagulation and antiplatelet therapies in response to hemorrhagic or ischemic events
  d. Identifying and quantifying neurological injury
    i. Role of physical examination
    ii. Role of imaging
      1. Importance of pre-operative imaging
    iii. Defining deficit through imaging and prognosticating deficit through physical examination
  e. Risk stratifying patients based on
    i. Size and location of deficit
    ii. Hemorrhagic vs ischemic- does it matter?
    iii. Degree of physical impairment
  f. Restarting unfractionated heparin: when, and how much
  g. Monitoring neurological function
    i. Surveillance imaging
    ii. Role of physical examination
    iii. Role of PT and OT

            iv. Promoting neurological recovery
4. Driveline infections
    a. Definitions of driveline infections
        i. ISHLT definitions
    b. Frequency of driveline infections in children on VADS
    c. Risk factors for developing a driveline infection
    d. Diagnosis and evaluation of driveline infections
        i. Role of swabs and blood cultures
        ii. Role of imaging studies (ultrasound, CT and echocardiogram)
    e. Medical and surgical management strategies for driveline infections
        i. Medical:
            1. Antibiotic therapy (IV vs. po)
            2. Suppressive therapy
            3. Dressing changes
        ii. Surgical:
            1. Debridement
            2. Pump exchange or removal
            3. Transplant
    f. To describe potential mechanisms for prevention of driveline infections
        i. Suppressive therapy
        ii. Identifying lifestyle issues
5. Pump Thrombosis
    a. Diagnosis
        i. Signs of Hemolysis
            1. Rising LDH and plasma free HGB
            2. Dark urine
            3. Changes in VAD parameters
                a. Continuous flow VADS
                    i. Change in Watts and calculated flow
                    ii. Change in PI or pulsatility index
                    iii. Ramp study
                b. Berlin Heart EXCOR
                    i. Visual thrombus vs fibrin
                    ii. Change in CO
    b. Treatment
        i. Heparin treatment and observation
        ii. Pump change out (especially in the Berlin patients)
        iii. Catheter directed TPA
        iv. Use of alternative anticoagulation strategies for recurrent pump thrombosis
        v. Surgical removal of thrombosed pump

Key References:
20, 103-127

Section X: Anticoagulation Management

Learning Objectives for anticoagulants and their use:

A. **Describe the normal coagulation pathway and how the mechanisms of the commonly used anti-coagulation medications.**
B. **Understand the indications for anticoagulation medications in the pediatric population and currently available anti-coagulation medications.**
C. **Explain challenges and benefits of anticoagulation management for mechanical circulatory support (dosing, dose titration, and monitoring)**
D. **Understand center variations in anti-thrombotic practices worldwide as it pertains to pediatric ventricular device support.**
E. **Understand different tests for measuring anticoagulation and antiplatelet effect.**
F. **Appreciate and understand the variability, precision, and reliability of current testing for anticoagulation and antiplatelet effect.**
G. **Describe current anti-thrombosis protocols as they pertain to anti-thrombosis monitoring and testing.**
H. **Understand the impact of inflammation on hemostasis.**
I. **Understand the role of steroids for decreasing inflammation- When? Why? How much? And for how long?**
J. **Describe the spectrum of complications that may arise secondary to anti-thrombotic therapies as they pertain to sub- or supra-therapeutic anticoagulation and antiplatelet medications.**
K. **Appreciate the complexity of restarting anticoagulation post hemorrhagic and ischemic cerebrovascular events.**

1. The coagulation pathway
    a. Intrinsic pathway
    b. Extrinsic pathway
2. Mechanisms of action of the commonly used anti-coagulation/anti-platelet medications
    a. Heparin
    b. Low molecular weight heparin
    c. Argatroban
    d. Biliverdin
    e. Warfarin
    f. Aspirin
    g. Dipyridamole
    h. Role of sildenafil, milrinone and inhaled nitric oxide
3. Current anti-thrombosis practices in early post-operative period (<7 days)
    a. Berlin devices
        i. Anticoagulation therapy
        ii. Antiplatelet therapy
        iii. Optimal device parameters to prevent thrombosis
    b. Continuous flow devices

        i. Anticoagulation therapy
        ii. Antiplatelet therapy
    c. TAH
        i. Anticoagulation therapy
        ii. Antiplatelet therapy
4. Current anti-thrombosis practices in late post-operative period (>7 days)
5. Alternative anticoagulation options
    a. Indications for alternative/novel anticoagulation
        i. Treatment failure with standard anticoagulation (pump thrombosis or TE events)
        ii. Heparin Induced Thrombocytopenia (HIT)
    b. Types of alternative/novel anticoagulation medications
        i. Oral medications
        ii. Intravenous medications
        iii. Subcutaneous medications
    c. Dosing and monitoring of alternative anticoagulation medications
        i. Oral medications
        ii. Intravenous medications
        iii. Subcutaneous medications
    d. Challenges of alternative anticoagulation strategies
        i. Monitoring
        ii. Reversibility
        iii. Pharmacokinetics and pharmacodynamics in pediatrics
    e. Benefits of alternative anticoagulation strategies
        i. Monitoring
        ii. Adverse event profile
        iii. Non responders to traditional anticoagulation strategies
6. Examples of difficult clinical cases
    a. Anti-thrombosis management with acute hemorrhagic cerebrovascular event
    b. Recurrent pump thrombosis despite optimal anticoagulation and antiplatelet therapy
    c. Recurrent bleeding events with standard anticoagulation therapy
    d. Management of anti-coagulation during interventional or operative procedures including ICD placement
7. Current available testing for anticoagulation and antiplatelet
    a. PTT, PT, anti-Xa level assays, thrombin time
    b. INR
    c. Thromboelastogram (TEG) with platelet mapping
    d. ROTEM
    e. VerifyNow point of care
    f. Urine thromboaxane
8. Correlation between testing
    a. PTT and anti-Xa levels
    b. PTT and anti-Xa assay variability and the role of thrombin
    c. INR laboratory and point of care correlation (when to trust and when not to trust)
9. Intrinsic pro-coagulant and anti-coagulants
    a. Developmental hemostasis
    b. Inflammation and infection
    c. Other medication effect (Milrinone, nitric oxide, nutritional supplements)

    d. Impact on anticoagulation and antiplatelet testing

10. Pro and anti-coagulant effect of inflammation
    a. Key Inflammatory markers
        i. CRP
        ii. ESR
        iii. Metalloproteinases
        iv. WBC
        v. Novel inflammatory markers
        vi. PET imaging
11. Monitoring inflammation
    a. Markers
    b. Timing of testing
12. Steroids and inflammation
    a. Criteria for initiation
    b. Dosing
    c. Monitoring effect
    d. Adverse effects: immunosuppression, risk of infection, wound healing
13. When to increase or decrease anticoagulation with inflammation
    a. Risk stratifying patients through comprehensive coagulation testing (role of TEG, ROTEM, platelet mapping in addition to standard assessment of coagulation)

Key References:

115, 116, 128-145

Section XI: Optimization of Ventricular Assist Device Settings

Learning Objectives for Optimization of Ventricular Assist Device Settings:

1. **Identify methods to monitor for adequate cardiac output while on support.**
2. **Identify echocardiographic findings that may alter device management.**
3. **Discuss settings and parameters on the different VADS that may give the care providers insight to device issues.**
4. **Discuss monitoring for myocardial recovery on a VAD.**

1. Invasive and Non-invasive monitoring of CO
    a. Early post-operative monitoring
        i. NIRS, mixed Venous Sat
        ii. CVP, RAP, LAP
        iii. End organ indices
        iv. Urine output monitoring
        v. LFTs, renal function, other biomarkers
    b. Late post-operative monitoring
        i. Mean arterial pressure & clinical exam
        ii. Device specific monitoring
    c. Echocardiographic parameters
        i. Septal position
        ii. Aortic valve opening and aortic insufficiency
        iii. Assessment of right heart function
            a. RV Dimensions, Tricuspid regurgitation
2. Device Specific Monitoring
    a. Recognize the inaccuracies associated with the device flow estimates
        i. Berlin Heart – Visual Inspection: full eject & full fill
        ii. HVAD- Speed, power, waveforms
        iii. HeartMate II- Speed, power, pulsatility index
        iv. Jarvik 2000
        v. Total artificial heart- CO, fills, waveforms, partial fill & full eject
3. Exercise testing
    a. 6 minute walk
    b. VO2 by treadmill, bike etc
4. End-organ recovery
    a. Renal function
    b. Pulmonary compliance
    c. Hepatic function
    d. Muscle strength, nutrition
5. Echocardiographic
    a. Pre-operative Evaluation
        i. Chamber size evaluation
        ii. Evaluation for thrombus
        iii. Atrial septal inspection for PFO/ASD
        iv. Aortic valve assessment – monitoring for AI
        v. Pulmonary valve – PI or significant PS/dysplasia

        vi. Mitral valve – inflow velocity, chordal obstruction
        vii. Tricuspid valve: TR velocity and severity, TS
    b. Post-operative implantation
        i. LV size
        ii. Inflow cannula placement
        iii. Septal position (goal of neutral)
            a. Over-emptying: R->L bowing; diminutive LV
            b. Under-emptying: large LV, poor inflow Doppler
        iv. LA volume
        v. Inflow cannula position
            a. Position by 2D or 3D
        vi. RV size and function
        vii. Mitral valve insufficiency
        viii. Monitor outflow graft
        ix. Pericardium for effusion
    c. Monitoring for pump malfunction
        i. Multi-modality including clinical, biomarkers, pump settings, CT, US
            a. Inflow malfunction
                i. Inflow cannula obstruction, malposition, hyperdynamic LV apical function
                ii. Cannula thrombosis
                    A. Other intracardiac thrombosis
            b. Chamber obliteration/underfilling
                i. LVAD induced ectopy
            c. Outflow malfunction
                i. Kinking or thrombus
            d. Significant AI due to cannula misplacement
    d. Monitoring for recovery
        i. Repeat echocardiogram at lower support
        ii. Continuous flow VAD
            a. Ramp study
            b. RPM reduction for 2-4 weeks
                i. Repeat echo imaging and clinical testing
                ii. Review of data and protocols
        iii. Pump stop with Berlin Heart
            a. With or without Dobutamine stress
            b. Review of data and protocols
6. Running your VADs at lower RPMs than recommended: What are the risks. What do we know?
    a. London/U of L experience with recovery protocol in adults
        i. Intensive medication approach
        ii. Weaning of RPM and follow up
    b. Parameters to consider before weaning
        i. EF, LVED, and pump goals
        ii. RV function
        iii. Patient goals
    c. Thrombosis risk
        i. Is a change in anti-thrombotics warranted
7. Chronic use and myocardial recovery
    a. Optimal settings for recovery

   b. Medications used for remodeling
   c. Monitoring for recovery with decreasing settings/Echo parameters and exercise testing
   d. Anti-coagulation management during wean or trial off
   e. Explant in the patient that has recovered

Key References:
146-152

Section XII: Discharging a Pediatric Patient Back into the Community

Learning Objectives for Discharging a Pediatric Patient Back into the Community:

- **A. Understand education and training of parents, school personnel and paramedics for home discharge.**
- **B. Recognize the importance of school integration for children.**
- **C. Understand important medical and social obstacles impacting success at home on VAD support.**
- **D. Learn the needs of pediatric patients discharged on VAD support.**
- **E. Learn outpatient management (ex: timing, echocardiographic follow-up, adjusting pump speed to the needs of children at home).**
- **F. Recognize reasons for readmissions and complications for outpatient management.**
- **G. Learn psychosocial considerations of children discharged home on LVAD and safety of typical childhood activities on VAD support.**

1. Discharge Planning and Teaching
   a. Essential issues to consider before discharge
   b. Patient criteria for discharge
   c. Draft of a discharge protocol
2. Education and Training
   a. Emergency Algorithm for EMS/Paramedics/Primary Care Physicians
   b. Family Centered Simulations
   c. Practical Workshop
   d. Essential principles for Preparation for school integration
3. Equipment for Home
   a. Practical hands-on training
4. Practical VAD Simulation Workshop
5. Outpatient Care and Anti-Coagulation Team
   a. Trouble-shooting for outpatients
   b. Anticoagulation and activities
   c. Reasons for re-admission: what we can and can't learn from the adults

Key References:
40, 153-156

Section XIII: Preparing for Cardiac Transplant

Learning Objectives for preparing for cardiac transplant:

A. **Recognize the increased rate of sensitization associated with VAD therapy.**
B. **Understand the importance of optimizing nutrition and providing a cardiac rehabilitation program while patients await cardiac transplant.**
C. **Understand the data regarding transplant outcomes in patients supported with a VAD while waiting.**

1. Sensitization while on a VAD
    a. Adult experience (see also section VII)
    b. Pediatric experience

2. VAD/TAH explantation for transplantation
    a. Management of anti-coagulation during time from organ acceptance to OR
    b. Technical aspects and going on cardiopulmonary bypass
3. Rehabilitation
    a. Transitioning to floor
    b. Cardiac rehabilitation programs
    c. Differences in goals between various centers to achieve prior to transplant activation
4. Optimizing nutrition to improve post-transplant outcomes
5. Transplant outcomes post pediatric VAD support

Key References:
91-102, 157-163

Section XIV: Pediatric VAD Program Development for Children and Adults Congenital Heart Disease

Learning objectives for Pediatric VAD Program Development:

A. **Understand the structure required to start a program, including identifying core team, education plans and determining what devices that your institution will purchase.**
B. **Define the role of improvement science in VAD programs including how to determine quality metrics and initiatives to improve outcomes.**

1. Essential members of the team
    a. Champion

    b. Surgeon
    c. Perfusion
    d. VAD Coordinator
    e. Hematology
    f. Laboratory partners
    g. Physical/occupational therapy
    h. Social work
    i. Consultants
        i. Neurology
        ii. Infectious Disease
2. Define the equipment components of a pediatric VAD program by support duration and determine feasibility for your program
    a. Short-term support
        i. ECMO
        ii. Temporary continuous flow devices
            1. Rotaflow (Maquet)
            2. CentriMag/PediMag (Thoratec)
            3. Other
        iii. Percutaneous
            1. Tandem Heart
            2. Impella
            3. Aortic Balloon Pump
            4. Other
    b. Long-term support strategies
        i. Berlin
        ii. HeartMate II (Thoratec)
        iii. HVAD (HeartWare)
        iv. TAH (Syncardia)
        v. Jarvik 2000
        vi. Other
3. Define the types of devices needed in a pediatric VAD program by patient size
    a. Neonates
        i. Pedimag
        ii. Berlin
    b. School Aged
        i. Centrimag or Rotaflow
        ii. Berlin
        iii. HeartWare
    c. Adolescents
        i. Centrimag or Rotaflow
        ii. HeartWare
        iii. Heart Mate II
4. Define a biventricular support strategy for your institution
    a. Syncardia
    b. Bi-Ventricular HVAD
    c. Bi-Ventricular Berlin
    d. Short-term RV support with durable left side device
5. The compliance and regulatory issues required to use off label devices
    a. Approved ages
    b. Industry size recommendations

6. Various educational models that could be effective
    a. For parents/families/patients
    b. Human factors testing
        i. Adult devices being used off label
    c. For nurses/ancillary staff
        i. End users
        ii. Code team
    d. For core team
        i. Industry trained core
    e. Community health care providers
        i. EMS
        ii. School
7. Process to define quality metrics and improvement initiatives
    a. Various centers experience
    b. Importance of working with other centers
8. Registries
    a. PediMACS
    b. INTERMACS

Section XV: Simulation And Education of the Team

Learning objectives for Simulation and Education of the Team:

A. Understand the importance of all 3 aspects of education: simulation training, hands on experience, and didactics.
B. Define common scenarios that are well received with simulation training.

1. How to establish a VAD education program
   a. Adequate personnel required to train the team
   b. Didactics
   c. Hands on
      i. Set up
      ii. Alarm troubleshooting
   d. Simulation training
      i. Learning from ECMO
      ii. Learning from surgical simulation
   e. Maintaining proficiency
      i. Initial and annual competency
      ii. Just-in-time training
      iii. Daily bedside device rounds
      iv. Knowledge assessment

2. Hands on Simulations for pediatric VAD programs
   f. Personnel that is needed for a simulation
      i. Bedside nurse
      ii. VAD coordinator
      iii. Medical Provider
      iv. Family members
   g. Goals
      i. System check
      ii. Latent safety threats
      iii. Team dynamics
   h. Location: in-situ or in simulation center
   i. Examples of simulation experiences:
      i. Right heart failure
      ii. Dehydration of an Outpatient
      iii. HTN Crisis
      iv. Device failure

Key References:
164-168

Section XVI: Specialized VAD Core Team Education

Learning objectives for Specialized VAD Core Team Education:

A. **Understand the importance of having identified VAD core team members who have received specialized training to troubleshoot devices.**
B. **Recognize the importance of a training curriculum that aims at educating providers on pediatric and ACHD VAD specific issues.**

1. Recognize the Need for Pediatric VAD training and Core Competencies
    a. Complexity of Diseases and Diagnostic Evaluation
    b. Risks of wrong device selection
    c. Importance of continuity
    d. Ownership of anti-coagulation
2. Multidisciplinary Team of:
    a. VAD Coordinator
    b. Surgery
    c. Perfusion
    d. Nursing
    e. Providers
3. Roles and Responsibilities of Team
    a. Initial evaluation
    b. Daily follow up
    c. Dressing changes
    d. Patient and family education
    e. Develop care guidelines
    f. Monitor and support medical team
    g. 24/7 on call coverage

Section XVII: Difficult Decisions: End-Of Life Care of the Pediatric Heart Failure Patient

Learning Objectives for Palliative Care in Pediatric MCS patients:

A. **Understand the tools available to assess quality of life in pediatric and adult congenital heart disease VAD patients.**
B. **Understand the importance of advanced medical directives in the pediatric VAD supported patient.**
C. **Understand the impact of chronic (destination) therapy or discontinuation of care on families.**
D. **Understand the need for multi-institutional pediatric palliative care research and quality improvement initiatives.**

1. Review of current QoL available and current best practices for assessing adequate pain control
    a. PedsQL 4.0
    b. Seattle Heart Failure Score
2. Advanced directives role in MCS care:
    a. Review current legal requirements in many States for patients with poor prognosis.
    b. Involve patient in decision-making process if possible
    c. Ensure that parents and healthcare providers have shared mental model
3. Review of common psychiatric difficulties in MCS patients
    a. Depression
    b. Anxiety
    c. Post-traumatic Distress
    d. Insomnia
4. There is a major impact of the families of pediatric patients with MCS:
    a. Review coping strategies: religion, life philosophy, etc.
    b. Impact of bereavement on family especially siblings (survivor guilt, parental overprotection, etc)
5. Destination or chronic therapy in pediatrics:
    a. Destination device therapy in the pediatric population
    b. Financial burden of destination therapy
    c. Ethics of discontinuing mechanical support
    d. Expected symptoms /course with discontinuation
    e. Role of palliative care
    f. Establishment of DNR/DNI and decisions regarding when to return to hospital
6. Review obstacles to effective pediatric palliative care research:
    g. Inadequate funding
    h. Inadequate researcher workforce
    i. Public and professional misunderstanding of palliative and discomfort with end of life.
    j. Differences between adult and pediatric palliative care

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