SPECIAL CONSIDERATIONS AND CLINICAL DECISION MAKING IN PEDIATRIC CRITICAL CARE

LEARNING OBJECTIVES
1. Identify special considerations to promote patient safety while working with an interdisciplinary team in the pediatric critical care setting.
2. Identify challenges with functional mobility and therapeutic exercise in pediatric patients requiring mechanical ventilation, ventricular assist devices, and ECMO.
3. Utilize clinical decision making skills to determine appropriateness for initiation of and progression of age appropriate therapeutic interventions.
4. Educate patient families and promote parental/care giver interaction in order to facilitate age-appropriate activities while in the ICU setting.

DISCLOSURES
No relevant financial relationship exists.

WHAT IS PT IN THE PEDIATRIC CRITICAL CARE SETTING
- What the research supports
- Goals of physical therapy interventions in critical care
- Advocating for our patients
- Differences in adult and pediatric populations

WHAT IS PT IN THE PEDIATRIC CRITICAL CARE SETTING
- Goals of Physical Therapy interventions in critical care
  - Optimize positioning while immobilized
  - Promote early mobilization and rehabilitation
  - Improve mobility, strength, cardiopulmonary endurance
  - Prevent ICU acquired weakness

[1- Cameron, 2013; 2- Wicks, 2015]
### SPECIAL CONSIDERATIONS AND CLINICAL DECISION MAKING IN PEDIATRIC CRITICAL CARE

**WHAT IS PT IN THE PEDIATRIC CRITICAL CARE SETTING**

- Advocating for our patients
  - Interdisciplinary team communication
  - Family interaction, support, involvement

**WHAT IS PT IN THE PEDIATRIC CRITICAL CARE SETTING**

- Differences in Adult and Pediatric populations
  - Developmental milestones
  - Gross motor skills
  - Age appropriate behavior and play
  - Maturity/age
  - Motivation

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**AGE EXAMPLES ICU VS PICU**

- Interdisciplinary team
- Lines and Leads
- Cardio-pulmonary
- Surgical considerations
- Cognition
- Positioning
- Family interaction

**SPECIAL CONSIDERATIONS FOR PHYSICAL THERAPY IN PEDIATRIC CRITICAL CARE SETTING**

- Interdisciplinary team
- Lines and Leads
- Cardio-pulmonary
- Surgical considerations
- Cognition
- Positioning
- Family interaction

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**PICTURE EXAMPLE OF LINES**

**SPECIAL CONSIDERATIONS- INTERDISCIPLINARY TEAM**

- Critical Care Team
- Consulting Medical Teams
  - Transplant
  - Renal
  - Liver
  - Neurosurgery
  - Trauma
  - Orthopedics
  - Plastics
  - CV surgery
  - Palliative
  - Neurology
  - ENT
  - Hematology/Oncology
### SPECIAL CONSIDERATIONS - INTERDISCIPLINARY TEAM

- Ancillary Services/Providers
  - Child Life Specialists
  - Music Therapy
  - Pet Therapy
  - Occupational Therapy
  - Speech Therapy
  - Respiratory Therapy
  - Nursing
  - Chaplain
  - Nutrition
  - Social Work
  - Care Management

### SPECIAL CONSIDERATIONS - LINES AND LEADS

#### THERAPY SERVICES

- Ancillary Services/Providers
  - Child Life Specialists
  - Music Therapy
  - Pet Therapy
  - Occupational Therapy
  - Speech Therapy
  - Respiratory Therapy
  - Nursing
  - Chaplain
  - Nutrition
  - Social Work
  - Care Management

### SPECIAL CONSIDERATIONS - LINES AND LEADS

#### Dialysis Catheters
  - Continuous Renal Replacement Therapy (CRRT)
  - Peritoneal

#### Arterial Lines
  - External Ventricular Drainage catheter (EVD)

#### Mechanical Ventilation Lines
  - Endotracheal tubes (ETT)
  - Nasotracheal tubes (NTT)
  - Tracheostomy

#### Extracorporeal Membrane Oxygenation (ECMO)

### SPECIAL CONSIDERATIONS - CARDIOPULMONARY

- Arrhythmias
- Coagulation
- Hemodynamic Stability
SPECIAL CONSIDERATIONS- CARDIOPULMONARY

- Ventilatory Support
  - Settings
    - Positive end-expiratory pressure (PEEP)
    - FiO2
    - Pressure Support trials
    - Airway Pressure Release Ventilation (APRV)
    - High Frequency Oscillatory Ventilation (HFOV)

SPECIAL CONSIDERATIONS- SURGICAL

- Restrictions and Precautions
  - Orthopedic Surgery / Trauma
  - Plastics
  - Neurosurgery
  - Cardiothoracic Surgery
  - Other
  - Clinical Judgment with Consulting Services
    - Getting clearance from primary team

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SPECIAL CONSIDERATIONS AND CLINICAL DECISION MAKING IN PEDIATRIC CRITICAL CARE

SPECIAL CONSIDERATIONS AND CLINICAL DECISION MAKING IN PEDIATRIC CRITICAL CARE

<table>
<thead>
<tr>
<th>SURGICAL CONSIDERATION</th>
<th>SOLUTION</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cardiac</td>
<td>Sternotomy with sternal precautions</td>
</tr>
<tr>
<td></td>
<td>School age-adults: no pushing, pulling, or lifting &gt; 5K</td>
</tr>
<tr>
<td></td>
<td>Pediatric: no tummy time, pull to sit, lifting under arms</td>
</tr>
<tr>
<td></td>
<td>Schedule PT session with RN to maximize effects of pain control medication</td>
</tr>
<tr>
<td></td>
<td>Family education</td>
</tr>
<tr>
<td>Other</td>
<td>Abdominal incision</td>
</tr>
<tr>
<td></td>
<td>Pain control</td>
</tr>
<tr>
<td></td>
<td>Schedule PT session with RN to maximize effects of pain control medication</td>
</tr>
<tr>
<td></td>
<td>Abdominal binder</td>
</tr>
<tr>
<td></td>
<td>Family education</td>
</tr>
</tbody>
</table>

(Saliski, 2015)

SPECIAL CONSIDERATIONS - MENTAL STATUS

- Sedation and Pain Management
  - Optimize sedation and analgesia is necessary to promote early mobility
  - Scheduling treatment times accordingly
  - Pain medication availability
  - Safety Risks
  - Some research states no accidental extubations or decannulations or bleeding despite period of no sedation
  - However, PICUs are known to have higher rates of unplanned extubations compared to adults

(Saliski, 2015)

SPECIAL CONSIDERATIONS - MENTAL STATUS

- ICU Delirium
  - Delirium is a manifestation of acute brain dysfunction characterized by an acute disturbance of consciousness accompanied by inattention, disorganized thinking, perceptual disturbances that fluctuate over a short period of time
  - Implementing a schedule and early mobility
  - Promoting appropriate sleep/wake cycles

(Banerjee, 2011)

BARRIER CONSIDERATION | SOLUTION
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Sedation</td>
<td>Do not sedate</td>
</tr>
<tr>
<td></td>
<td>Schedule PT session around sedation and administration</td>
</tr>
<tr>
<td></td>
<td>Primary team discussion</td>
</tr>
<tr>
<td></td>
<td>Maintain patient environment</td>
</tr>
<tr>
<td>Agitation</td>
<td>Cause of agitation</td>
</tr>
<tr>
<td></td>
<td>Tolerating tactile stimulation</td>
</tr>
<tr>
<td></td>
<td>Risk vs. benefit</td>
</tr>
<tr>
<td></td>
<td>Level of cardiac/respiratory support</td>
</tr>
<tr>
<td></td>
<td>Hypodynamically unstable</td>
</tr>
<tr>
<td></td>
<td>Mixed v/s no support</td>
</tr>
<tr>
<td></td>
<td>Utilize RN assistance to prevent unplanned extubation</td>
</tr>
<tr>
<td></td>
<td>Modify or hold PT services</td>
</tr>
<tr>
<td>ICU Delirium</td>
<td>Interference with appropriate sleep/wake cycle</td>
</tr>
<tr>
<td></td>
<td>Interference with safe mobility</td>
</tr>
<tr>
<td></td>
<td>Encourage appropriate circadian rhythms</td>
</tr>
</tbody>
</table>
|                       | Involve Child Life 
|                       | Utilize daily schedule |
|                       | Family education to encourage sleep/wake cycle |

(Cahalin, 2011)

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SPECIAL CONSIDERATIONS AND CLINICAL DECISION MAKING IN PEDIATRIC CRITICAL CARE

SPECIAL CONSIDERATIONS- POSITIONING

- Therapeutic Positioning Devices
  - Tumbleform chair
  - Boppy/nursing pillow
  - Cube chair
  - Pediatric chair
  - High chair
  - Bouncy seat
  - Floor mat
  - Therapy ball
  - Jump-a-roo

- Other
  - Splints
  - Restraints/ pedi-wraps
  - Support for lines
  - Family holding
  - Skin integrity
  - Bed surface
  - PRAs/Fs

Progressing developmental therapy in the Pediatric Critical Care Setting

1. Tolerance to supine activity: ROM, midline skills, visual tracking, kicking
2. Tolerance to upright positioning: supported sitting and tumbleform chair
3. Progress mobility: more independent sitting, prop sitting, independent head control
4. Progress to out of crib: play mat, therapy ball, cube chair
5. Progress mobility: supported standing, pull to stand, cruising

SPECIAL CONSIDERATIONS- FAMILY INTERACTION

- Education for family
  - Patient’s mobility is impacted by family support
    - Precautions
    - Importance of mobility
    - Reinforce goals of therapy
    - Safety with lines and leads
    - Sibling involvement
  - Parental holding to promote comfort and bonding

CONCLUSION

NEW ERA OF PEDIATRIC VENTRICULAR ASSIST DEVICES AND IMPLICATIONS TO PHYSICAL THERAPY

Robin Schlosser, PT, DPT

BACKGROUND:

- Pediatric Cardiac Transplant Trends
  - Zafar et al reviewed UNOS data from 1999-2012
  - Patients supported with a VAD were four times more likely to survive to transplant

<table>
<thead>
<tr>
<th></th>
<th>Era 1</th>
<th>Era 2</th>
</tr>
</thead>
<tbody>
<tr>
<td>% of pediatric patients listed for cardiac txp</td>
<td>2.1%</td>
<td>3.34%</td>
</tr>
<tr>
<td>Waiting list mortality</td>
<td>10%</td>
<td>8%</td>
</tr>
<tr>
<td>Patients on VADs</td>
<td>6%</td>
<td>16%</td>
</tr>
<tr>
<td>UNOS Status 1A</td>
<td>68%</td>
<td>80%</td>
</tr>
</tbody>
</table>

(Zafar et al, 2015)
NEW ERA OF VADS

- Reviewed UNOS data from 2006-2014
- <18 years at listing for heart transplant
- Supported by a long term/durable VAD at listing and/or transplant
- Supported by a long term/durable VAD at transplant

<table>
<thead>
<tr>
<th></th>
<th></th>
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</tr>
</thead>
<tbody>
<tr>
<td>% Supported by VADs</td>
<td>11%</td>
<td>16%</td>
</tr>
<tr>
<td>&lt;25kg</td>
<td>7%</td>
<td>11%</td>
</tr>
<tr>
<td>25-50kg</td>
<td>13%</td>
<td>14%</td>
</tr>
<tr>
<td>&gt;50kg</td>
<td>17%</td>
<td>26%</td>
</tr>
<tr>
<td>Continuous flow VAD (cfVAD)</td>
<td>7%</td>
<td>52%</td>
</tr>
</tbody>
</table>

(Stilla et al., 2017)

NEW ERA OF VADS

- Limitations:
  - Data taken at listing and at transplant
  - Does not account for:
    - Patients on VADs not listed for transplant
    - Waiting days for patients improved after listing

<table>
<thead>
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</tr>
</tbody>
</table>

(Stilla et al., 2017)

CONTINUOUS FLOW (cfVAD) VS. PULSATILE

CONTINUOUS FLOW
- ROTAFLOW (short term)
- Impella (short term)
- Heartware (HVAD)
- Heartmate II

PULSATILE
- Berlin Heart EXCOR
- Syncardia Total Artificial heart

TCH MECHANICAL SUPPORT PATHWAY

SPECIAL CONSIDERATIONS FOR ALL PEDIATRIC VADS

- Increased risk for stroke (Jaquiss, 2017; Coffin, 2015)
- Thorough evaluation, constant reassessment
- Therapist education on devices
- Constantly reassess patient’s condition
- Family education from day one
- Importance of Interdisciplinary Collaboration

(Stilla et al., 2017; Coffin et al., 2015)
GOALS OF THERAPY
- Functional Mobility/strength
- Balance
- Increase Endurance
- Increase Independence
- Achieve Developmental milestones
- Prepare for Community Reintegration
- Patient to manage device

INITIATION OF THERAPY
- As soon as possible
- Ideally 1st 48 hours

TCH MECHANICAL SUPPORT PATHWAY

LONG TERM SUPPORT: INFANTS AND TODDLERS
Berlin Heart ExcOR VAD - At our institution utilized for patients with body surface area and chest too small for Heartware
- Pulsatile, pneumatic pump
  - FDA approval 2011
  - 10 cc to 60cc can support adults
- Only the Berlin Heart EXCOR, is approved by the FDA as a Bridge to Transplant in pediatric patients.
  - ~30% stroke rate


LONGTERM VAD SUPPORT - BERLIN HEART

Battery limitations
- Flex ahead (flexing room, extension cord)
- Be creative
- Flex ahead
- For the future, “Jarvick 2015 (ventricular assist device “PumpKIN Trail”)

Must remain infantile while on device
- Keep comfortable
- Work on their level with what interests them

Measuring progress
- Standardized tests as appropriate may require omission of items

SPECIAL CONSIDERATIONS AND CLINICAL DECISION MAKING IN PEDIATRIC CRITICAL CARE
THE FUTURE OF INFANTS AND TODDLERS NEEDING VENTRICULAR ASSIST DEVICES??

- New technology:
  - Jarvik 2015 “PumpKIN”
  - Currently in FDA trial

BERLIN HEART EXCOR PEDIATRIC VAD

LONG TERM SUPPORT: CHILDREN TO ADOLESCENTS

Heartmate II  Heartware

LONG TERM VAD SUPPORT: CHILDREN TO ADOLESCENTS HEARTWARE AND HEARTMATE II

<table>
<thead>
<tr>
<th>SPECIAL CONSIDERATION/BARRIER</th>
<th>SOLUTION/RECOMMENDATION</th>
</tr>
</thead>
<tbody>
<tr>
<td>Understanding of device</td>
<td>Parent education and patient education when appropriate</td>
</tr>
<tr>
<td>Unplugging power sources</td>
<td></td>
</tr>
<tr>
<td>Activity limitations</td>
<td></td>
</tr>
<tr>
<td>Running, jumping, contact sports</td>
<td></td>
</tr>
<tr>
<td>No bath or swimming</td>
<td></td>
</tr>
<tr>
<td>Initially sternal precautions</td>
<td></td>
</tr>
<tr>
<td>Anticoagulation</td>
<td></td>
</tr>
<tr>
<td>Measuring progress</td>
<td></td>
</tr>
</tbody>
</table>

Heartware® (HVAD)

- Percutaneous drive line connects to external controller
- Continuous flow 1800-4000 RPM can flow up to 10LPM
- Magnetically suspended impeller
- Batteries last 4-6 hours
- No pump pocket
- Smallest patient at our institution 11kg

LONG TERM SUPPORT: CHILDREN TO ADOLESCENTS HEARTWARE® (HVAD)

COMPARATIVE ANALYSIS

“Similar hemodynamic unloading, pre-transplant end-organ function and post transplant outcomes in patients bridged to transplantation with both the HVAD and HMII LVAD”

HVAD SPECIAL CONSIDERATIONS - PT IMPLICATIONS

**Consideration:** Weight of device and batteries
- Heartware batteries and controller weigh 3lbs
- Smallest patient at our institution 11kg = 24.25lbs
- Heart ware + 2 batteries = 12.37% of patient's weight

**Goal for patients to carry:**
- Backup controller and batteries in a backpack at all times

**Recommendation/PT Implications:**
- Address balance, be aware of center of gravity
- Support weight of batteries
- Creative weight distribution

HEARTMATE II

- More prevalent at presenter's institution prior to Heartware
- Requires a pump pocket

A PARENT’S PERSPECTIVE

- Video

THROUGH THE EYES OF A CHILD

- Video

LONG TERM SUPPORT - BIVAD

- Less Frequent
- Same principles apply

LONG TERM SUPPORT – Syncardia TAH
LONG TERM SUPPORT: SYNCARDIA TOTAL ARTIFICIAL HEART

Potential Barriers
- Bleeding/Tamponade
- Line interference (PICC lines, central lines) lines too far into heart, interfering with valves
- Equipment size – although now improved
- Drive line management

[Shah et al., 2012]

LONG TERM SUPPORT – CAPTURING PROGRESS

- 6 min walk tests
- Peabody
- Balance
- Timed Up and Go
- MMT

SHORT TERM SUPPORT: IMPELLA

- Bridge to Recovery or Bridge to Transplant
- Percutaneous left ventricular assist device (LVAD)
- Minimally invasive, percutaneous axial flow pump (both inserted percutaneously through femoral or axillary artery)
- Can provide non-pulsatile circulatory support of up to 2.5-5.0 L/min
- Works by:
  - Actively unload LV
  - Decrease workload and oxygen consumption
  - Cardiac output
  - Coronary and end-organ perfusion

[McCullough, 2012]

SHORT TERM SUPPORT: IMPELLA – PT CONSIDERATIONS

For femoral placement:
- Consideration:
- Ensure leg is fully extended and neutral position
- Do not cause AOD > 15 degrees angle
- Use low profile cannulas to maintain access artereugraphy and prevent kinking

For femoral/subfemoral placement:
- Consideration:
- Ensure leg is fully extended at neutral position
- Do not cause aseptic inflammation
- Do not allow red Impella plug to hang freely from catheter or device

SHORT TERM SUPPORT: ROTAFLOW

- Short Term Continuum: Heart (AHA, 2016)
- Percutaneous left ventricular assist device (LVAD)
- Minimally invasive, ventricular unloading axial flow pump that can be inserted percutaneously through femoral or axillary artery
- Continuous non-pulsatile circulatory support of up to 2.5-5.0 L/min
- Works by:
  - Actively unload LV
  - Decrease myocardial work and oxygen consumption
  - Increase cardiac output
  - Improve coronary and end-organ perfusion

[McCullough, 2012]
SPECIAL CONSIDERATIONS AND CLINICAL DECISION MAKING IN PEDIATRIC CRITICAL CARE

CASE STUDY: PUTTING IT ALL TOGETHER – MORE THAN JUST A PEDIATRIC PATIENT WITH A VAD

- Autism
- Heart Failure
- VAD
- Trach
- Renal Failure
- Sepsis

PHYSICAL THERAPY WITH THE PEDIATRIC PATIENT ON ECMO

Emily Hermes, PT, DPT

WHAT IS ECMO

- Types of ECMO
  - veno-venous ECMO (VV ECMO)
    - blood is returned to the venous side of the circulation
    - provides gas exchange but cannot give cardiac support
  - veno-arterial ECMO (VA ECMO)
    - blood is returned to the arterial side of the circulation
    - can be employed for both gas exchange and cardiac support

WHAT IS ECMO

Extracorporeal Membrane Oxygenation

- form of mechanical assist therapy - extracorporeal blood circuit including oxygenator and pump
- standard respiratory ECMO
  - two vascular accesses, one for removal of venous blood and the other for infusion of oxygenated blood
  - blood drained from a major vein - pumped through circuit that includes oxygenator, which oxygenates blood and removes carbon dioxide (CO₂) - oxygenated blood returned via the other cannula

TCH MECHANICAL SUPPORT PATHWAY

vv vs va ECMO

[Diagram: VV vs VA ECMO]

[Diagram: TCH MECHANICAL SUPPORT PATHWAY]
**GOALS OF ECMO REHABILITATION**

- Optimize physical conditioning while on ECMO support
- Facilitate developmental milestones
- Increase strength, endurance and mobility
- Engagement in meaningful activity
- Promote family interaction

**ECMO THERAPY INDICATIONS**

- Safe mobility and exercise
- Minimize deconditioning
- Fabrication of stabilization device
- Comprehensive interdisciplinary collaboration

**ECMO THERAPY CONSIDERATIONS**

- Precautions
  - Unstable heart rate
  - Unstable oxygen saturation
  - Fever
  - Unstable femoral cannula
  - Excessive medication per medical team
  - Changes in mental status
  - Bleeding from femoral cannula site
  - Stuffed in ECMO circuit
  - ECMO flow outside of expected limits per ECM specialist

- Contraindications
  - No nurse available at bedside
  - No ECM specialist available at bedside
  - Patient medically unstable

**INITIATION OF PT SERVICES**

- Therapy begins once medically stable
  - Post extubation/post tracheostomy
  - If prolonged intubation, begin while intubated
  - PRAFOs
  - Stabilization device
FABRICATION OF STABILIZATION DEVICE

- Headband
  - Soft strap with Velcro closure, Duoderm
  - Soft strap with Velcro closure and Velcro cannula support, Duoderm
  - Soft strap with ETT fastener
- Anchor
- Knit headband

STABILIZATION DEVICE IS A COLLABORATIVE EFFORT

- Each case is unique
  - Cannula positioning
  - Patient size
  - Level of mobility
  - Safety awareness
- Collaborative effort between therapy, ECLS team and Critical Care team to fabricate appropriate device specific to each patient

SOFT STRAP WITH VELCRO

SOFT STRAP WITH ETT FASTENER

SOFT STRAP WITH VELCRO AND VELCRO CANNULA SUPPORT

ANCHOR
SPECIAL CONSIDERATIONS AND CLINICAL DECISION MAKING IN PEDIATRIC CRITICAL CARE

KNIT HEADBAND

AGE SPECIFIC PT INTERVENTION
- Infant
  - Developmental Therapy, ROM
- Toddler/School Aged
  - Developmental Therapy, ROM, Rehabilitation
- Adolescent
  - ROM, Rehabilitation

PROGRESSION OF THERAPY
- PROM → AROM → AAROM
- Progressive tolerance to upright positioning
- Elevate head of bed, bed in chair mode
- Sitting up edge of bed
  - Tolerance to upright positioning, endurance, strength, sitting balance, weight bearing, pre-gait, UE orthosis
- Standing at bedside
  - Tolerance to upright position, endurance, strength, standing balance, weight bearing, pre-transfer, pre-gait
- Transfer to bedside chair
- Ambulation

ROLES OF OTHER INTERDISCIPLINARY TEAM MEMBERS

**TEAM MEMBER**

**ROLES**

- **Bedside Nurse**
  - Day to day care
  - Communicate appropriateness for therapy
  - Monitor vitals
  - Assist with line management

- **Child Life Specialist**
  - Helping transitions
  - Medical play for child and siblings
  - Support for family and siblings
  - Distraction during therapy

- **Chaplain and Social Work**
  - Patient and family support

BARRIERS/SOLUTIONS
- Room size/set up
  - Rearrange room
  - Rotate bed

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## BARRIERS/SOLUTIONS

### Equipment
- Rearrange room
- Consolidate lines to one IV pole, transport ventilator
- All lines going to same side of bed

### Family engagement
- Education for family members
- Benefits of therapy

### Temperature regulation
- Adaptive clothing
- Bair hugger
- Warm blankets

### Need for interdisciplinary staff support
- Build strong relationships
- Communicate frequently
- Provide education
- Attend daily rounds
BARRIERS/SOLUTIONS

• Critical medical status
  • Hold therapy
  • Follow up daily in rounds/with RN
  • Thinking outside the box for treatment interventions

AREAS FOR GROWTH AND IMPROVEMENT

• Continued education on importance of therapy with this patient population
  • Multidisciplinary team
  • Therapy staff – thorough training/competency
  • Continued development of more secure stabilization devices
  • Trialing various equipment for improved out of bed mobility

CONCLUSION

• Although these patients are critically ill and on heroic life support, with properly trained staff and appropriate equipment, they can greatly benefit from therapeutic interventions.

• Treatment of this patient population MUST be an interdisciplinary approach with open communication.

• During a treatment session, each staff member must be comfortable and confident in their role and carry out their responsibilities to ensure patient safety.

• In the pediatric ECMO patient, ventilation is not always necessary. It is important to incorporate other age appropriate treatment interventions when facilitating early rehabilitations.

• Through continued contribution and feedback put forth from all multidisciplinary team members, rehabilitation with pediatric patients on ECMO will continue to evolve into a successful standard of care.

REFERENCES:  


REFERENCES CONTINUED:


This is a work in progress and will be finalized shortly. The author(s) reserve the right to make changes at any time before final publication.