Disclosures

None –

However, I am a perfusionist and I have a bias toward perfusionists!

Purpose - Today

• Show the work completed to date

• Get your input
Purpose - Document

• AmSECT will recommend the use of this document

• Provide a framework

Approach

• 2012 BOD request
• 2013 Draft document submitted
• 2014 AmSECT International
• 2014 Public comment
• 2015 BOD requested ICEBP review
• 2016 AmSECT International

Definitions

• Standard
  • Practices, technology and/or conduct of care that institutions shall meet in order to fulfill the minimum requirements for Mechanical Circulatory Support.

• Shall
  • A mandatory requirement
Definitions

- **Guideline**
  - A recommendation that should be considered and may assist in the development and implementation of protocols

- **Should**
  - A recommendation

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**Definitions**

- **Protocol**
  - An institution-specific written document, derived from professional standards and guidelines, which contains decision and treatment algorithms.

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**Definitions**

- **Mechanical Circulatory Support**
  - Implantable, paracorporeal, and percutaneous univentricular and biventricular devices used as acute or chronic support for assisting or replacing the failing heart
Definitions

- Which of these are MCS devices to you?
  - HeartMate

Definitions

- Which of these are MCS devices to you?
  - Impella

Definitions

- Which of these are MCS devices to you?
  - IABP
Definitions

- Which of these are MCS devices to you?
  - ECMO

Indicators

- Joint Commission standard or recommendation
- In conjunction with AmSECT Perfusion Standards and Guidelines

Your Vote

- Up or down on each Standard/Guideline
- Open discussion at the end
Standard 1: Development of Institutionally Based Protocols

Standard 1.1: As a mechanism for applying each standard to clinical practice, an institution or service provider shall develop and implement an operating procedure (protocol) for each of the standards.

Standard 1.2: The protocol shall be:
- Approved by the Leader of the Multidisciplinary Team, or his/her designee, Director of Perfusion or equivalent, and other relevant clinical governance committees if available.
- Reviewed and revised annually or more frequently when deemed necessary.

Standard 1: Development of Institutionally Based Protocols

Standard 1.3: Perfusionists shall participate in MCS Clinical Practice Protocol development.

Standard 1.4: Perfusionists should participate in hospital compliance with the Disease Specific Care standards required to achieve MCS Program Certification from an accrediting body.

Guideline 1.1: Deviation from protocol may be at the discretion of the Multidisciplinary Team and should be documented in the perfusion record.
Standard 2: Qualifications, Competency, Education and Proficiency

Standard 2.1: A Perfusionist, who is Board Certified by the American Board of Cardiovascular Perfusion or who demonstrates equivalent qualifications and competency, shall provide MCS services.

Standard 2.2: The MCS Team leader(s) shall make certain that practitioners practice within the scope of their licensure, certification, training, and current competency.

Standard 2.3: Competency shall be assessed and documented at the time of hire and at least annually to evaluate compliance with departmental MCS protocols.

Standard 2.4: Members of the MCS team should attend, participate, and engage in MCS-related continuing education.

Standard 2.5: Orientation shall provide information and necessary training pertinent to the practitioner’s responsibilities. Completion of the orientation shall be documented.

Guideline 2.1: Resource material, specific for perfusion practices, for each MCS device should be readily available.
**Standard 3: Participation in a Multidisciplinary MCS Team**

**Standard 3.1:** Perfusionists shall be active participants in a multidisciplinary MCS program.

**Guideline 3.1:** Perfusionists should directly participate or supervise MCS including, but not limited to, device selection, application, initiation, termination, management, support and instruction in coordination with the MCS Team.

**Standard 4: Documentation**

**Standard 4.1:** The MCS record (written and/or electronic) for each MCS procedure shall be included as part of the patient’s permanent medical record. The MCS record shall be maintained and stored according to institution policy for retaining patient medical records.

**Standard 4.2:** Documentation should include the technical, laboratory, and physiologic parameters pertinent to the patient/device operation, upon initiation and at a minimum frequency according to established institutional protocols (Appendix A, B).

**Standard 4.3:** A checklist shall be used for all MCS procedures. The checklist shall be included in the patient’s permanent medical record.
Appendix A

- Patient specific identifiers, demographics and diagnosis
- Extracorporeal equipment in use; make, model and serial or lot number
- Mechanical circulatory support (MCS) implantables and supplies assigned to the patient; make, model and serial or lot number
- Names of Perfusion practitioners and associated personnel responsible for MCS order and management
- Signature of the practitioner providing MCS services
- Function of equipment
- Availability of backup equipment
- Those physiologic parameters of the patient directly associated with ongoing care
- Laboratory tests pertinent to the procedure
- Comments and interventions

Appendix B

- Heart rate
- Blood pressures
- Temperature
- Medications
- Input and output of fluids
- pH
- pH
- Sodium Bicarbonate
- O2 saturation PaO2
- O2 saturation PvO2
- Hemoglobin/Hematocrit
- Sodium
- Potassium
- Ionized Calcium
- Glucose
- Lactate
- Activated Coagulation Time (ACT)
- Anti-Xa test
- Activated partial thrombin time (aPTT)
- Prothrombin time (PT)
- Heparin-protamine titration test (HPT)
- Antithrombin function
- Thromboelastography
- International normalized ratio (INR)
- Pump rate
- Device power source
- Battery charge
- Blood flow
- Integrity of MCS circuit
- Alarm function and parameters
- Backup settings
- Device specific operating parameters

Standard 4: Documentation
Standard 5: Responsibilities

Standard 5.1: Setup and initiation of support with all MCS devices shall be according to protocol.

Standard 5.2: Perfusionist shall provide support, instruction and troubleshooting as appropriate to all members of the MCS team.

Standard 5.3: A protocol shall exist to ensure the safe transport of MCS device patients within or between hospitals.

Guideline 5.1: Perfusionists should be involved in the assembly and preparation of MCS devices for implantation.

Guideline 5.2: Perfusionists should be involved in the transport of MCS devices during support for patients, both within and between institutions.

Guideline 5.3: Perfusionists should conduct routine assessments for proper and optimal functioning of MCS devices with all in-patients, either as part of formal medical rounds or as an independent event.

Guideline 5.4: Perfusionists should support the training and education of other MCS direct patient care providers and patient caregivers.
Standard 6: Safety

Standard 6.1: The Perfusion department shall have protocols in place to address device failure or complications.

Standard 6.2: MCS devices shall be equipped with available safety devices.

Standard 7: Anticoagulation Management

Standard 7.1: Anticoagulation testing equipment shall be available for proper maintenance of anticoagulation during MCS per manufacturer’s guidelines.
Standard 7: Anticoagulation Management

Standard 8: Quality Assurance and Improvement

Standard 8.1: Perfusionists shall support MCS data collection.

Standard 8.2: The perfusionist shall actively participate in both institutional and departmental MCS quality assurance and improvement programs.

Guideline 8.1: A Perfusionist should contribute to the institution’s MCS data collection system for use in a national registry, performance improvement, quality assessment, evaluation and research.
Standard 9: Device and Equipment Maintenance

Standard 9.1: All MCS equipment is properly maintained to a safe and functional condition per manufacturer specifications.

Standard 9.2: Adequate backup equipment for all MCS devices in use at the institution must be accessible and in good working order (maintained).

Guideline 9.1: The Perfusionist should evaluate and minimize risks to power, gas, and communication for safe and continuous operation of MCS devices in compliance with the institution’s MCS protocol.

ECMO

- Should AmSECT create a similar document regarding ECMO?