American Society of ExtraCorporeal Technology

Standards and Guidelines

for Mechanical Circulatory Support

The American Society of ExtraCorporeal Technology (AmSECT) has created the following document based on clinical evidence and currently accepted perfusion practices. Perfusionists are the only allied healthcare professionals formally trained and educated in the field of extracorporeal science and whose scope of practice expressly includes the utilization of extracorporeal devices. The document is intended to serve as a useful guide for teams developing institution-specific protocols to improve the reliability, safety and effectiveness of mechanical circulatory support (MCS).

Goal Statement

The goal of this project was to provide perfusionists with a framework to guide safe and effective MCS care to their patients. AmSECT recommends that clinical teams use this document as a guide for developing institution-specific protocols for patients receiving MCS.

Approach

In 2012, the AmSECT Board of Directors (BOD) requested the MCS Committee to generate a MCS Standards and Guidelines document. In 2013, the MCS committee submitted a proposed MCS Standards and Guidelines to the BOD for review. Following that review, the document was shared with the perfusion community at AmSECT's International conference in 2014. Based on feedback from conference attendees, the MCS Committee submitted a revised document to the membership for public comment. In December of 2015 the BOD requested the International Consortium for Evidence-Based Perfusion (ICEBP) Committee review the document. The feedback from the public comment and ICEBP review were incorporated into the document and again presented to the membership at AmSECT's 54th International Conference in 2016. These Standards and Guidelines will be reviewed and updated as necessary or as deemed appropriate by AmSECT's BOD.

Definitions:

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

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

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

Mechanical Circulatory Support (MCS): Implantable, paracorporeal, and percutaneous univentricular and biventricular devices used as acute or chronic support for assisting or replacing the failing heart.

Word Usage:

Shall: In this document, the word shall is used to indicate a mandatory requirement.

Should: In this document, the word should is used to indicate a recommendation.

Index: AmSECT Standards for Mechanical Circulatory Support

Standard 1: Development of Institutionally-based Protocols[1]

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[a].

Standard 1.3: Perfusionists shall participate in mechanical circulatory support (MCS) Clinical Practice Protocol development.

Standard 1.4: Perfusionists shall 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.

[a] Joint Commission standard/ recommendation

Standard 2: Qualifications, Competency, Education and Proficiency [3-7, 15]

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 mechanical circulatory support (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[b].

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[c].

Standard 2.4: Members of the MCS team shall 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[d].

Guideline 2.1: Resource material, specific for perfusion practices, for each MCS device should be readily available.

[b] Joint Commission standard/ recommendation
[c] Joint Commission standard/ recommendation
[d] Joint Commission standard/ recommendation

Standard 3: Participation in a Multidisciplinary Mechanical Circulatory Support Team[1, 2, 19]

Standard 3.1: Perfusionists shall be active participants in a multidisciplinary mechanical circulatory support (MCS) program as directed by institutional protocol.

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 [9-14]

Standard 4.1: The mechanical circulatory support (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 shall 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[e] : A checklist shall be used for MCS procedures. The checklist shall be included in the patient's permanent medical record.

[e] To be considered in conjunction with AmSECT Perfusion Standards and Guidelines, Standard 4: Checklist

Standard 5: Responsibilities

Standard 5.1: Setup and initiation of support with all mechanical circulatory support (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 caregivers.

Standard 6: Safety[8]

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

Standard 6.2: Mechanical circulatory support (MCS) devices shall be equipped with available safety devices.

Standards 7: Anticoagulation Management [16-18]

Standard 7.1: Anticoagulation testing equipment or access to laboratory services shall be available for proper maintenance of anticoagulation during mechanical circulatory support (MCS) per manufacturer's guidelines.

Standard 8[f]: Quality Assurance and Improvement [4,5]

Standard 8.1: Perfusionists shall support mechanical circulatory 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.

[f] [f]To be considered in conjunction with AmSECT Perfusion Standards and Guidelines, Standard 13: Quality Assurance and Improvement

Standard 9[b]: Device and Equipment Maintenance[8]

Standard 9.1: All mechanical circulatory support (MCS) equipment shall be properly maintained in a safe and functional condition per manufacturer specifications.

Standard 9.2: Adequate backup equipment for all MCS devices in use at the institution shall 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.

References:

1. Murray MA, Osaki S, Edwards NM, et al. Multidisciplinary approach decreases length of stay and reduces cost for ventricular assist device therapy. Interact Cardiovasc Thorac Surg 2009;8:84-8.

2. Joint Commission Requirements for Ventricular Assist Device Destination Therapy Advanced Certification. 2016.

3. The Joint Commission. *2016 Comprehensive Accreditation Manual for Hospitals: The Official Handbook.* Oakbrook Terrace, IL: Author. 2016.

4. Joint Commission HEALTH CARE STAFFING SERVICES PERFORMANCE MEASUREMENT IMPLEMENTATION GUIDE 2ND EDITION

5. AmSECT Position Statement on Portable and Percutaneous Extracorporeal and Mechanical Circulatory Support Devices

6. Joint Commission on Accreditation of Healthcare Organizations. *Assessing Hospital Staff Competence.* Oakbrook Terrace, IL: Joint Commission Resources; 2007.

7. IOM (Institute of Medicine). 2010. *Redesigning Continuing Education in the Health Professions.* Washington, DC: The National Academies Press.

8. Centers for Medicare and Medicaid Services §482.41(c)(2) - Facilities, supplies, and equipment must be maintained to ensure an acceptable level of safety and quality. Interpretive Guidelines §482.41(c)(2)
9. Recommendations for standards of monitoring during cardiopulmonary bypass. July, 2007. http://www.scps.org.uk/index.php?option=com_content&task=view&id=27&Itemid=42

10. Guidelines for Medical Record and Clinical Documentation
WHO-SEARO coding workshop September 2007

11. Smith, CM. "Documentation Requirements for the Acute Care Inpatient Record (AHIMA Practice Brief)." Journal of AHIMA 72, no.3 (2001): 56A-G.

12. Guidelines for Medical Record and Clinical Documentation WHO-SEARO coding workshop September 2007
http://occupationaltherapy2012.files.wordpress.com/2012/03/2007_guidelines_for_clinical_doc.pdf

13. Department of Health and Human Services. "42 CFR, Part 482 Conditions of Participation for Hospitals." http://www.access.gpo.gov/nara/cfr/waisidx_99/42cfr482_99.html

14. Staunton & Chiarella Nursing and the Law 5th Edit Churchill Livingstone 2003
American Health Information Management Association - Legal Documentation Standards
http://www.ahima.org/resources/infocenter/ltc/guide5.aspx

15. Stahl MA, Richards NM. Ventricular assist devices: developing and maintaining a training and competency program. J Cardiovasc Nurs 2002;16:34-43.

16. Slaughter et al, Clinical management of continuous-flow left ventricular assist devices in advanced heart failure J Heart Lung Transplant 2010;29:S1–S39

17. Feldman et al, The 2013 International Society for Heart and Lung Transplantation Guidelines for mechanical circulatory support: Executive summary J Heart Lung Transplant 2013;32:157–187

18. Hunt et al, 2009 Focused Update Incorporated Into the ACC/AHA 2005 Guidelines for the Diagnosis and Management of Heart Failure in Adults JACC Vol. 53, No. 15, 2009

19. Deng et al., Destination Mechanical Circulatory Support: Proposal for Clinical Standards J Heart Lung Transplant 2003;22:365–369

Appendix A:

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

Appendix B:

Patient Physiologic Parameters;

1. Heart rate
2. Blood pressures
3. Temperature
4. Medications
5. Input and output of fluids

Patient Laboratory Values - patient arterial and/or venous blood analysis for;

1. pH
2. pCO2
3. pO2
4. Sodium Bicarbonate
5. O2 saturation Pa O2
6. O2 saturation Pv O2
7. Hemoglobin/Hematocrit

8. Sodium
9. Potassium
10. Ionized Calcium
11. Glucose
12. Lactate
13. Activated Coagulation Time (ACT)
14. Anti-Xa test
15. Activated partial thrombin time (aPTT)
16. Prothrombin time (PT)
17. Heparin-protamine titration test (HPT)
18. Antithrombin function
19. Thromboelastography
20. International normalized ratio (INR)

Support Device and Circuit Parameters - information specific to the implanted device upon initiation of mechanical circulatory support and at a minimum frequency according to established institutional protocols[g].

1. Pump rate
2. Blood flow
3. Device power source
4. Battery charge
5. Integrity of MCS circuit
6. Alarm function and parameters
7. Backup settings
8. Device specific operating parameters

[g] Joint Commission standard/ recommendation

Appendix C: Regulatory documents, Revision 2016

REGULATORY CITATION LEGEND

Regulations, Standards and Guidelines Resources	Citation Prefix
DNV-GL Healthcare **VAD Facility Credentialing Program Requirements 4.0** - 2014	**DNV-GL**
The Joint Commission **Disease-Specific Care: Ventricular Assist Device (VAD) Destination Therapy Certification** - 2016	**TJC-DSC**
*Note: The Centers for Medicare & Medicaid Services (CMS) outlines the criteria required for payment of provision of services and for program certification requirements by CMS approved Credentialing Organizations in the *National Coverage Determination (NCD) for Ventricular Assist Devices* document (Publication #: 100-3; Manual Section #: 20.9.1; Manual Section Title: Ventricular Assist Devices; Version # 1; Effective Date: 10/30/2013; Implementation Date: 9/30/2014). **Note: As of September 2016 the current CMS approved Ventricular Assist Device Credentialing Organizations include: 1) The Joint Commission (TJC) and 2) DNV-GL Healthcare	

Standard/Guideline	*Regulations, Standards and Guidelines Resources*	***Section***
Standard 1.1	***DNV-GL***	***QM.1_CR.5; QM.2; QM.6_CR.2; PC.2_CR.1, CR.3 – CR.4; SM.1; PR.1***
	TJC-DSC	***DSPR.1_EP.5; DSPR.2_EP 1 – EP 4; DSPR.3_EP 1; DSPR.5_EP 1; DSDF.2_EP 1 – EP 3; DSPM.1_EP 1 – EP 3***
Standard 1.2 • *Dot Point 1*	***DNV-GL***	***QM.1_CR.5; QM.2; PC.2_CR.1, CR.3 – CR.4***
	TJC-DSC	***DSPR.1_EP.5; DSPR.2_EP1– EP 4; DSPR.3_EP 1; DSPR.5_EP1;DSDF.2_EP1–EP3; DSPM.1_EP 1 – EP 3***
• *Dot Point 2*	***DNV-GL***	***QM.1_CR 5a; PC.2_CR.1, CR.3 – CR.4***
	TJC-DSC	***DSDF.2_EP 6;***
Standard 1.3	***DNV-GL***	***QM.1_CR.5; QM.2; PC.2_CR.1, CR.3 – CR.4***
	TJC-DSC	***DSPR.1_EP.5; DSPR.2_EP1– EP 4; DSPR.3_EP 1; DSPR.5_EP1;DSDF.2_EP1–EP3; DSPM.1_EP 1 – EP 3***
Standard 1.4	***DNV-GL***	***PM.1_CR.1 (a-e)***
	TJC-DSC	***DSPR.1_EP.5; DSPR.2_EP1– EP 4; DSPR.3_EP 1; DSPR.5_EP1;DSDF.2_EP1–EP3; DSPM.1_EP 1 – EP 3***
Guideline 1.1	***DNV-GL***	***QM.7_CR.1b;***
	TJC-DSC	***DSPR.4_EP 1; DSPM.4_EP 2 – EP 3***
Standard 2.1	***DNV-GL***	***PC.5_CR.1;PC.5_CR.1c;PC.5_CR.1e;SM.1_CR. 1***
	TJC-DSC	***DSDF.1_EP 1 – EP 3; DSDF.1_EP 6;***

Standard 2.2	***DNV-GL***	***PM.1_CR.1a***
	TJC-DSC	***DSDF.1_EP 1 - 4; DSPR.1_EP 7***
Standard 2.3	***DNV-GL***	***PC.2_CR.5;SM.1_CR.3; SM.6_CR.1; SM.6_CR.2***
	TJC-DSC	***DSDF.1_EP 3, EP 5***
Standard 2.4	***DNV-GL***	***PC.2_CR.5;SM.1_CR.2; SM.1_CR.4; SM.6_CR.6***
	TJC-DSC	***DSDF.1_EP 7***
Standard 2.5	***DNV-GL***	***SM.1_CR.1; SM.5_CR.1***
	TJC-DSC	***DSDF.1_EP 4***
Guideline 2.1	***DNV-GL***	***PM.2_CR.3***
	TJC-DSC	***DSPR.6_EP 1 – EP 2; DSDF.1_EP 6 – EP 7***
Standard 3.1	***DNV-GL***	***PC.5_CR.1f***
	TJC-DSC	***DSPR.1_EP 3; DSPR.1_EP 6; DSPR.2_EP 1 – EP 4***
Guideline 3.1	***DNV-GL***	***PC.8_CR.1; PC.5_CR.2; PE.5_CR.1***
	TJC-DSC	***DSPR.1_EP 5; DSDF.2_EP 4; DSPM.4_EP 2a***
Standard 4.1	***DNV-GL***	***PC.8_CR.4e;MR.1_CR.1–CR.3;MR.2_CR.1CR.2; MR.4_CR.1 – CR.5; MR.5_CR.3 – CR.4, CR.6***
	TJC-DSC	***DSCT.1_EP 3 – EP 4; DSCT.2_EP 2 – EP 5; DSCT.3_EP 1 – EP 2; DSCT.5_EP1 – EP 7***
Standard 4.2	***DNV-GL***	***PC.8_CR.4e; PC.9_CR.1 – CR.2; MR.1_CR.1; MR.4_CR.1***
	TJC-DSC	***DSCT.2_EP 2 – EP 5; DSCT.5_EP 2 – EP 7***
Standard 4.3[h]	***DNV-GL***	***MR.1_CR.1; MR.2_CR.1***

[h] To be considered in conjunction with AmSECT Perfusion Standards and Guidelines, Standard 4: Checklist

	TJC-DSC	***DSCT.2_EP2–EP5;DSCT.3_EP 2; DSCT.5_EP2–EP 7***
Standard 5.1	***DNV-GL***	***QM.1_CR.5; QM.6_CR.2***
	TJC-DSC	***DSPR.1_EP.5; DSPR.2_EP 1 – EP 4; DSPR.3_EP 1; DSPR.5_EP 1; DSDF.2_EP 1 – EP 3***
Standard 5.2	***DNV-GL***	***PC.3_CR.2; PC.5_CR.1***
	TJC-DSC	***DSDF.2_EP 4***
Standard 5.3	***DNV-GL***	***QM.1_CR.5; QM.6_CR.2***
	TJC-DSC	***DSPR.1_EP.5;DSPR.2_EP1 – EP 4; DSPR.3_EP 1; DSPR.5_EP 1; DSDF.2_EP 1 – EP 3***
Guideline 5.1	***DNV-GL***	***QM.1_CR.5; QM.6_CR.2***
	TJC-DSC	***DSPR.1_EP.5; DSPR.2_EP1 –EP 4; DSPR.3_EP 1; DSPR.5_EP 1; DSDF.2_EP 1 – EP 3***
Guideline 5.2	***DNV-GL***	***QM.1_CR.5; QM.6_CR.2***
	TJC-DSC	***DSPR.1_EP.5; DSPR.2_EP1 –EP 4; DSPR.3_EP 1; DSPR.5_EP 1; DSDF.2_EP 1 – EP 3***
Guideline 5.3	***DNV-GL***	***PM.3_CR.2 – CR.5; QM.7_CR.7; PC.10_CR.2; NS.1_CR.2***
	TJC-DSC	***DSDF.4_EP 1 – EP 4, EP 7 – EP 8***
Guideline 5.4	***DNV-GL***	***QM.7_CR.6;PC.8_CR.2,CR.4;NS.1_CR.3; SM.2_CR.1;SM.2_CR.4;SM.2_CR.6; SM.2_CR.7;***
	TJC-DSC	***DSPR.5_EP 2, EP 5 – 6; DSDF.4_EP 5 – EP 8; DSDF.5_EP 1 – EP 3; DSDF.6_EP 1 – EP 4; DSSE.1_EP 2 – EP 5; DSSE.2_EP 5 -EP6; DSSE.3_EP 1 – EP 5; DSCT.4_EP 2***

Standard 6.1	***DNV-GL***	***QM.1_CR.5;QM.6_CR.2; PE.5_CR.1; PE.6_CR.2***
	TJC-DSC	***DSPR.7_EP 7 – EP 11***
Standard 6.2	***DNV-GL***	***QM.1_CR.5; QM.6_CR.1 – CR.2***
	TJC-DSC	***DSPR.7_EP 7 – EP 8***
Standard 7.1	***DNV-GL***	***PC.9_CR.1 – CR.2; PE.3_CR.1***
	TJC-DSC	***DSPR.1_EP.5; DSPR.2_EP 1 – EP 4; DSPR.3_EP 1; DSPR.5_EP 1;DSDF.2_EP 1 – EP 3; DSPM.1_EP 1 – EP 3***
Standard 8.1	***DNV-GL***	***QM1_CR.1 – CR.4, CR.7 – CR.9; QM.2; QM.3; QM.4; QM.5; QM.6_CR.1 – CR.4; QM.7_CR.1, CR.7; PC.5_CR.1h***
	TJC-DSC	***CPR 4; CPR 5; DSPM.1_EP 1 – EP 7; DSPM PM.2_EP 1 – EP 6; DSPM.3_EP 1 - EP 4; DSPM.4_EP 1 - EP3; DSPM.6_EP 1 – EP 4***
Standard 8.2	***DNV-GL***	***QM1_CR.1 – CR.4, CR.7 – CR.9; QM.2; QM.3; QM.4; QM.5; QM.6_CR.1 – CR.4; QM.7_CR.1, CR.7***
	TJC-DSC	***CPR 4; CPR 5; DSPM.1_EP 1 – EP 7; DSPM PM.2_EP 1 – EP 6; DSPM.3_EP 1 - EP 4; DSPM.4_EP 1 - EP3; DSPM.6_EP 1 – EP 4***
Guideline 8.1	***DNV-GL***	***QM1_CR.1 – CR.4, CR.7 – CR.9; QM.2; QM.3; QM.4; QM.5; QM.6_CR.1 – CR.4; QM.7_CR.1, CR.7***
	TJC-DSC	***CPR 4; CPR 5; DSPM.1_EP 1 – EP 7; DSPM PM.2_EP 1 – EP 6; DSPM.3_EP 1 - EP 4; DSPM.4_EP 1 - EP3; DSPM.6_EP 1 – EP 4***
Standard 9.1	***DNV-GL***	***PE.3_CR.1 – CR.2; PE.5_CR.1 -CR.2***
	TJC-DSC	***DSPR.7_EP 7 – EP 8; DSPR.7_EP 11***

Standard 9.2	***DNV-GL***	***PE.6_CR.1 – CR.3***
	TJC-DSC	***DSPR.7_EP 7 – EP 8; DSPR.7_EP 11***
Guideline 9.1	***DNV-GL***	***PE.6_CR.1 – CR.3***
	TJC-DSC	***DSPR.7_EP 7 – EP 10; DSPR.7_EP 11***