Changes in Standards and Guidelines from 2017

Additions to the preamble:

Unless otherwise stated, Standards and Guidelines are written for perfusion services, with the intent to be disseminated and adopted across members of this team.

This document is aimed for adult perfusion practices. For pediatric patients, please see the AmSECT Standards and Guidelines for Pediatric and Congenital Perfusion Practice document.

The term ‘supervising physician’ is intended to describe the physician responsible, at that given time, for the patient and their hemodynamics.

The word ‘continuously’ describes an action that occurs without ceasing, whereas the word ‘continually’ is intended to describe an action that recurs frequently or regularly.

Appendix: The appendices are presented as documents to help with institutional implementation of specified Standards and Guidelines. As such, appendices are meant solely as supporting material.

“Disclaimer” in preamble reworded to “special note”

Proposed New Addition

Standard 1.3: Perfusion emergency protocols shall be accessible to help guide the user during an event.

Added footnote for S1.3: AmSECT Failure Mode and Effects Analysis examples: https://www.amsect.org/page/fmea-archives

Added footnote for S1.3: OSHA and The Joint Commission. Safety and Health Management Systems and Joint Commission Standards. https://www.osha.gov/sites/default/files/2.2_SHMS-JCAHO_comparison_508.pdf (accessed August 6, 2022)

Rationale: Protocols need to be readily available during a case to allow guidance during an emergency – safety issue; added OSHA/TJC footnote link

---

Rewording

Current Guideline 1.1: Deviation from protocol may be at the discretion of the Surgical Care Team and should be documented in the perfusion record.

Proposed Guideline 1.1: Deviations from protocol or intended treatment care plan may be at the discretion of the supervising physician and should be documented in the perfusion record.

Rationale: Addition allowed for simplification/incorporation of G10.1, G11.1

Rewording

Current Standard 2.5: A process to educate, train, and annually evaluate perfusion staff shall be developed and followed.

Proposed Standard 2.5: An outline detailing the onboarding process shall be developed in order to ensure new hires are oriented and able to safely perform perfusion related responsibilities, including training with hazardous materials (e.g., radiation or chemotherapy) relevant to work duties. Onboarding process shall be documented and retained upon completion.

Rationale: To allow sufficient time for training, to avoid the tendency to rush the process and put someone on call too early – safety issue. Annual competencies are still addressed in S2.2 and S2.3

Moved to standard

Guideline 3.3 -> Standard 3.3 The primary perfusionist shall participate in the post-procedure debrief with the surgical team

Rationale: Pre-op briefing is a standard, the post should be as well. Discussion for improvements in the protocol/case, discuss safety events, equipment issues

---

Proposed New Addition

Guideline 3.3: Topics that should be considered during the post-op brief include, but are not limited to, communication, additional training, equipment or disposables issues, post-op instructions, and safety events.

Rationale: Topics that may be considered to accompany proposed S3.3 post op debrief

---

Proposed New Addition

Guideline 3.4: Deviations from the intended treatment care plan should be appropriately communicated to the supervising physician and documented to allow for changes in the management plan.

Rationale: To stress the importance of communication when a protocol or plan deviates, also covers some of the removed standards/guidelines to reduce redundancy

---

Proposed Addition of Footnote

Current Standard 6.4: Temperature monitoring of the arterial outflow from the oxygenator shall be employed during CPB procedures. The temperature sensor shall include an audible and visual alarm to prevent high arterial outlet temperatures

Proposed accompanying footnote: Engelman R, Baker RA, Likosky DS, Grigore A, Dickinson TA, Shore-Lesserson L, Hammon JW. The Society of Thoracic Surgeons, The Society of Cardiovascular Anesthesiologists, and The American Society of ExtraCorporeal Technology: Clinical Practice Guidelines for Cardiopulmonary Bypass—Temperature Management during Cardiopulmonary Bypass. J Extra Corpor Technol. 2015 Sep;47(3):145-54. PMID: 26543248.

Rationale: To include a reference for guidance on temperature management.

Rewording

Current Standard 6.5: An arterial-line filter shall be employed during CPB procedures

Proposed Standard 6.5: An arterial-line filter, external or integrated, shall be employed during cardiopulmonary bypass procedures.

Rationale: To include the possibilities of different types of arterial line filters.

Rewording

Current Standard 6.11: A back-up battery supply for the CPB machine shall be available during CPB procedures.

Proposed Standard 6.11: The cardiopulmonary bypass machine shall have a backup power source that allows for uninterrupted power supply during cardiopulmonary bypass procedures.

Rationale: Added a backup power source that allows for uninterrupted power supply.

Proposed Merged and Moved to Standard

Current Standard 7.3 Arterial blood flow shall be monitored continually during CPB.

Current Guideline 7.6 Arterial blood flow should be monitored continually at a point in the CPB circuit where it accurately reflects the flow delivered to the patient during CPB (e.g., distal to intra- circuit shunts)

Proposed merged Standard 7.3: Arterial blood flow shall be monitored continuously at a point in the cardiopulmonary bypass circuit where it accurately reflects the flow delivered to the patient during extracorporeal support procedures (e.g., distal to intra-circuit shunts).

Rationale: Guideline 7.6 merged with Standard 7.3 which already stated to monitor arterial blood flow continuously, but now makes monitoring flow distal to all shunts a standard

---

Rewording

Current Standard 7.8: Oxygen fraction and gas flow rates shall be monitored continually during CPB (Appendix D).

Proposed Standard 7.8: Oxygen fraction and gas flow rates shall be monitored continually during CPB.

Rationale: reference to Appendix D removed, not relevant

Proposed addition of footnote

Current Standard 7.9 The percentage of venous line occlusion of the venous occluder shall be monitored continually during CPB.

Proposed accompanying footnote: Monitoring of the venous line occluder only applies if a venous occluder is being utilized

Rationale: Too specific, not looking to make venous occluder a requirement, but if in use then it should be monitored

---

Merged and Moved to Standard

Current Standard 8.1: The Perfusionist, in collaboration with the physician-in-charge, shall define the intended treatment algorithm for anticoagulation management (heparin) and an alternative algorithm for when heparin is not suitable, including acceptable ranges for ACT.

Current Standard 8.2: The Perfusionist shall work closely with the surgical care team to monitor and treat the patient's anticoagulation status before, during, and after the cardiopulmonary bypass (CPB) period.

Current Guideline 8.1: The surgical care team should determine the target activated clotting time by considering relevant factors; including variability in the measurement of activated clotting time (ACT) attributed to the device's performance characteristics.

Current Guideline 8.2: Patient-specific initial heparin dose should be determined by one of the following methods:

- Weight
- Dose Response Curve (automated or manual)
- Blood Volume
- Body Surface Area

Proposed merged Standard 8.1: The Perfusionist, in collaboration with the supervising physician, shall define the intended anticoagulation management algorithm, including:

- Acceptable target and range for activated clotting time (ACT), considering relevant factors that include the variability in ACT measurement attributed to the measuring device's performance characteristics.

- Monitoring and treating the patient's anticoagulation status before, during, and after the cardiopulmonary bypass period at a determined frequency.
- Patient-specific initial heparin dosage using one of the following methods:
    - Weight
    - Dose Response Curve (automated or manual)
    - Blood Volume
    - Body Surface Area
- Preparing alternative means of anticoagulation for when heparin is not suitable.

Commented [CAD1]: Additions from S8.1, G8.1, G8.2

Rationale: S8.2, G8.1, G8.2 merged into S8.1 to help clarify anticoagulation management algorithm and reduce redundancy

---

Rewording

Current Guideline 8.4: Additional doses of heparin during CPB should be determined by using an ACT and/or Heparin/Protamine titration.

Proposed Guideline 8.2: Additional doses of anticoagulant during cardiopulmonary bypass procedures should be determined by using an appropriate anticoagulation test.

Rationale: revised to allow anticoagulation test to be determined by your institution.

Rewording

Current Guideline 8.5: Heparin reversal should be confirmed by ACT and/or heparin/protamine titration.

Proposed Guideline 8.3: Heparin reversal management strategy should aim to limit over-exposure to protamine and should be confirmed by ACT and/or heparin/protamine titration

Rationale: Added phrase to limit excess administration of protamine

---

Rewording

Current Standard 9.1 Gas exchange shall be maintained during cardiopulmonary bypass (CPB) according to protocol, accounting for:

- The individual patient characteristics/risk profile
- Oxygenator type, design and instructions for use
- Blood flow, temperature and metabolic demand

Proposed wording Standard 9.1: Gas exchange shall be maintained during cardiopulmonary bypass procedures according to protocol, accounting for individual patient needs.

Rationale: To make the standard more concise, and leave specific decisions up to the institution

---

Proposed removal

Current Standard 9.2: Devices used to measure gas exchange shall be calibrated according to the manufacturer's instructions for use.

Rationale: Topic covered in S18.2

Change in references

Removal of current reference for proposed Standard 9.2: Justison G. Is Timing Everything. J Extra Corpor Technol. 2017;49:13-18.

Addition of references for proposed Standard 9.2:

Newland RF, Baker RA. Low Oxygen Delivery as a Predictor of Acute Kidney Injury during Cardiopulmonary Bypass. J Extra Corpor Technol. 2017;49:224–230.

[1] Ranucci M, Johnson I, Willcox T, Baker RA, Boer C, Baumann A, Justison GA, de Somer F, Exton P, Agarwal S, Parke R, Newland RF, Haumann RG, Buchwald D, Weitzel N, Venkateswaran R, Ambrogi F, Pistuddi V. Goal-directed perfusion to reduce acute kidney injury: A randomized trial. J Thorac Cardiovasc Surg. 2018 Nov;156(5):1918-1927.e2.

[1] Ranucci M, Romitti F, Isgro G, et al. Oxygen delivery during cardiopulmonary bypass and acute renal failure after coronary operations. Ann Thorac Surg 2005;80:2213-20.

Rationale: Reference removed since it is not peer-reviewed, other articles added to provide additional support for utilizing DO2 in adult patients.

Proposed removal

Current Standard 9.3: Blood gas analysis shall be performed and recorded according to protocol.

Rationale: Topic already covered in S4.2, 7.6, App C

Moved to Standard

Proposed Standard 9.2 Indexed Oxygen delivery and consumption calculations shall be utilized to evaluate and optimize gas exchange.

- Oxygen Delivery: DO2i = 10 x CI x CaO2
- Oxygen Consumption: VO2i = 10 x CI x (CaO2 – CvO2)

Where:

CaO2 (arterial oxygen content) = (Hb x 1.36 x SaO2) + (0.0031 x PaO2), and

CvO2 (mixed venous oxygen content) = (Hb x 1.36 x SvO2) + (0.0031 x PvO2)

CI = cardiac index

Hb = hemoglobin

SaO2 = arterial oxygen saturation

PaO2 = partial pressure of oxygen in arterial blood

SvO2 = venous oxygen saturation

PvO2 = partial pressure of oxygen in venous blood

Rationale: Guideline 9.2 was moved to a standard, and the word Indexed added. Enough literature to support DO2 being more than a recommendation. Footnote references #17,18,19 added

---

Proposed removal

Guideline 10.1: Variance from intended and targeted blood flow should be communicated to the physician-in-charge

Rationale: Already covered in G1.1

Rewording

Current Guideline 10.2: Appropriate blood flow rate should be determined by evaluation of:

- Acid base balance
  - Base Excess
- Anesthetic level
- Arterial blood pressure
- Cerebral oximetry
- Lactate burden
- Oxygen delivery and consumption (refer to guideline 10.2 for formula)
  - Venous pO_2
  - Arterial pO_2
  - Hemoglobin concentration
  - Arterial oxygen saturation
- Systemic vascular resistance (SVR)
- Temperature
- Venous oxygen saturation

Proposed Guideline 10.1: Appropriate blood flow rate should be determined by evaluation of:

- Acid base balance
- Anesthetic level
- Arterial blood pressure
- Cerebral oximetry
- Lactate burden
- Oxygen delivery and consumption (refer to Standard 9.2 for formula)
    - Venous pO2
    - Arterial pO2
    - Hemoglobin concentration
    - Arterial oxygen saturation
- Temperature
- Venous oxygen saturation

Rationale: Words SVR and Base excess were removed, and the formula reference numbers were changed to the proposed Standard 9.2

Proposed removal

Standard 11.2: The Perfusionist shall work closely with the surgical care team to maintain blood pressure according to protocol during CPB.

Rationale: Repetition of S11.1, no added value

Proposed removal

Guideline 11.1: Variance from the intended and targeted blood pressure should be communicated to the physician in charge to allow for changes in the blood pressure management plan.

Rationale: Already covered in G1.1

Rewording

Current Standard 13.1: The Perfusionist shall participate in efforts to minimize hemodilution and avoid unnecessary blood transfusions.

Proposed Standard 13.1: The Perfusionist shall utilize the timely and collaborative application of evidence-based medical and surgical concepts (see Guideline 13.1) designed to maintain hemoglobin concentration, optimize hemostasis, and minimize blood loss in an effort to improve patient outcome.

Rationale: intended to promote a collaborative, multi-modal effort to patient blood management.

Rewording

Current Standard 13.3: The Perfusionist shall calculate and communicate to the surgical team prior to initiating CPB, a patient's predicted post-dilutional hemoglobin or hematocrit.

Proposed Standard 13.3: The Perfusionist shall calculate and communicate to the surgical team prior to initiating cardiopulmonary bypass a patient's predicted post-dilutional hemoglobin or hematocrit to allow time to prepare alternative strategies or changes to the care plan.

Rationale: To encourage the practice of calculating and communicating the dilutional hematocrit to the team in preparation for the procedure, to allow time to prepare for alternative strategies or discussion a care plan.

Rewording

Current Guideline 13.1: Blood management efforts should include the following:

- Participate in pre-operative briefings (discussions) with the surgical care team (Standard 5.1) regarding transfusion strategies and target hematocrit values.
- Participation in a multidisciplinary blood management team.
- Minimize hemodilution by:
    - Matching the size of the CPB circuit to the size of the patient
    - Autologous priming of CPB circuit, including retrograde arterial and venous antegrade priming
    - Biocompatible coating on the surface of all CPB components
    - Perioperative blood cell recovery and reinfusion after being appropriately processed.
    - CPB circuit blood salvage at the end of the procedure

Proposed Guideline 13.1: Blood management efforts should include the following:

- Participate in pre-operative briefings (discussions) with the surgical care team (Standard 3.1) regarding transfusion strategies and target hematocrit values.
- Participation in a multidisciplinary blood management team.
- Minimize hemodilution by:

- Ultrafiltration
- Matching the size of the cardiopulmonary bypass circuit to the size of the patient
- Autologous priming of cardiopulmonary bypass circuit, including retrograde arterial and/or venous antegrade priming
- Biocompatible coating on the surface of all cardiopulmonary bypass circuitry
- Perioperative blood cell recovery, appropriate processing, and reinfusion
- Cardiopulmonary bypass circuit blood salvage at the end of the procedure

Footnote addition: Task Force on Patient Blood Management for Adult Cardiac Surgery of the European Association for Cardio-Thoracic Surgery (EACTS) and the European Association of Cardiothoracic Anaesthesiology (EACTA), Boer C, Meesters MI, Milojevic M, Benedetto U, Bolliger D, von Heymann C, Jeppsson A, Koster A, Osnabrugge RL, Ranucci M, Ravn HB, Vonk ABA, Wahba A, Pagano D. 2017 EACTS/EACTA Guidelines on patient blood management for adult cardiac surgery. J Cardiothorac Vasc Anesth. 2018 Feb;32(1):88-120. doi: 10.1053/j.jvca.2017.06.026. Epub 2017 Sep 30. PMID: 29029990.

Rationale: To add extra methods for minimizing hemodilution, update the correct reference standard, and add a citation for patient blood management.

Rewording

Current Guideline 13.2: Point-of-Care hemostasis monitoring should be utilized to minimize blood loss. Monitoring may include:

- International normalized ratio
- Partial thromboplastin time
- Prothrombin time
- Thrombin time
- Thromboelastography/Thromboelastometry
- Platelet count
- Platelet function analysis

Proposed Guideline 13.2: Laboratory and Point-of-Care hemostasis monitoring should be utilized to minimize blood loss. Monitoring may include:

- International normalized ratio
- Partial Thromboplastin time
- Prothrombin time
- Thrombin time
- Thromboelastography/Thromboelastometry
- Platelet count
- Platelet function analysis
- Fibrinogen

Rationale: Included laboratory wording, as many of the tests mentioned are not Point-of-care tests. Fibrinogen was added as a possible test for hemostasis management.

Rewording

Current Standard 14.2: One Perfusionist shall be assigned for each such procedure.

Proposed Standard 14.2: One Perfusionist shall be assigned for each such standby procedure.

Rationale: To specify a perfusionist is needed for each standby procedure, clarifies wording from Standard 14.1.

Proposed New Addition

Standard 14.4: Assembly and maintenance of circuit shall be regulated according to institutional protocol using aseptic technique

Corresponding Footnote addition: Considerations for pre-priming medical devices. The Joint Commission. https://www.jointcommission.org/standards/standard-faqs/hospital-and-hospital-clinics/infection-prevention-and-control-ic/000002338/?p=1. (Accessed March 20, 2022)

Rationale: To provide guidance with circuit setup and sterility – ultimately to be determined by your institution

---

Proposed removal

Guideline 14.2: A heart-lung machine consisting of a sterile extracorporeal set-up and ancillary equipment (Ref: Appendix B) should be readily available for emergency procedures or as part of disaster planning protocols.

Rationale: Redundant, already covered in S14.3

Rewording

Current Standard 17.1: The Perfusionist shall actively participate in both institutional and departmental quality assurance and improvement programs

Proposed Standard 17.1: The Perfusionist shall actively participate in both institutional and departmental quality assurance and improvement programs, and safety reporting systems.

Rationale: Reworded to include the use of safety reporting, encourage safety-focused environment.

Merged and Moved to Standard

Current Guideline 17.1 The Perfusionist should collect data concerning the conduct of perfusion via a clinical registry or database.

Current Guideline 17.2: The Perfusionist should use such data for quality assurance, and improvement projects.

Proposed Standard 17.2: The Perfusionist shall collect data concerning the conduct of perfusion via a clinical registry or database to advance quality and safety.

Rationale: G17.1 and G17.2 were merged into S.17.2. Data collection to improve quality is now a standard. If perfusion programs hope to improve, benchmarking and quality projects are required. The type of registry or database is not specified/limited.

Rewording

Current Standard 18.1: The Perfusionist shall assure that properly maintained and functioning equipment is used in the conduct of cardiopulmonary bypass (CPB), including (but not limited to):

- Heart lung machine
    - Pumps
    - Timers
    - Pressure monitors
    - Temperature monitors
    - Low Level alarm
    - Air bubble detector(s)
    - Blood flow sensors
- Heater/Cooler
- Anesthetic vaporizer
- Oxygen Blender/Flow Meter
- Oxygen analyzer
- Ancillary Equipment
    - IABP
    - VAD device
    - Cell salvage device

Proposed Standard 18.1: The Perfusionist shall ensure that equipment used in the conduct of cardiopulmonary bypass is properly maintained and functioning, including cleaning and disinfecting.

Rationale: To simplify the standard by removing the long list, the standard applies to all equipment and does not represent a comprehensive list. Cleaning and Disinfecting as been added to comply with JC standards.

Rewording

Current Standard 18.4: Appropriate backup perfusion supplies shall be readily available.

Proposed Standard 18.4: Appropriate backup perfusion supplies and equipment shall be readily available.

Rationale: The word equipment was added to ensure a backup is available.

Proposed New Section 19: Crisis Management

Proposed Addition Standard 19.1 The perfusionist shall participate in a collaborative effort to implement an actionable crisis management plan for unforeseen circumstances that may prohibit the ability to perform standard duties.

Proposed Addition Guideline 19.1: Alternate vendors for vital equipment should be identified in order to address supply chain interruptions.

Proposed Addition Guideline 19.2: Alternate storage and staging areas should be identified in the event primary/routine areas are compromised.

Proposed Addition Guideline 19.3: Perfusionist should have a working knowledge of the infrastructure of the institution in order to identify operating room facilities that are suitable for extracorporeal support procedures when routine surgical suites are unavailable.

Proposed Addition Guideline 19.4: Clinical personnel should have a procedure for patient evacuation and potential support for patients committed to extracorporeal support while evacuations are in progress.

Proposed Addition Guideline 19.5: Clinical expertise, education, and proper role assignment should be considered if Perfusion staff repurposing is required.

Proposed Footnote Addition to Standard 19.1 “Crisis management plans should be reviewed and approved by the Chairman of Cardiac Surgery, or their designee, Director of Perfusion, or equivalent, and other relevant clinical governance committees if available. See Standard 1.2.”

Rationale: Part of the NEW Crisis Management Section to prepare perfusion departments for hazards, unidentifiable risks, and mitigate loss.

Proposed New Addition

Proposed changes to Appendix F (Checklist)

- Proposed wording change in “Initiation” checklist:
  - From checkbox reading “anticoagulation tested and reported”
  - To checkbox reading “anticoagulation target achieved, and results communicated”
- Proposed change of subtitle from “Termination” checklist to “Weaning and Termination” checklist
- Addition of checkboxes to “post-bypass checklist”

- All cannulas out
- Perfusion lines disconnected from patient

Rationale: To prevent sentinel events, to further define the timeline of perfusion responsibility during a case to be in the room from 'cannula in, to cannula out'

-End of comparison changes document-