American Society of ExtraCorporeal Technology
Standards and Guidelines
for Pediatric and Congenital Perfusion Practice

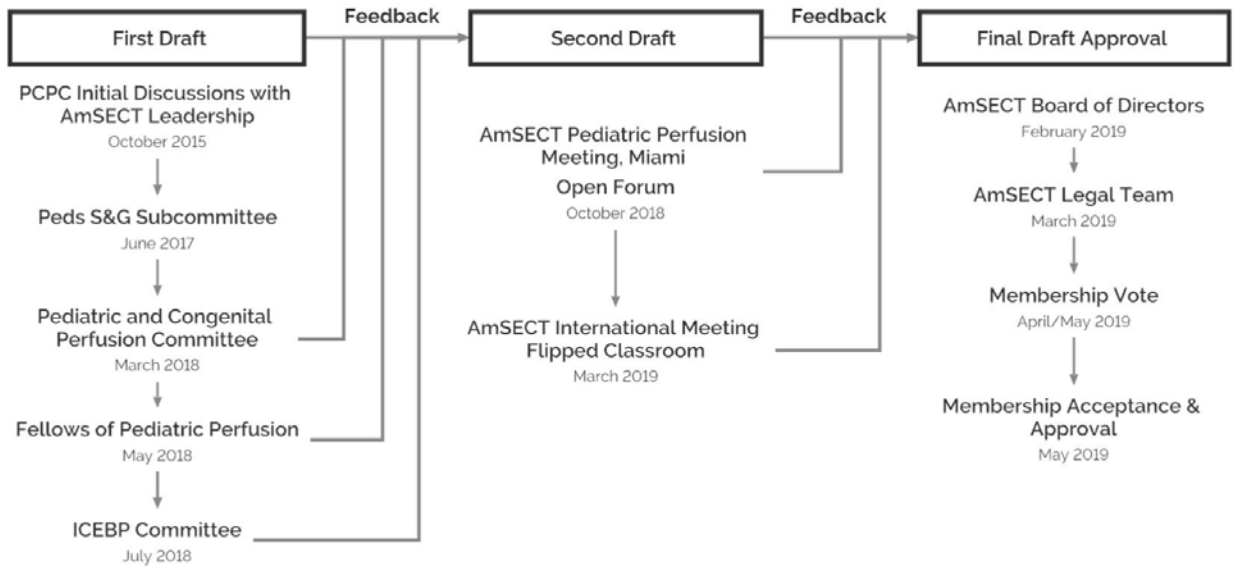
The American Society of ExtraCorporeal Technology (AmSECT) has created the following document based on clinical evidence and currently accepted perfusion practices. Perfusionists are allied healthcare professionals formally trained and educated in the field of extracorporeal science and whose scope of 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 extracorporeal support services.

Goal Statement

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

Approach

In 2023, the AmSECT Pediatric and Congenital Perfusion Committee assigned a Task Force to begin a review and update of the Standards and Guidelines for Pediatric and Congenital Perfusion Practice. The original document was completed and adopted by AmSECT's membership in 2019. A report of this work is published in the Journal of Extracorporeal Technology (J Extra Corporeal Technol. 2020 Oct;52:319-26) and co-published in World Journal for Pediatric and Congenital Heart Surgery (World Journal for Pediatric and Congenital Heart Surgery. 2020 Aug;12(1):84-92). The table below shows the workflow of the initial development of the document.



The Task Force began their review of the Standards and Guidelines for Pediatric and Congenital Perfusion Practice by comparing revisions to the recently approved AmSECT Standards and Guidelines for Perfusion Practice document (2023). Similar to this document, the 2024 update includes modifications to existing standards (and their respective guidelines) to enhance their interpretation and use, as well as updating references. In addition, the update includes a new Standard 19 that focuses on crisis management.

To facilitate the understanding of the Standards and Guidelines, we define important terms used through the document below. Unless otherwise stated, Standards and Guidelines are written for perfusion services, with the intent to be disseminated and adopted across members of the team.

Definitions:

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

***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.

Word Usage:

Shall: In this document, the word shall is used to indicate that AmSECT recommends a requirement be made mandatory by the adapting institution.

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

Surgical Care Team: In this document, the term surgical care team is used to indicate the group surgeon, anesthesiologist, perfusionist, nurse, and technicians.

Supervising Physician: In this document, the term supervising physician is intended to describe the physician responsible, at that given time, for the patient and their hemodynamics.

Continuously: In this document, the word 'continuously' describes an action that occurs without ceasing.

Continually: In this document, the word 'continually' describes an action that recurs frequently or regularly.

Special Note: As noted above, the intent of these Standards and Guidelines for Perfusion Practice is to help healthcare professionals with evidence-based recommendations regarding safe and effective extracorporeal support care for their patients. The Standards and Guidelines do not include all potential options for care, and they are not intended and should not be used as a substitute for the provider's clinical judgment and experience. The responsible provider must make all treatment decisions based upon their independent judgment and the patient's presentation. Although the Standards and Guidelines have been reviewed with significant care, they are provided as is. By using this document, the user agrees that AmSECT shall not be liable for any direct, indirect, special, incidental, or consequential damages related to the use or misuse of the information contained herein. AmSECT recognizes that individual medical centers may have local policies that may supersede AmSECT's Standards and Guidelines. Likewise, AmSECT recognizes that some local districts or states may have laws that supersede AmSECT Standards and Guidelines. As a result, perfusionists practicing within those jurisdictions should comply in all respects with those policies and laws.

American Society of ExtraCorporeal Technology

Standards and Guidelines

For Pediatric and Congenital Perfusion Practice

Standard 1:	**Development of Institutionally-based Protocols**
Standard 2:	**Qualification, Competency and Support Staff**
Standard 3:	**Communication**
Standard 4:	**Perfusion Record**
Standard 5:	**Checklist**
Standard 6:	**Safety Devices**
Standard 7:	**Monitoring**
Standard 8:	**Anticoagulation**
Standard 9:	**Gas Exchange**
Standard 10:	**Blood Flow**
Standard 11:	**Blood Pressure**
Standard 12:	**Circuitry**
Standard 13	**Priming**
Standard 14:	**Protamine and Cardiotomy Suction**
Standard 15:	**Blood Management**
Standard 16:	**Fluid Management**
Standard 17:	**Level of Readiness**
Standard 18:	**Staffing**
Standard 19	**Duty Hours**
Standard 20:	**Quality Assurance and Improvement**
Standard 21:	**Maintenance**
Standard 22:	**Crisis Management**

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 Chair of Cardiac Surgery, their 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 1.3: Perfusion emergency protocols shall be accessible to help guide the perfusionist during an event.[1,2]

Guideline 1.1: Deviation from protocol may be at the discretion of the supervising physician and should be documented in the perfusion record.

[1] AmSECT Failure Mode and Effects Analysis examples: https://www.amsect.org/page/fmea-archives (accessed June 4, 2024)

[2] 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 May 29, 2024)

Standard 2: Qualification, Competency and Support Staff

Standard 2.1: A perfusionist, who is board certified by the American Board of Cardiovascular Perfusion or who demonstrates equivalent qualifications and competency, shall conduct cardiopulmonary bypass procedures.[3]

Standard 2.2: Perfusionist competency shall be assessed annually, in order to evaluate compliance with departmental protocols.

Standard 2.3: The perfusionist shall attend, participate, and engage in perfusion-related continuing education courses on an annual basis.[4]

Standard 2.4: Support staff shall be available on site to assist the primary perfusionist during cardiopulmonary bypass procedures**.**

Standard 2.5: An outline detailing the onboarding process shall be developed to ensure new hires are oriented and able to safely perform pediatric and congenital perfusion-related responsibilities, including training with hazardous materials (e.g., radiation or chemotherapy) relevant to work duties. The onboarding process shall be documented and retained upon the staff member's completion.[5]

Guideline 2.1: An individual graduating from an accredited perfusion education program should complete all requirements for American Board of Cardiovascular Perfusion certification within three years of graduation.

Guideline 2.2: A standardized process should be developed and followed to identify, orient, and educate support staff to ensure that they have general knowledge of the duties performed by the perfusionist, flow of the operation and location of primary and ancillary items required during cardiopulmonary bypass. Support staff may include a perfusionist, nursing, technical, or non-technical staff.

Guideline 2.3: American Board of Cardiovascular Perfusion continuing education units (CEUs) should be obtained from pediatric content whenever possible.

[3] AmSECT recognizes that individual states may license perfusionists based on other criteria. These laws supersede this standard.

[4] American Board of Cardiovascular Perfusion, www.abcp.org (accessed June 4, 2024)

[5] Kalangos A, Coselli JS, Kirali K. Perfusion Training. *Cardiopulmonary Bypass*. Academic Press; 2023:463-469.

Standard 3: Communication

Standard 3.1: A patient-specific management plan for the cardiopulmonary bypass procedure shall be prepared and communicated to the surgical team, either during the pre-operative briefing or prior to beginning the procedure.[6]

Standard 3.2: The primary perfusionist shall use a set handoff protocol (e.g. SBAR - Situation, Background, Assessment, Recommendation) when transitioning the management of the case to a second Perfusionist.[7]

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

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

Standard 3.5: Protocol driven communication (e.g. closed-loop), shall be utilized to acknowledge verbal commands, verify the content, and reduce ambiguity.[8,9,10]

Guideline 3.1: The use of cellular telephone technology in the operating room should be guided by the principles of ST-59 Statement on use of cell phones in the operating room, written by the American College of Surgeons.[11]

Guideline 3.2: Topics that should be considered during the post-procedure debrief include, but are not limited to, communication, additional training, equipment or disposables issues, post-operative instructions, and safety events.

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[6] World Health Organization surgical safety checklist and implementation manual. World Health Organization, https://www.who.int/docs/default-source/patient-safety/9789241598590-eng-checklist.pdf (accessed May 26, 2024)

[7] The Joint Commission. Hot Topics in Health Care. Transitions of Care: The need for a more effective approach to continuing patient care. https://flbog.sip.ufl.edu/risk-rx-article/ transitions-of-care-the-need-for-a-more-effective-approach-to-continuing-patient-care/ (accessed May 26, 2024)

[8] Wadhera RK, Parker SH, Burkhart HM, Greason KL, Neal JR, Levenick KM, Wiegmann DA, Sundt TM 3rd. Is the "sterile cockpit" concept applicable to cardiovascular surgery critical intervals or critical events? The impact of protocol-driven communication during cardiopulmonary bypass. J Thorac Cardiovasc Surg. 2010 Feb;139(2):312-9. doi: 10.1016/j.jtcvs.2009.10.048. PMID: 20106395.

[9] Whyte S, Cartmill C, Gardezi F, Reznick R, Orser BA, Doran D, Lingard L. Uptake of a team briefing in the operating theatre: a Burkean dramatistic analysis. Soc Sci Med. 2009 Dec;69(12):1757-66. doi: 10.1016/j.socscimed.2009.09.054. Epub 2009 Oct 23. PMID: 19853344.

[10] de Vries EN, Prins HA, Crolla RM, den Outer AJ, van Andel G, van Helden SH, Schlack WS, van Putten MA, Gouma DJ, Dijkgraaf MG, Smorenburg SM, Boermeester MA; SURPASS Collaborative Group. Effect of a comprehensive surgical safety system on patient outcomes. N Engl J Med. 2010 Nov 11;363(20):1928-37. doi: 10.1056/NEJMsa0911535. PMID: 21067384.

[11] Statement on distractions in the operating room, September 1, 2016. https://www.facs.org/about-acs/statements/distractions-in-the-operating-room/ (accessed May 26, 2024)

Standard 4: Perfusion Record

Standard 4:1: The perfusion record (written and/or electronic) for each cardiopulmonary bypass procedure shall be included as part of the patient's permanent medical record. The perfusion records shall be maintained and stored according to institution policy for retaining patient medical records.

Standard 4.2: The record shall include:

- Patient information including demographics and pre-operative risk factors (Appendix A).
- Information sufficient to accurately describe the procedure, personnel, and equipment (Appendix B).
- Patient physiological parameters documented at a frequency determined by institutional protocol (Appendix C).
- Blood gas and anticoagulation monitoring results (Appendix D).
- Signature of the Perfusionist (and all relief perfusionists) performing the procedure.

Guideline 4.1: The perfusion record should include open text (factual) commentary including supervising physician verbal orders pertinent to the cardiopulmonary bypass procedure.

Guideline 4.2: The perfusion record should include the signatures of the physician(s) providing oversight for the cardiopulmonary bypass procedure.

Guideline 4.3: Raw data (e.g. blood flow, pressure and temperature values) contained in electronic perfusion databases should be stored for a time period in accordance with your institution's policy for retaining electronic patient medical records.

Standard 5: Checklist

Standard 5.1: The perfusionist shall use a checklist for each cardiopulmonary bypass procedure.[12]

Standard 5.2: Checklists shall be included as part of the patient's permanent medical record.

Guideline 5.1: The perfusionist should use checklists in a read-verify manner where critical steps that should have been performed are confirmed.[13] Completion of the checklist should be performed by two people, one person being the primary perfusionist responsible for operation of the heart lung machine during the intra-operative period.

Guideline 5.2: The perfusionist should utilize a checklist throughout the entire peri-operative period (e.g. set-up, pre-bypass, initial onset of bypass, prior to cessation of bypass, post bypass, and/or any return to bypass).

Guideline 5.3: The perfusionist should utilize a checklist for other ancillary perfusion services (e.g. cell salvage, intra-aortic balloon pump, extracorporeal membrane oxygenation).

[12] Haynes AB, Weiser TG, Berry WR, Lipsitz SR, Breizat AH, Dellinger EP, Herbosa T, Joseph S, Kibatala PL, Lapitan MC, Merry AF, Moorthy K, Reznick RK, Taylor B, Gawande AA; Safe Surgery Saves Lives Study Group. A surgical safety checklist to reduce morbidity and mortality in a global population. N Engl J Med. 2009 Jan 29;360(5):491-9. doi: 10.1056/NEJMsa0810119. Epub 2009 Jan 14. PMID: 19144931.

[13] Advancing Patient Safety in the U.S. Department of Veterans Affairs. Preoperative Briefing Guide for Use in the Operating Room. Commonwealth Fund Pub. 1477, Vol 9. https://www.commonwealthfund.org/sites/default/files/documents/___media_files_publications_case_study_2011_mar_1477_mccarthy_va_case_study_final_march_v2.pdf (accessed June 4, 2024).

Standard *6: Safety Devices*

Standard 6.1: Pressure monitoring of the arterial line, cardioplegia delivery systems, and venous reservoir (when augmented venous drainage is utilized) shall be employed during cardiopulmonary bypass procedures.

- The pressure monitor shall be either servo-regulated to control the arterial/cardioplegia pump or to allow interruption to the arterial/cardioplegia flow.
- The pressure monitor shall include an audible and visual alarm.

Standard 6.2: A bubble detector shall be employed during cardiopulmonary bypass procedures.

- The gross/macro bubble detector shall be used to control the arterial pump or to allow interruption of the arterial blood flow.
- The detector system shall include an audible and visual alarm and be positioned according to manufacturer instructions for use to enable timely identification and action.

Standard 6.3: A level sensor shall be employed during cardiopulmonary bypass procedures utilizing a (hard-shell) reservoir.

- The level sensor shall be either servoregulated to control the arterial pump or to allow interruption of the arterial blood flow.
- The level sensor shall include an audible and visual alarm and be positioned according to manufacturer's instructions to allow an appropriate reaction time and a safe operational volume.

Standard 6.4: Temperature monitoring of the arterial outflow from the oxygenator shall be employed during cardiopulmonary bypass procedures.

- The temperature sensor shall include an audible and visual alarm to prevent high arterial outlet temperatures.[14]

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

Standard 6.6: A one-way valve in the vent line shall be employed during cardiopulmonary bypass procedures.

Standard 6.7: A method for retrograde flow avoidance when using a centrifugal pump shall be employed during cardiopulmonary bypass procedures.

- Examples of retrograde avoidance systems may include the following:
  - One-way flow valves
  - Hard stop detent controls to prevent accidental reduction in pump speed
  - Electronically activated arterial line clamps
  - Low speed visual and audible alarm

[14] 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.

Standard 6.8: An anesthetic gas scavenge line shall be employed whenever inhalation agents are introduced into the circuit during cardiopulmonary bypass procedures.

Standard 6.9: Hand cranks shall be readily available during cardiopulmonary bypass procedures.

Standard 6.10: A back-up gas supply shall be readily available during cardiopulmonary bypass procedures.

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

Guideline 6.1: A device that is capable of detecting disconnection of components of the gas exchange system should be used continuously and provide an audible signal when the alarm threshold is exceeded.[15]

Guideline 6.2: A level sensor should be employed during cardiopulmonary bypass procedures utilizing a soft-shell reservoir.

- The level sensor should be either servo-regulated to control the arterial pump or to allow interruption of the arterial blood flow.
- The level sensor should include an audible and visual alarm, and be positioned according to manufacturer's instructions to allow an appropriate reaction time and a safe operational volume.
- The use of an air bubble detector distal to the outlet can be utilized as a surrogate level detector.

Guideline 6.3: The gross/macro bubble detector should be used to control the cardioplegia pump to allow interruption of the cardioplegia and/or modified ultrafiltration (MUF) blood flow.

[15] Standards for Basic Anesthetic Monitoring. American Society of Anesthesiologists. Published December 13, 2020. https://www.asahq.org/standards-and-practice-parameters/standards-for-basic-anesthetic-monitoring.

Standard 7: Monitoring[16]

Standard 7.1: Patient arterial blood pressure shall be monitored continuously during cardiopulmonary bypass procedures.[17]

Standard 7.2: Arterial line pressure shall be monitored continuously during cardiopulmonary bypass procedures.

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 cardiopulmonary bypass procedures (e.g., distal to intra-circuit shunts).[18,19]

Standard 7.4: Cardioplegia dose, temperature, delivery method, line pressure (antegrade), coronary sinus pressure (retrograde) and ischemic intervals shall be monitored continually during cardiopulmonary bypass procedures.

Standard 7.5: Patient and device temperatures shall be monitored continually during cardiopulmonary bypass procedures.

- Patient (e.g. nasopharyngeal, rectal, bladder, esophageal)
- Heart lung machine (arterial, venous, and cardioplegia)
- Heater cooler (H_20 temperature)

Standard 7.6: Blood gas analysis shall be monitored continually or at regular intervals during cardiopulmonary bypass procedures (Appendix D).

Standard 7.7: Continuous blood gas monitoring shall be used during cardiopulmonary bypass procedures.[20,21]

Standard 7.8 Hematocrit (or hemoglobin) shall be monitored continuously during cardiopulmonary bypass procedures.

Standard 7.9: Oxygen fraction and gas flow rates shall be monitored continually during cardiopulmonary bypass procedures.

Standard 7.10: The percentage of venous line occlusion of the venous occluder shall be monitored continually during cardiopulmonary bypass procedures.[22]

Standard 7.11: Venous oxygen saturation shall be monitored continuously during cardiopulmonary bypass procedures.

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[16] To be performed in conjunction with Standard 3.

[17] Here, and throughout this document, 'continuously' describes an action that occurs without ceasing, whereas the word 'continually' is intended to describe an action that recurs frequently or regularly.

[18] Lee-Sensiba K, et al. Errors in Flow and Pressure related to the arterial filter purge line. J Extra Corpor Technol. 1998; 30(2):77-82. PMID: 10182117.

[19] Wang S, Miller A, Myers J, Undar A. "Stolen" Blood Flow: Effect of an Open Arterial Filter Purge Line in a Simulated Neonatal CPB Model. ASAIO 2008; 54:432-435. PMID: 18645363.

[20] Ottens J, Tuble SC, Sanderson AJ, Knight JL, Baker RA. Improving cardiopulmonary bypass: Does continuous blood gas monitoring have a role to play? J Extra Corpor Technol. 2010;42(3):191-198. PMID: 21114221.

[21] Trowbridge CC, Vasquez M, Stammers AH, et al. The effects of continuous blood gas monitoring during cardiopulmonary bypass: A prospective, randomized study--part II. J Extra Corpor Technol. 2000;32(3):129. PMID: 11146956.

[22] Monitoring of the venous line occluder only applies if a venous line occluder is being utilized.

Standard 7.12: Arterial oxygen saturation shall be monitored continuously during cardiopulmonary bypass procedures.

Standard 7.13: Cerebral oximetry shall be monitored continuously during cardiopulmonary bypass procedures.[23,24,25,26, 27]

Guideline 7.1: Carbon dioxide removal should be monitored continually during cardiopulmonary bypass procedures.

Guideline 7.2**:** The patient's central venous pressure (CVP) should be monitored during cardiopulmonary bypass procedures.

Guideline 7.3: Somatic oximetry should be monitored continuously during cardiopulmonary bypass procedures.[26, 27, 28, 29, 30, 31, 32]

Guideline 7.4**:** The perfusionist should maintain institutionally approved temperature gradients during cooling and rewarming on cardiopulmonary bypass.

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[23] Hoffman, George M., Ghanayem, Nancy S., Scott, John P., Tweddell, James S., Mitchell, Michael E., Mussatto, Kathleen A.. Postoperative cerebral and somatic near-infrared spectroscopy saturations and outcome in hypoplastic left heart syndrome. Ann Thorac Surg. 2016;103(5):1527-1535. PMID: 28012642.

[24] Redlin M, Koster A, Huebler M, et al. Regional differences in tissue oxygenation during cardiopulmonary bypass for correction of congenital heart disease in neonates and small infants: Relevance of near-infrared spectroscopy. The J Thorac Cardiovasc Surg. 2008;136(4):962-967. PMID: 18954637.

[25] Fenton KN et al. The significance of baseline cerebral oxygen saturation in children undergoing congenital heart surgery. Am J surg. 2005;190:260-3. PMID: 16023442.

[26] Zaleski KL, Staffa SJ, Kussman BD. A survey of the Congenital Cardiac Anesthesia Society on the use and clinical application of near- infrared tissue oximetry in pediatric cardiac surgery. J Cardiothorac Vasc Anesth. 2022;36:3617–25. PMID: 35691856.

[27] Hirai N, Saito J, Nakai K, Noguchi S, Hashiba E, Hirota K. Association between regional oxygen saturation and central venous saturation in pediatric patients undergoing cardiac surgery: A prospective observational study. Pediatric Anesthesia. 2023;33:913–22. PMID: 37534800.

[28] Booth EA, Dukatz C, Ausman J, Wider M. Cerebral and somatic venous oximetry in adults and infants. Surgical neurology international. 2010;1(1):75. PMID: 21170366.

[29] Bojan M, Bonaveglio E, Dolcino A, Mirabile C. Somatic and cerebral near infrared spectroscopy for the monitoring of perfusion during neonatal cardiopulmonary bypass. Interactive CardioVascular and Thoracic Surgery. 2019;29:955–9. PMID: 31384917.

[30] Zhang L, Liu L, Zhong Z, Jin H, Jia J, Meng L, et al. The effect of selective cerebral perfusion on cerebral versus somatic tissue oxygenation during aortic coarctation repair in neonates and infants. BMC Anesthesiology. 2021;21. PMID: 34781876.

[31] Joffe R, Al Aklabi M, Bhattacharya S, Cave D, Calleja T, Garros D, et al. Cardiac surgery–associated kidney injury in children and renal oximetry. Pediatric Critical Care Medicine. 2018;19:839–45. PMID: 30028784.

[32] Monitoring of the somatic oximetry only applies if somatic oximetry is being utilized.

Standard 8: Anticoagulation

Standard 8.1: The perfusionist, in collaboration with the supervising physician, shall define the intended treatment algorithm for anticoagulation management (heparin), 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.[33]
- 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.

Standard 8.2: A process shall exist for identifying and managing heparin resistance.

Guideline 8.1: Anticoagulation monitoring should include the testing of ACT. Additional monitoring tests may include:

- Heparin level measurement (e.g. heparin/protamine titration or unfractionated heparin level)
- Partial Thromboplastin Time
- Viscoelastic Testing
- Thrombin Time
- Anti Xa

Guideline 8.2: Additional doses of heparin during cardiopulmonary bypass procedures should be determined by using an appropriate anticoagulation test. [34]

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.

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[33] Shore-Lesserson LJ, Baker RA, Ferraris V, Greilich PE, Fitzgerald DJ, Roman P, Hammon J. STS/SCA/AmSECT Clinical Practice Guidelines: Anticoagulation during Cardiopulmonary Bypass. Ann Thorac Surg. 2018 Feb;105(2):650-662. doi: 10.1016/j.athoracsur.2017.09.061. PMID: 29362176.

[34] In patients requiring longer cardiopulmonary bypass times (>2 to 3 hours), maintenance of higher and/or patient-specific heparin concentrations during cardiopulmonary bypass may be considered to reduce hemostatic system activation, reduce consumption of platelets and coagulation proteins, and to reduce blood transfusion. (Class IIb, Level of evidence B). Reference: Society of Thoracic Surgeons Blood Conservation Guideline Task Force, Ferraris VA, Brown JR, Despotis. PMID: 21353044.

Standard 9: Gas Exchange

Standard 9.1: Gas exchange shall be maintained during cardiopulmonary bypass procedures according to protocol, accounting for:

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

Standard 9.2: Indexed oxygen delivery and consumption calculations shall be utilized to evaluate and optimize gas exchange. [35, 36, 37, 38, 39]

- Indexed Oxygen Delivery: $DO_2I = 10 \times CI \times CaO_2$
- Oxygen Consumption: $VO_2 = 10 \times CI \times (CaO_2 - CvO_2)$

Where:
CaO_2 (arterial oxygen content) = (Hb x 1.36 x SaO_2) + (0.0031 x PaO_2), and
CvO_2 (mixed venous oxygen content) = (Hb x 1.36 x SvO_2) + (0.0031 x PvO_2)
CI = cardiac index
HB = hemoglobin
SaO_2 = arterial oxygen saturation
PaO_2 = partial pressure of oxygen in arterial blood
SvO_2 = venous oxygen saturation
PvO_2 = partial pressure of oxygen in venous blood

Standard 9.3: Devices used to measure gas exchange via continuous blood gas analyzers shall be calibrated according to the manufacturer's instructions for use.

Standard 9.4: Point-of-Care testing shall be utilized to provide accurate and timely information for blood gas analysis.[40]

Standard 9.5: The use of supplemental CO_2 and a microregulator shall be available to optimize blood gas management. [41,42]

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[35] De Somer F, Mulholland JW, Bryan MR, Aloisio T, Van Nooten GJ, Ranucci M. O2 and CO2 production during cardiopulmonary bypass as determinants of acute kidney injury: time for a goal-directed perfusion management? Crit Care. 2011 Aug 10;15(4):R192. doi: 10.1186/cc10349. PMID: 21831302; PMCID: PMC3387634.

[36] Newland RF, Baker RA, Woodman RJ, Barnes MB, Willcox TW; Australian and New Zealand Collaborative Perfusion Registry. Predictive Capacity of Oxygen Delivery During Cardiopulmonary Bypass on Acute Kidney Injury. Ann Thorac Surg. 2019 Dec;108(6):1807- 1814. PMID: 31238029.

[37] Newland RF, Baker RA. Low Oxygen Delivery as a Predictor of Acute Kidney Injury during Cardiopulmonary Bypass. J Extra Corpor Technol. 2017 Dec;49(4):224-230. PMID: 29302112; PMCID: PMC5737422.

[38] 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. PMID: 29778331.

[39] 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. PMID: 16305874.

[40] Nichols, JH. Laboratory Medicine Practice Guidelines. Evidence-based practice for point-of-care testing. American Association for Clinical Chemistry Press. 2006. https://www.myadlm.org/science-and-research/practice-guidelines/point-of-care-testing. (accessed May 26, 2024).

[41] Pappa A, Shankaran S, Laptook AR, et al. Hypocarbia and Adverse Outcome in Neonatal Hypoxic-Ischemic Encephalopathy. J Pediatr. 2011;158(5):752-758. PMID: 21146184.

[42] Quarti A, Nardone S, Manfrini F, et al. Effect of the adjunct of carbon dioxide during cardiopulmonary bypass on cerebral oxygenation. Perfusion. 2013;28(2):152-155. PMID: 23095347.

Guideline 9.1: The use of pH stat blood gas management strategy should be considered for neonates and infants undergoing hypothermia during cardiopulmonary bypass.[43,44,45,46,47]

[43] Sakamoto T, Kurosawa H, Shin'oka T, Aoki M, Isomatsu Y. The influence of pH strategy on cerebral and collateral circulation during hypothermic cardiopulmonary bypass in cyanotic patients with heart disease: results of a randomized trial and real-time monitoring. J Thorac Cardiovasc Surg 2004;127:12–19. PMID: 14752407.

[44] Hickey PR. Neurologic sequelae associated with deep hypothermic circulatory arrest. Ann Thorac Surg 1998;65:S65–S69. PMID: 9647142.

[45] du Plessis AJ, Jonas RA, Wypij D, Hickey PR, Riviello J, Wessel DL, Roth SJ, Burrows FA, Walter G, Farrell DM, Walsh AZ, Plumb CA, del Nido P, Burke RP, Castaneda AR, Mayer JE Jr, Newburger JW. Perioperative effects of alpha-stat versus pH-stat strategies for deep hypothermic cardiopulmonary bypass in infants. J Thorac Cardiovasc Surg 1997; 114:991–1000. PMID: 9434694.

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[47] Pearl JM, Thomas DW, Grist G, Duffy JY, Manning PB. Hyperoxia for management of acid-base status during deep hypothermia with circulatory arrest. Ann Thorac Surg. 2000;70(3):751-755. PMID: 11016305.

Standard 10: Blood Flow

Standard 10.1: Target blood flow rates shall be determined prior to cardiopulmonary bypass according to protocol.

Standard 10.2: Blood flow rates shall be calculated utilizing one of the following methods:

- L/min/m^2
- mL/kg/min

Standard 10.3: The perfusionist shall work closely with the supervising physician to maintain targeted blood flow rate during cardiopulmonary bypass procedures.

Standard 10.4: Aortic root vent flow shall be monitored and cardiopulmonary bypass flow shall be adjusted to accommodate for shunting so that total blood flow to the patient is not compromised.

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

- Acid base balance
- Base excess/deficit
- Anesthetic level
- Arterial blood pressure
- Cerebral oximetry
- Lactate burden
- Oxygen delivery and consumption (refer to Standard 9.2 for formula)
    - Venous pO_2
    - Arterial pO_2
    - Hemoglobin concentration
    - Arterial oxygen saturation
- Systemic vascular resistance (SVR)
- Temperature
- Venous oxygen saturation

Guideline 10.2: Due to the higher metabolic demands of the pediatric patient, the perfusionist should consider higher blood flow rates to achieve adequate perfusion and DO_2 requirements.[48,49,50,51,52]

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[49] Zhang Y, Wang B, Zhou X, Zhou R. Nadir oxygen delivery during pediatric bypass as a predictor of acute kidney injury. Ann Thorac Surg 2022; 113:647-53. PMID: 33524358.

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Standard 11: Blood Pressure

Standard 11.1: The perfusionist, in collaboration with the surgical care team, shall define and communicate the intended treatment algorithm for blood pressure management prior to cardiopulmonary bypass procedures, including acceptable ranges for blood pressure based on age or weight.[53]

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

[53] In many circumstances, the physician-in-charge may direct the perfusionist to modify the intended blood pressure management to address circumstances occurring during the cardiopulmonary bypass procedure.

Standard 12. Circuitry

Standard 12.1: The perfusionist shall select circuit components taking into consideration prime volume, surface area, safety, and the expected metabolic requirements of the patient.

Standard 12.2: Both the number and size of shunts within the circuit shall be minimized to prevent steal from arterial blood flow.[54,55]

Guideline 12.1: The perfusionist should consider assisted venous return acknowledging any patient specific contraindications.[56,57,58,59,60,61]

[54] Lee-Sensiba K, et al. Errors in Flow and Pressure related to the arterial filter purge line. J Extra Corpor Technol. 1998; 30(2):77-82. PMID: 10182117.

[55] Wang S, Miller A, Myers J, Undar A. "Stolen" Blood Flow: Effect of an Open Arterial Filter Purge Line in a Simulated Neonatal CPB Model. ASAIO 2008; 54:432-435. PMID: 18645363.

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[57] Durandy Y. Vacuum-Assisted Venous Drainage, Angel or Demon: PRO. JECT 2013;45:122-127. PMID: 23930382.

[58] Durandy Y. The impact of VAVD and miniaturized bypass circuits on blood transfusion in pediatric cardiac surgery. ASAIO J 2009;55:117-120. PMID: 19092654.

[59] Nakanishi K, et al. Usefulness of vacuum-assisted cardiopulmonary bypass circuit for pediatric open-heart surgery in reducing homologous blood transfusion. Eur J Cardiothorac Surg 2001; 20:233-238. PMID: 11463537.

[60] Kwak JG, Lee J, Park M, Seo YJ, Lee CH. Hemolysis During Open-Heart Surgery With Vacuum-Assisted Venous Drainage at Different Negative Pressures in Pediatric Patients Weighing Less Than 10 kilograms. World J Pediatr Congenit Heart Surg. 2017 Mar;8(2):161-165. doi: 10.1177/2150135116681734. PMID: 28329457.

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Standard 13. Priming

Standard 13.1: The perfusionist shall consider the impact the prime composition has on the smaller circulating blood volume of the pediatric patient and its effect on:

- electrolyte levels
- colloid osmotic pressure
- coagulation
- dilutional hematocrit
- osmolarity/osmolality[62]

Standard 13.2: When priming with exogenous blood products, a circuit prime gas and electrolyte levels shall be obtained and documented prior to initiation of bypass and adjustments made to correct any physiologic abnormalities with consideration of patient's physiology (Appendix D). [63,64]

Standard 13.3: When priming with exogenous blood products, the use of prebypass ultrafiltration (PBUF) and/or washed red blood cells shall be used during the priming procedure. [65,66,67,68,69,70]

Guideline 13.1: The perfusionist should consider matching blood prime composition to the individual patient's values.

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[62] Striker CW, Woldorf S, Holt D. Modification of sodium, glucose, potassium, and osmolarity in packed red blood cells and fresh frozen plasma using a desktop hemoconcentrator setup. J Extra Corpor Technol. 2012 Jun;44(2):60-5. PMID: 22893984; PMCID: PMC4557452.

[63] Malmqvist G, Claesson Lingehall H, Appelblad M, Svenmarker S. Cardiopulmonary bypass prime composition: Beyond crystalloids versus colloids. Perfusion. 2018;1-6. PMID: 30114960.

[64] Liskaser FJ, Bellomo R, Hayhoe M, Story D, Poustie S, Smith B, Letis A, Bennett M. Role of pump prime in the etiology and pathogenesis of cardiopulmonary bypass-associated acidosis. Anesthesiology. 2000 Nov;93(5):1170-3. doi: 10.1097/00000542-200011000-00006. PMID: 11046201.

[65] Cholette JM, Henrichs KF, Alfieris GM, et al. Washing red blood cells and platelets transfused in cardiac surgery reduces postoperative inflammation and number of transfusions: Results of a prospective, randomized, controlled clinical trial. Pediatric Critical Care Medicine. 2012;13(3):290-299. PMID: 21926663.

[66] O'Leary MF, Szklarski P, Klein TM & Young PP. Hemolysis of red blood cells after cell washing with different automated technologies: clinical implications in a neonatal cardiac surgery population. Transfusion Practice. 2011;51:955-960. PMID: 21091957.

[67] Sasaki J, Tirotta C, Lim H, et al. Comparison of stored red blood cell washing techniques for priming extracorporeal circuits. Perfusion. 2018;33(2): 130-135. PMID: 28925857.

[68] Shimpo H, Shimamoto A, Miyake Y, et al. Effect of ultrafiltration on priming solution with preserved blood for extracorporeal circulation in infants. ASAIO J. 1996;42:M792–4. PMID: 8944991.

[69] Swindell CG, Barker TA, McGuirk SP, et al. Washing of irradiated red blood cells prevents hyperkalemia during cardiopulmonary bypass in neonates and infants undergoing surgery for complex congenital heart disease. European Journal of Cardiothoracic Surgery. 2007;31;659-664. PMID: 17291775.

[70] Kohlsaat, Katherine, et al. "Impact of pre-bypass ultrafiltration on prime values and clinical outcomes in neonatal and infant cardiopulmonary bypass." The Journal of ExtraCorporeal Technology 55.4 (2023): 175-184.

Standard 14. Protamine and Cardiotomy Suction

Standard 14.1: Cardiotomy suction shall be discontinued at the onset of protamine administration to avoid clotting within the cardiopulmonary bypass circuit.

Standard 15: Blood Management

Standard 15.1: The Perfusionist shall utilize the timely and collaborative application of evidence-based medical and surgical concepts (see Guideline 15.1) designed to maintain hemoglobin concentration, optimize hemostasis, and minimize blood loss in an effort to improve patient outcome.[71]

Standard 15.2: The Perfusionist shall minimize the cardiopulmonary bypass circuit size to reduce prime volume. See Standard 12: Circuitry.

Standard 15.3: The Perfusionist shall calculate and communicate to the surgical team prior to initiating cardiopulmonary bypass, a patient's predicted post-dilutional hemoglobin or hematocrit.

Standard 15.4: Minimum acceptable hematocrit during and prior to termination of cardiopulmonary bypass shall be maintained according to institutional protocol.

Standard 15.5: The perfusionist shall consider the contribution of hemoglobin to patient DO2 and transfuse if indicated. See Standard 9 Gas Exchange & Standard 10 Blood Flow.

Guideline 15.1**:** Blood management efforts should include the following:

- 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. See Standard 12: Circuitry.
    - Autologous priming of cardiopulmonary bypass circuit, including retrograde arterial and venous antegrade priming
- Biocompatible coating on the surface of all cardiopulmonary bypass components
- Perioperative blood cell recovery and reinfusion after being appropriately processed
- Cardiopulmonary bypass circuit blood salvage at the end of the procedure
- Preoperative whole blood removal: Acute Normovolemic Hemodilution (ANH)[72,73]

[71] Ferraris VA, et al. 2011 update to the Society of Thoracic Surgeons and the Society of Cardiovascular Anesthesiologists blood conservation clinical practice guidelines. Ann Thorac Surg 2011 Mar;91(3):944-82. PMID: 21352044.

[72] Crescini WM, Muralidaran A, Shen I, et al. The use of acute normovolemic hemodilution in pediatric cardiac surgery. Acta Anaesthesiologica Scandinavica. 2018;62:756-764. PMID: 29504128.

[73] Freisen RH, Perryman KM, Weigers KR, et al. A trial of fresh autologous whole blood to treat dilutional coagulopathy following cardiopulmonary bypass in infants. Pediatric Anesthesia. 2006;16(4):429-435. PMID: 16618298.

Guideline 15.2: Point-of-Care hemostasis monitoring should be utilized to minimize blood loss.

Monitoring may include:

- International normalized ratio
- Partial thromboplastin time
- Thrombin time
- Viscoelastic testing
- Platelet count
- Platelet function analysis
- Fibrinogen

Guideline 15.3: The surgical team should consider the age of transfused blood. [74, 75, 76 ,77,78]

Guideline 15.4: Efforts should be made to reduce the total number of donor exposures and utilize components from the same donor whenever possible. [79]

Guideline 15.5: Packed red blood cells should be washed via autotransfusion device or blood bank prior to transfusion whenever possible. [80,81]

[74] Cholette JM, Pietropaoli AP, Henrichs KF, et al. Longer RBC storage duration is associated with increased postoperative infections in pediatric cardiac surgery. Pediatric critical care medicine : a journal of the Society of Critical Care Medicine and the World Federation of Pediatric Intensive and Critical Care Societies. 2015;16(3):227- 235. PMID: 25607740.

[75] Manlhiot C, McCrindle, Brian W, Menjak, IB, Yoon, H, Holtby, HM, Brandão, LR, et al. Longer blood storage is associated with suboptimal outcomes in high-risk pediatric cardiac surgery. Annals of Thoracic Surgery. 2012;93(5):1563-1569. PMID: 22137242.

[76] Ranucci M, Carlucci C, Isgrò G, et al. Duration of red blood cell storage and outcomes in pediatric cardiac surgery: An association found for pump prime blood. Critical care (London, England). 2009;13(6):R207. PMID: 20025760.

[77] Redlin M, Habazettl H, Schoenfeld H, et al. Red blood cell storage duration is associated with various clinical outcomes in pediatric cardiac surgery. Transfusion Medicine and Hemotherapy. 2014;41(2):146-151. PMID: 24847191.

[78] Zürn, Christoph, et al. "Risk assessment of red cell transfusion in congenital heart disease." The Thoracic and Cardiovascular Surgeon 70.S 03 (2022): e15-e20.

[79] Jobes, D. R., Sesok-Pizzini, D., & Friedman, D. (2015). Reduced transfusion requirement with use of fresh whole blood in pediatric cardiac surgical procedures. The Annals of thoracic surgery, 99(5), 1706–1711. PMID: 25818574.

[80] Sheth, Michelle M., et al. "Pediatric blood management." Essentials of Blood Product Management in Anesthesia Practice (2021): 243-258.

[81] Hall TL, Barnes A, Miller JR, Bethencourt DM, Nestor L. Neonatal mortality following transfusion of red cells with high plasma potassium levels. Transfusion 1993;33(07): 606–609.

Standard 16: Fluid Management

Standard 16.1: Fluid balance shall be monitored continually and documented during cardiopulmonary bypass.[82, 83, 84, 85]

Guideline 16.1: The use of modified ultrafiltration (MUF) should be considered (unless contraindicated) to optimize hemodynamics and hematocrit. [86, 87, 88, 89, 90, 91, 92]

Guideline 16.2: The use of dilutional or zero balance ultrafiltration (ZBUF) should be considered during cardiopulmonary bypass.[93, 94, 95, 96, 97, 98]

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[82] Grist G, Whittaker C, Merrigan K, et al. The Correlation of Fluid Balance Changes During Cardiopulmonary Bypass to Mortality in Pediatric and Congenital Heart Surgery Patients. J Extra Corpor Technol. 2011;43(4):215-226. PMID: 22416601.

[83] Toraman F, Evrenkaya S, Yuce M, et al. Highly positive intraoperative fluid balance during cardiac surgery is associated with adverse outcome. Perfusion. 2004;19:85-91. PMID: 15162922.

[84] Lex DJ, Tóth R, Czobor NR, et al. Fluid Overload Is Associated With Higher Mortality and Morbidity in Pediatric Patients Undergoing Cardiac Surgery. Pediatr Crit Care Med. 2016 Apr;17(4):307-14. PMID: 26914622.

[85] Casteneda A et al. Cardiac surgery of neonate and infant: Chapter 2 Cardiopulmonary Bypass, hypothermia, and circulatory arrest. In: Morbidity of cardiopulmonary bypass, 1st Ed. Philadelphia: WB Saunders Company, 1994:25

[86] Ricci Z, Polito A, Netto R, et al. Assessment of modified ultrafiltration hemodynamic impact by pressure recording analytical method during pediatric cardiac surgery. Pediatric critical care medicine : a journal of the Society of Critical Care Medicine and the World Federation of Pediatric Intensive and Critical Care Societies. 2013;14(4):390-395. PMID: 23548961.

[87] Türköz A, Tunçay E, Balci ŞT, et al. The effect of modified ultrafiltration duration on pulmonary functions and hemodynamics in newborns and infants following arterial switch operation. Pediatric critical care medicine : a journal of the Society of Critical Care Medicine and the World Federation of Pediatric Intensive and Critical Care Societies. 2014;15(7):600-607. PMID: 24977688.

[88] Ziyaeifard M, Alizadehasl A, Aghdaii N, et al. The effect of combined conventional and modified ultrafiltration on mechanical ventilation and hemodynamic changes in congenital heart surgery. Journal of research in medical sciences : the official journal of Isfahan University of Medical Sciences. 2016;21(1):113. PMID: 28255321.

[89] Ziyaeifard M, Alizadehasl A, Massiumi G. Modified Ultrafiltration During Cardiopulmonary Bypass and Postoperative Course of Pediatric Cardiac Surgery. Red Cardiovasc Med. 2014; 3(2):e17830. PMID: 25478538.

[90] Hu J, Li P, Chen X, Yan J, Zhang J, Zhang C. Effects of modified ultrafiltration and conventional ultrafiltration combination on perioperative clinical outcomes in pediatric cardiac surgery: A meta-analysis. Medicine (Baltimore). 2021 Jan 22;100(3):e24221. doi: 10.1097/MD.0000000000024221. PMID: 33546042; PMCID: PMC7837856.

[91] Talwar S, Sujith NS, Rajashekar P, et al. Modified ultrafiltration and postoperative course in patients undergoing repair of tetralogy of fallot. J Card Surg. 2021;36(10):3679-3687. doi:10.1111/jocs.15841 PMID: 34324231.

[92] Singh, S., Okyere, I., & Mahrous, D.E. The Effect of Combined Conventional and Modified Ultrafiltration on Mechanical Ventilation and Hemodynamic Changes in Paediatric Congenital Heart Surgery. EAS J Anesthesiol Crit Care 2020;2(1):30-39. DOI:10.36349/easjacc.2020.v02i01.06

[93] Huang H, Yao T, Wang W, et al. Continuous ultrafiltration attenuates the pulmonary injury that follows open heart surgery with cardiopulmonary bypass. The Annals of Thoracic Surgery. 2003;76(1):136. PMID: 12842527.

[94] Journois D, Isreael-Beit D, Pourard P, et al. High volume, Zero-balanced Hemofiltration to Reduce Delayed Inflammatory Response to Cardiopulmonary Bypass in Children. Anesthesiology. 1996;85:965-76. PMID: 8916812.

[95] Song L, Yinglong L, Jinping L. Effects of zero-balanced ultrafiltration on procalcitonin and respiratory function after cardiopulmonary bypass. Perfusion. 2007;22(5):339-343. PMID: 18416220.

[96] Tallman RD, Dumond M, Brown D. Inflammatory mediator removal by zero-balance ultrafiltration during cardiopulmonary bypass. Perfusion. 2002;17(2):111-115. PMID: 11958301.

[97] Zhu X, Ji B, Wang G, Liu J, Long C. The effects of zero-balance ultrafiltration on postoperative recovery after cardiopulmonary bypass: A meta-analysis of randomized controlled trials. Perfusion. 2012;27(5):386-392. PMID: 22677632.

[98];

Standard 17: **Level of Readiness for Procedures That May Require Cardiopulmonary Bypass Support**

Standard 17.1: Procedures identified preoperatively to be at elevated risk of requiring conversion to a cardiopulmonary bypass procedure shall have a protocol for transition.

Standard 17.2: One perfusionist shall be assigned for each standby procedure.

Standard 17.3: A heart-lung machine consisting of a sterile extracorporeal set-up and ancillary equipment (Ref: Appendix B) shall be readily available for the procedure.

Standard 17.4: Assembly and maintenance of circuit shall be regulated according to institutional protocol using aseptic technique.[99]

Guideline 17.1: The level of readiness for utilizing cardiopulmonary bypass during a surgical procedure should be determined through consultation with the surgical team.

[99] Considerations when 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%20. (accessed November 20, 2024)

Standard 18: Staffing and On-call

Standard 18.1: At minimum, the "n+1" staffing model shall be utilized at all times, where "n" equals the number of operating/procedure rooms in use at any given time at a single site.[100, 101,102,103]

Guideline 18.1**:** An on-call perfusionist should be present and clinically ready for unscheduled and emergency procedures within 60 minutes of being called.

[100] Generally, the minimum safe number of perfusion staff: defined as n+1, where n equals the number of operating/procedure rooms in use at any given time at a single site. (Ref: UK Code of Practice https://assets.website-files.com/5da4ad68b9d5374c5a54c71d/5da742c4b9d497537544e0b7_SCPS-%20CODE%20OF%20PRACTICE%20-%202019.pdf; accessed May 26, 2024).
Example: If three operating/procedure rooms are concurrently in use then the minimum safe number of clinical perfusionists available to cover this level of activity is deemed to be four. Non-qualified staff members (e.g students or staff who have not completed training adequate to meet the requirements of the activity.) must not be included in calculating the minimum safe number of staff.

[101] Conliffe JA, Riley JB, Clutter J, Wolf K, Murtha S. A report of perfusion staffing survey: Decision factors that influence staffing of perfusion teams. J Extra Corpor Technol. 2007;39(4):249. PMID: 18293811.

[102] Lawson DS, Darling EM, Collins K, Smigla GR, Shearer IR. Staffing issues at open-heart centers offering both pediatric and adult perfusion service: 1998 survey results. J Extra Corpor Technol. 1999;31(2):91. PMID: 10724649.

[103] Stammers AH, Mejak BL. An update on perfusion safety: Does the type of perfusion practice affect the rate of incidents related to cardiopulmonary bypass? Perfusion. 2001;16(3):189-198. doi: 10.1177/026765910101600304. PMID: 11419654.

Standard 19: Duty Hours

Standard 19.1: In order for the perfusionist to ensure proper provision of care, he/she shall receive an adequate rest period between scheduled work hours. [104]

Guideline 19.1: The perfusionist should receive a minimum of 8 hours of rest period for every 16-hour consecutive work period.

[104] 10.0 Tiredness and European Working Time Directive (EWTD). The Society of Clinical Perfusion Scientists of Great Britain and Ireland and The College of Clinical Perfusion Scientists of Great Britain and Ireland Standards of Practice Document https://assets.website-files.com/5da4ad68b9d5374c5a54c71d/5da743ffa1b0aaa1cb7351e0_SCPS%20-%20Standards%20Of%20Practice%20-%202019.pdf (accessed May 26, 2024).

Standard 20: Quality Assurance and Improvement

Standard 20.1: The perfusionist shall actively participate in institutional and/or departmental quality assurance and improvement programs and safety reporting systems.

Standard 20.2: The perfusionist shall collect data concerning the conduct of perfusion via a clinical registry or database to advance quality and safety.[105,106]

Guideline 20.1: The perfusionist should use data for quality assurance and improvement projects.

[105] Warren CS, DeFoe GR, Groom RC, Pieroni JW, Groski CS, Morse CB, Connors EM, Lataille PJ, Ross CS, Likosky DS; Northern New England Cardiovascular Disease Study Group. Variation in arterial inflow temperature: a regional quality improvement project. J Extra Corpor Technol. 2011 Jun;43(2):58-63. PMID: 21848173; PMCID: PMC4680024.

[106] Baker RA, Newland RF, Fenton C, McDonald M, Willcox TW, Merry AF; Perfusion Downunder Collaboration. Developing a benchmarking process in perfusion: a report of the Perfusion Downunder Collaboration. J Extra Corpor Technol. 2012 Mar;44(1):26-33. PMID: 22730861; PMCID: PMC4557436.

Standard 21: Maintenance

Standard 21.1: The perfusionist shall ensure that equipment used in the conduct of cardiopulmonary bypass is properly maintained and functioning, which includes cleaning and disinfection processes.

Standard 21.2: Preventive maintenance on perfusion equipment shall be performed by appropriately trained and qualified manufacturer technicians, representatives or Bio-Medical technicians. Regularly scheduled maintenance shall be documented by the perfusion department and/or Bio-Medical engineering staff. The interval of such maintenance shall be consistent with manufacturer recommendations, applicable external accrediting agency guidelines and institutional requirements.

Standard 21.3: The organization shall follow a protocol for perfusion equipment failures.[107]

Standard 21.4: Appropriate backup perfusion supplies and equipment shall be readily available.

Standard 21.5: The organization shall follow a protocol for acknowledging and addressing perfusion equipment notices (e.g., recalls, warnings, and advisories).

[107] New CMS & Joint Commission Regulations on Medical Equipment Maintenance: Taking the Smart Approach to Compliance. ABM Healthcare Support Services. https://info.abm.com/New-CMS-Joint-LP.html (Accessed May 30, 2024)

Standard 22: Crisis Management

Standard 22.1: 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.[108,109]

Guideline 22.1: Alternate vendors for vital equipment should be identified in order to prepare for supply chain interruptions.

Guideline 22.2: Alternate storage and staging areas should be identified in the event primary/routine areas are compromised.

Guideline 22.3: The perfusionist should have a working knowledge of the infrastructure of the institution in order to identify operating room facilities that are suitable for cardiopulmonary bypass procedures when routine surgical suites are unavailable.

Guideline 22.4: Clinical personnel should have a procedure for patient evacuation and potential support for patients committed to cardiopulmonary bypass while evacuations are in progress.

Guideline 22.5: Clinical expertise, education, and proper role assignment should be considered if Perfusion staff repurposing is required.

[108] Preparedness for Specific Types of Emergencies. Centers for Disease Control and Prevention. https://emergency.cdc.gov/planning/ (accessed June 4, 2024).

[109] Crisis management plans should be reviewed and approved by the Chair of Cardiac Surgery, or their designee, Director of Perfusion, or equivalent, and other relevant clinical governance committees if available. See Standard 1.2.

Relevant Publications

1. American Society of Extra-Corporeal Technology. Perfusion practice survey, September, 1993. *Perfusion Life* 1994; **11**: 42–45.
2. American Society of Extra-Corporeal Technology. Guidelines for perfusion practice. *Perfusion Life* 1995; **12**: 20–22.
3. American Society of Extra-Corporeal Technology. Members accept essentials; approve revised code of ethics. *Perfusion Life* 1993; **10**: 14.
4. Kurusz M. Standards of practice in perfusion. *Perfusion* 1994; **9**: 211–15.
5. Aaron G Hill, Mark Kurusz. Perfusion Standards and Practice. *Perfusion* 1997; 12:251-255.
6. The Society of Clinical Perfusion Scientists of Great Britain and Ireland *and* The College of Clinical Perfusion Scientists of Great Britain and Ireland
    - Standards of Practice Document. https://global-uploads.webflow.com/5da4ad68b9d5374c5a54c71d/5da4ad68b9d537cbe854ca4a_Recommended%20Standards%20Of%20Monitoring%20During%20Cardiopulmonary%20ByPass.pdf (Accessed May 30, 2024)
    - Codes of Practice Document. https://global-uploads.webflow.com/5da4ad68b9d5374c5a54c71d/5da4ad68b9d537fd6654c82a_SCPS%20-%20Good%20Practice%20Guide.pdf (Accessed May 30, 2024)
7. The Australian and New Zealand College of Perfusion.
    - ANZCP Code of Ethical Practice. (https://anzcp.org/wp-content/uploads/2020/06/ANZCP-IT-Code-of-Ethical-Practice.pdf. Accessed June 4, 2024)
    - ANZCP Code of Professional Conduct. (https://anzcp.org/wp-content/uploads/2022/02/ANZCP-Code-of-Professional-Conduct-Final-Approved-21022022.pdf. Accessed June 4, 2024)

Appendix A: Patient information

1. Medical Record Number
2. Patient Surname, first name
3. Demographics:
    a. Age (DOB)
    b. Gender
    c. Height
    d. Weight
    e. Body surface Area (BSA)
4. Blood Type
5. Laboratory Data:
    a. Hemoglobin/Hematocrit
    b. Predicted Hematocrit on Bypass
    c. White Blood Cell Count
    d. Platelet Count
    e. aPTT
    f. Na
    g. K+
    h. BUN/CR
    i. Glucose
    j. Albumin
    k. Other Relevant Lab values
6. Patient Allergies
7. Planned Procedure
8. Medical History/Risk Factors (recommended):
    a. Cardiovascular
    b. Pulmonary
    c. Renal
    d. Neurologic
    e. GI/Endocrine

Appendix B: Information sufficient to accurately describe the procedure, personnel, and equipment

1. Date of Procedure
2. Type of Procedure
3. Perfusionist(s) Name:
    a. Detail to clearly demonstrate the Perfusionist in charge of the case at all times.
4. Surgeon(s) Name
5. Anesthesiologist(s) Name
6. Nurse (s) name
7. Operating Room Number
8. Comments/Events (recommended)
9. Equipment:
    a. Heart Lung Machine
    b. Cell Salvage (autotransfusion) Device
    c. Heater/Cooler

    Note: Items A-C must be uniquely identified (e.g. Pump 1, 2, 3 etc.) The related serial numbers for each component (e.g. roller pumps, vaporizer, blender, etc) are documented and stored locally.
10. Disposables:
    a. Oxygenator
    b. Cardiotomy reservoir
    c. Tubing pack/arterial line filter
    d. Centrifugal pump head
    e. Cardioplegia delivery System
    f. Cell salvage (autotransfusion)
    g. Ultrafiltration device
    h. Arterial cannula
    i. Venous cannula
    j. Cardioplegia cannula
    k. Sump/vent(s)

Note: Manufacturer, model, serial and/or lot numbers should be documented with items a-k.

Appendix C: Patient Physiological and Perfusionist Practice Parameters Documented at a Frequency Determined by Institutional Protocol

1. Pump Speed (RPM) and Blood Flow Rates (LPM)
2. Arterial Blood Pressure
3. Arterial Line Pressure
4. Central Venous/Pulmonary Artery Pressure
5. Vacuum Assist Venous Drainage (VAVD):
    a. VAVD pressure
    b. Venous Inlet Pressure (VIP)
6. Arterial/Venous Blood Gases
7. Venous Oxygen Saturation
8. Patient Temperatures, including:
    a. Patient core (at least one):
        i. Nasopharyngeal
        ii. Bladder
        iii. Esophageal
        iv. Rectal
        v. Tympanic
    b. Optional:
        i. i. Myocardium
9. Cardiopulmonary bypass temperatures:
    a. Blood temperatures:
        vi. Venous return blood
        vii. Arterial blood inflow
    b. Optional
        i. i. Water bath(s)
10. Oxygenator gases including gas flow rate and concentration(s) CO_2 flow rate
11. Input fluid volumes including:
    a. Prime
    b. Blood Products
    c. Asanguineous Fluids
    d. Cardioplegic Solution
    e. Autologous Components
12. Cardioplegia:
    a. Solution (ratio)
    b. Route
    c. Flow
    d. Pressure
    e. Temperature
    f. Volume

13. Output Fluid Volumes, including:

    g. Urine output
    h. Ultrafiltrate
    i. Other

14. Medications and/or inhalational anesthetic agents administered via extracorporeal circuit.

Appendix D: Blood gas, electrolyte and anticoagulation monitoring results

1. Blood gases:
    a. pO_2
    b. pCO_2
    c. pH
    d. Base excess
    e. Bicarbonate concentration
    f. Saturation
    g. Potassium concentration
    h. Ionized calcium concentration
    i. Sodium concentration
    j. Lactate
    k. Glucose
    l. Hemoglobin/hematocrit
2. Activated Clotting Times (ACT) and/or Heparin/Protamine assay results and/or Viscoelastic Testing results

Appendix E: Regulatory Documents

Regulations, Standards and Guidelines Resources	Citation Prefix
AABB Standards for Perioperative Autologous Blood Collection and Administration (9th Edition 2021)	**AABB**
College of American Pathologists (8/01/2022) All Common Checklist/POC	**CAP**
Center for Improvement in Healthcare Quality (April 2022)	**CIHQ**
Centers for Medicare & Medicaid Conditions of Participation (CoP) – Hospitals (Title 42 Part 482)	**CMS-H**
CLIA Laboratory Regulations (Eff. 01/01/2016)	**CMS-L**
Commission on Office Laboratory Accreditation (March 2022)	**COLA**
Healthcare Facility Accreditation Program (2018 v2)	**HFAP**
National Integrated Accreditation for Healthcare Organizations (Rev 20-1, 09/21/2020)	**NIAHO**
International Organization for Standardization (Standard 9001:2015)	**ISO 9001**
Joint Commission Hospital Accreditation Standards 2023	**TJC-H**
Joint Commission Laboratory Accreditation Standards 2023	**TJC-L**

Please note, the ISO 9001 standards are included due to the link between NIAHO Accreditation and the requirement for the hospital to become either ISO Compliant or Certified.

Standard/Guideline	***Regulations, Standards and Guidelines Resources***	***Section***
Standard 1.1	*AABB*	*1.3, 6.0, 6.1.1*
	CAP-C	*COM.10000*
	CAP-G	*GEN.20374, GEN.20375*
	CMS-H	*§482.11*
	HFAP	*30.00.09*
	NIAHO	*QM.1_SR.1a(2); QM.3; GB.1_SR.1a; SS.1*
	ISO 9001	*4.1; 4.2; 4.2.1; 4.2.2; 5.1*
	TJC-HAP	*LD.04.01.07;LD.04.01.07_EP2; LD.04.04.07_EP1–EP3; NS.02.02.01_EP3; NS.02.03.01*
	TJC-L	*DC.01.01.01_EP1-EP3; DC.02.02.01_EP1-EP4*
Standard 1.2 • Dot point 1	*AABB*	*1.1.1; 1.3; 1.4; 6.0; 6.1 (6.1.1, 6.1.3)*
	CAP-C	*COM.10000; COM.10200*
	CAP-G	*GEN.20375*
	CIHQ	*GL-4*
	CMS – L	*§493.1200 (a-c)*
	COLA	*ORG 11 E; LDR 3 E*
	HFAP	*30.00.09*
	NIAHO	*NS.2_SR.3*
	ISO 9001	*4.2.3*
	TJC–HAP	*LD.04.01.07_EP1; LD.04.04.07_EP4; NR.02.03.01_EP1-EP2;*
	TJC-L	*DC.02.01.01*

• Dot point 2	*AABB*	*6.1.4 (biennial)*
	CAP-C	*COM.10100 (biennial)*
	CIHQ	*GL-4 (triennial)*
	COLA	*ORG 15 R (annual)*
	NIAHO	*QM.5 (annual), SM.3_SR.6*
	ISO 9001	*4.2.3, 5.6.1*
Standard 1.3	*TJC-H*	*IM.03.01.01 EP1; IM.01.01.03, EP 2* *LD.01.03.01 EP5 (See also EM.10.01.01, EP 1; MM.09.01.01, EP 10; NR.01.01.01, EP 3)* *LD.04.01.07 EP1 (See also NR.02.03.01, EP 2; RI.01.07.01, EP 1)*
Guideline 1.1	*AABB*	*1.3.1, 5.4.2.2.1*
	CAP-C	*COM.10000*
	NIAHO	*QM.5*
	ISO-9001	*1.2*
Standard 2.1	*AABB*	*2.1; 2.1.1; 2.1.3*
	CAP-G	*GEN.54400, GEN.54750, GEN.55500*
	CAP-P	*POC.06800*
	CIHQ	*GL-3(G), HR-3(C), HR-4(E),MS-3(E), MS-5(B)*
	CMS-H	*§482.11(c), §482.23(3), §482.23(5), §482.51(4)*
	CMS-L	*§493.1423(e), §493.1423*
	COLA	*PER 2 E, PER 3 R, QC 31*
	HFAP	*01.00.04, 03.00.02, 03.01.06, 15.02.39, 16.00.04, 16.00.11, 18.00.06, 30.00.05,*
	NIAHO	*GB.1_SR.1c, NS.1, SM.1, SM.2, SS.3_SR.1*
	ISO 9001	*6.2.1, 6.2.2*
	TJC-HAP	*HR.01.02.01, HR.01.02.05, HR.01.06.01*
	TJC-L	*DC.02.02.01_EP1, HR.01.02.05_EP1-EP3,* ● *EP6, HR.01.02.07_EP1-EP2*

Standard 2.2	*AABB*	*2.1.3, 2.1.3.1*
	CAP-G	*GEN.55500, GEN.57000*
	CAP-P	*POC.06910*
	CIHQ	*HR-3(C)*
	CMS-H	*§482.23(3)*

	CMS-L	*§493.1235, §493.1423*
	COLA	*PER 5 R, QC 31*
	NIAHO	*SM.7_SR.1, SM.7_SR.2, SS.3_SR.1*
	TJC-HAP	*HR.01.06.01, HR.01.07.01 (EP1, EP2, EP5)*
	TJC-L	*HR.01.07.01_EP1-EP2*
Standard 2.3	*AABB*	*2.1.4*
	CAP-G	*GEN.54200*
	CIHQ	*MS-3(E)*
	CMS-L	*§493.557(a)(3)(iii)*
	COLA	*PER 6 R*
	HFAP	*01.00.04, 03.00.02, 16.00.06*
	NIAHO	*MS.10, SM.7_SR.6*
	ISO 9100	*6.2.2(e)*
	TJC-HAP	*HR.01.05.03*
	TJC-L	*HR.01.05.03_EP1, EP4-EP7*
Standard 2.5	*AABB*	*2.1.1, 2.1.2, 2.1.3, 2.1.4*
	CAP-G	*GEN.54200, GEN.54400, GEN.54750, GEN.55500, GEN.57000*
	CIHQ	*GL-3(G), HR-3(C), HR-4(E), MS-3(E), MS-5(B)*
	CMS-L	*§493.1423(e), §493.1423, §493.1235, §493.1423, §493.557(a)(3)(iii)*
	COLA	*PER 2 E, PER 3 R, PER 5 R, QC 31*
	HFAP	*01.00.04, 03.00.02, 03.01.06, 15.02.39, 16.00.04, 16.00.11, 18.00.06*

	NIAHO	*GB.1_SR.1c*
	ISO 9001	*6.2.1 (Note), 6.2.2*
	TJC-HAP	*HR.01.05.03_EP1, EP4*
	TJC-L	*HR.01.05.03_EP1, EP4-EP7*
Guideline 2.2	*CMS-H*	*§482.51(3)*
	HFAP	*18.00.07, 30.00.04*
	NIAHO	*SS.2_SR.3*
	ISO 9001	*6.2.1 (Note), 6.2.2(d)*
Standard 3.1	*CIHQ*	*NS-3*
	CMS-H	*§482.23(b)(4)*
	HFAP	*10.00.03; 10.01.26; 10.01.28; 16.00.10; 26.00.08; 26.0.11; 27.01.18*

	NIAHO	*NS.3_SR.1*
	TJC- HAP	*PC.01.03.01_EP1, EP3; PC.02.02.01_EP1; PC.02.02.01_EP1-EP2; UP.01.03.01_EP1-EP5*
Standard 3.2	*TJC- HAP*	*PC.02.02.01_EP1-EP2*
	TJC-L	*DC.03.03.01_EP1*
Guideline 3.2	*AABB*	*5.2.3*
	HFAP	*16.01.03, 16.01.04, 16.01.05*
	NIAHO	*MM.4_SR.2-SR.4*
	TJC- HAP	*LD.03.04.01_EP1; LD.03.04.02_EP3; LD.03.04.01_EP5*
Guideline 3.4	*TJC*	*PC 02.01.01 EP 1, 10, 15; 02.01.03 EP 1,7*
Standard 4.1	*AABB*	*5.1.6.1; 6.2; 6.2.1*
	CAP-G	*GEN.20377*
	CAP-P	*POC.04400*
	CIHQ	*MR-4; OI-8; AN-2*
	CMS-H	*§482.24*
	HFAP	*10.00.03; 10.01.01; 10.01.02;*

	NIAHO	*SS.6; AN.3; MR.2; MR.3_SR.1; MR.5; MR.7*
	ISO 9001	*4.2.1(c), 4.2.1(d)*
	TJC-H	*RC.01.01.01_EP1; RC.01.05.01*
Standard 4.2		
Dot point 1, Appendix A	*AABB*	*6.2; 6.2.1*
	CAP-P	*POC.04400*
	CIHQ	*OI-7; OI-8; AN-2*
	CMS-H	*§482.24*
	HFAP	*30.00.18*
	NIAHO	*SS.6; MR.5*
	TJC-H	*RC.01.01.01_EP5*
Dot point 2, Appendix B	*AABB*	*6.2.4*
	CIHQ	*OI-7*
	CMS-H	*§482.51*
	HFAP	*10.01.03; 30.00.18*
	NIAHO	*SS.6; SS.8 (SR.1 - SR.3); AN.3 (SR.2c, SR.2d1); MR.5; MR.7*
	TJC-H	*RC.01.01.01; RC.02.01.01*
Dot point 3, Appendix C	*AABB*	*6.2.4*
	CIHQ	*AN-2*
	CMS-H	*§482.24; §482.52*

	HFAP	*0.01.03; 30.00.19*
	NIAHO	*SS.6; SS.8 (SR.1 – SR.3); AN.3 (SR.2c, SR.2d1); MR.5_SR.1c; MR.7*
	TJC-H	*RC.01.01.01_EP7*
Dot point 4, Appendix D	*CAP-C*	*COM.29950*

	CIHQ	*AN-2*
	CMS-H	*§482.24*
	HFAP	*10.01.03; 30.00.19*
	NIAHO	*SS.6; SS.8 (SR.1 - SR.3); AN.3 (SR.2c, SR.2d1); MR.5_SR.1c; MR.7*
	TJC-H	*RC.01.01.01_EP7*
Dot point 5	*AABB*	*6.2.4*
	CAP-P	*POC.04700*
	CIHQ	*MR-4*
	CMS-H	*§482.23; §482.24; §482.51*
	HFAP	*10.01.03; 10.01.04; 30.00.19*
	NIAHO	*SS.8_SR.2; MR.5 (SR.2b, SR.4, SR.4a); MR.6*
	TJC-H	*RC.01.02.01; RC.02.03.07_EP1*
Standard 4.2	*CAP-G*	*GEN.41304;*
	CAP-P	*POC.04400; POC.04700*
	COLA	*LIS 2.7; APM 18 (PST) R*
	TJC-L	*DC.02.03.01*
Guideline 4.1	*NIAHO*	*MR.5 (SR.2 – SR.5)*
Guideline 4.2	*AABB*	*5.2.3*
	CIQH	*MR-4*
	CMS-H	*§482.23; §482.24; §482.51*
	COLA	*WAV 9 R*
	HFAP	10.01.03; 10.01.04; 30.00.19
	NIAHO	MR.5 (SR.2b, SR.3, SR.4, SR.5)
	TJC-H	RC.01.02.01; RC.02.03.07
Guideline 4.3	*AABB*	*6.2.8; 6.2.9*
	CAP-G	*GEN.20377; 20425*
	CIHQ	*MR-3*
	CMS-H	*§482.23; §482.24*

	CMS-L	*§493.1101; §493.1105*
	COLA	*WAV 9 R*
	HFAP	*10.00.03*
	NIAHO	*MR.3 (SR.1 – SR.2)*

	TJC-H	*RC.01.05.01*
	TJC-L	*DC.02.04.01*
Standard 5.1	*TJC-H*	*UP.01.01.01*
Standard 6	*NIAHO*	*SS.1; AS.1*
	TJC-H	*NPSG.06.01.01; LD.04.04.05*
Standard 6.1	*CIQH*	*QS-9*
	TJC-H	*NPSG.06.01.01*
Standard 6.2	*CIQH*	*QS-9*
	TJC-H	*NPSG.06.01.01*
Standard 6.3	*CIQH*	*QS-9*
	TJC-H	*NPSG.06.01.01*
Standard 6.4	*CIQH*	*QS-9*
	TJC-H	*NPSG.06.01.01*
Standard 6.7	*CIQH*	*QS-9*
	TJC-H	*NPSG.06.01.01*
Guideline 6.2	*CIQH*	*QS-9*
	TJC-H	*NPSG.06.01.01*
Standard 7	*CIHQ*	*AN-2 E*
	HFAP	*15.02.17*
	NIAHO	*AS.3_SR.2d(1)*
	TJC-H	*PC.01.02.01*
Standard 7.6	*CAP-G*	*GEN.41304;*
	CAP-P	*POC.04400; POC.04700*
	COLA	*LIS 2.7; APM 18 (PST) R*

	TJC-L	*DC.02.03.01*
Standard 8	*TJC*	*NPSG.03.05.01*
Standard 8.1	*CIHQ*	*NS-3*
	CMS-H	*§482.23(b)(4)*
	HFAP	*10.00.03; 10.01.26; 10.01.28; 16.00.10; 26.00.08; 26.0.11; 27.01.18*
	NIAHO	*NS.3_SR.1*
	TJC- HAP	*PC.01.03.01_EP1, EP3; PC.02.01.01_EP1; PC.02.02.01_EP1-EP2; UP01.03.01_EP1-EP5*
Standard 9.5	*CAP-G*	*GEN.41304; GEN.41345*
	TJC-L	*QSA.02.10.01; QSA.06.01.01; DC.02.03.01*
Standard 10.1	*CIHQ*	*NS-3*
	CMS-H	*§482.23(b)(4)*
	HFAP	*10.00.03; 10.01.26; 10.01.28; 16.00.10; 26.00.08; 26.0.11; 27.01.18*
	NIAHO	*NS.3_SR.1*

	TJC- HAP	*PC.01.03.01_EP1, EP3; PC.02.01.01_EP1; PC.02.02.01_EP1-EP2; UP.01.03.01_EP1-EP5*
Standard 11.1	*CIHQ*	*NS-3*
	CMS-H	*§482.23(b)(4)*
	HFAP	*10.00.03; 10.01.26; 10.01.28; 16.00.10; 26.00.08; 26.0.11; 27.01.18*
	NIAHO	*NS.3_SR.1*
	TJC- HAP	*PC.01.03.01_EP1, EP3; PC.02.01.01_EP1; PC.02.02.01_EP1-EP2; UP.01.03.01_EP1-EP5*
Standard 14.1	*AABB*	*5.2.3*
	HFAP	*16.01.03; 16.01.04; 16.01.05*
	NIAHO	*MM.4_SR.2-SR.4;*
	TJC- HAP	*LD.03.04.01_EP1; LD.03.04.02_EP3;*

		LD.03.04.01_EP5
Standard 17.1	*CIHQ*	*NS-3*
	CMS-H	*§482.23(b)(4)*
	HFAP	*10.00.03; 10.01.26; 10.01.28; 16.00.10; 26.00.08; 26.0.11; 27.01.18*
	NIAHO	*NS.3_SR.1*
	TJC- HAP	*PC.01.03.01_EP1, EP3; PC.02.01.01_EP1; PC.02.02.01_EP1-EP2; UP.01.03.01_EP1-EP5*
Guideline 17.1	*CIHQ*	*NS-3*
	CMS-H	*§482.23(b)(4)*
	HFAP	*10.00.03; 10.01.26; 10.01.28; 16.00.10; 26.00.08; 26.0.11; 27.01.18*
	NIAHO	*NS.3_SR.1*
	TJC- HAP	*PC.01.03.01_EP1, EP3; PC.02.01.01_EP1; PC.02.02.01_EP1-EP2; UP.01.03.01_EP1-EP5*
Standard 17.4	*TJC-H*	*USP797; JC FAQ (Infection Prevention and Control: Device pre-priming https://www.jointcommission.org/standards/standardfaqs/hospital-and-hospital-clinics/infection-prevention-and-controlic/000002338/?p=1)*
Standard 20.1	*AABB*	*5.1.2; 8.2; 9.0*
	CAP-C	*COM.04000; COM.04200*
	CAP-G	*GEN.13806*
	CIHQ	*QA-1*
	CMS-H	*§482.21*
	CMS-L	*§493.1200; §493.1230; §493.1239*

	COLA	*QA 1 E; QA 3 R; QA 4 R*
	HFAP	*12.00.00; 12.00.04*
	NIAHO	*QM.1 (SR.1-SR.2); QM.2; QM.3; QM.6*
	ISO 9001	*8.1; 8.2.1; 8.5.1; 8.5.3*
	TJC-H	*LD.04.04.01 (EP1-EP4); PI.01.01.01 (EP1-EP3)*

	TJC-L	*PI.01.01.01*
Standard 20.2	*AABB*	*5.1.2.1; 5.1.2.2; 8.3; 9.0; 9.1;9.2*
	CAP-C	*COM.04200*
	CAP-G	*GEN.16902; GEN.20316*
	CIHQ	*QA-2 (A-E); QA-4; QA-5*
	CMS-H	*§482.21*
	CMS-L	*§493.1200; §493.1230; §493.1239*
	COLA	*QA 2 E; QA 3 R; QA 4 R; QA 5 R*
	HFAP	*12.00.01; 12.00.02; 12.00.04; 12.01.02*
	NIAHO	*QM.5; QM.7; QM.8*
	ISO 9001	*8.2.2-3; 8.3; 8.4; 8.5.1; 8.5.2; 8.5.3*
	TJC-H	*PI.01.01.01 (EP); PI.02.01.01; PI.03.01.01*
	TJC-L	*PI.02.01.01; PI.03.01.01*
Standard 21.1	*AABB*	*3.5; 3.5.1; 3.5.1.1*
	CIHQ	*CE-8_A*
	CMS-H	*§482.26; §482.41; §482.53*
	CMS-L	*§493.1101; §493.1254*
	HFAP	*11.06.09; 11.06.10*
	NIAHO	*PE.1; PE.7*
	TJC-H	*EC.02.04.01; EC.02.04.03 EC030101E, EC020403, EC010101, EC020401 522.*
	TJC-L	*EC.02.04.01; EC.02.04.03*
Standard 21.2	*AABB*	*3.5; 3.5.1; 3.5.1.1*
	CAP-P	*POC.07300; POC.07512; POC.07540; POC08980; POC.09035; POC.09090; POC09145*
	CIHQ	*CE-8 (B, D)*
	CMS-H	*§482.26; §482.41; §482.53*
	CMS-L	*§493.1101; §493.1254*
	COLA	*LDR 2 E; QC 1 E; CA 1 R*
	HFAP	*11.06.09*
	NIAHO	*PE.1; PE.7_SR.6*

	TJC-H	*EC.02.04.01; EC.02.04.03*
	TJC-L	*EC.02.04.01; EC.02.04.03; QSA.02.02.01; QSA.02.03.01*
Standard 21.3	*CIQH*	*CE-8 (M, N)*
	NIAHO	*PE.7 (SR.4-SR.5)*
	TJC-H	*EC.02.04.01_EP9*
	TJC-L	*EC.02.04.01; EC.02.04.03*
Standard 21.4	*NIAHO*	*PE.7*
Standard 21.5	*HFAP*	*08.00.06; 25.00.00*
	CMS-H	*§482.25*
	NIAHO	*PE.1; PE.3; PE.7*
	TJC-H	*EC.02.02.01_EP11; MM.05.01.017*
	TJC-L	*EC.02.02.01_EP11*
Standard 22.1	*TJC-H*	*EM.12.02.03; EM.12.02.05; EM.15.01.01; EM.16.01.01; EC 02.04.01 EP9*

Appendix F: Perfusion Checklist

Perfusion Checklist

Patient ID _____

Check each item when completed, sign and date. If not applicable, ~~draw line through.~~ ***Bold italicized items for expedited set-up.***

- **PATIENT**
  - ☐ ***Patient identity confirmed***
  - ☐ ***Procedure confirmed***
  - ☐ ***Blood type, antibodies confirmed***
  - ☐ ***Allergies checked***
  - ☐ Blood bank number confirmed
  - ☐ Medical record number confirmed
  - ☐ Chart reviewed
- **STERILITY/CLEANLINESS**
  - ☐ ***Components checked for package integrity/expiration***
  - ☐ Equipment clean
  - ☐ Heat exchanger(s) leak-tested
- **PUMP**
  - ☐ ***Occlusion(s) set***
  - ☐ ***Speed controls operational***
  - ☐ ***Flow meter in correct direction and calibration***
  - ☐ ***Flow rate indicator correct for patient and/or tubing size***
  - ☐ ***Rollers rotate freely***
  - ☐ Pump head rotation smooth and quiet
  - ☐ Holders secure
  - ☐ Servoregulated connections tested
- **ELECTRICAL**
  - ☐ ***Power cord(s) connection(s) secure***
  - ☐ ***Servoregulation connections secure***
  - ☐ Batteries charged and operational
- **CARDIOPLEGIA**
  - ☐ ***System debubbled and operational***
  - ☐ System leak-free after pressurization
  - ☐ Solution(s) checked

- **GAS SUPPLY**
  - ☐ ***Gas line(s) and filter connections secure***
  - ☐ ***Gas exhaust unobstructed***
  - ☐ ***Source and appropriate connections of gas(es) confirmed***
  - ☐ ***Flow meter / gas blender operational***
  - ☐ Hoses leak-free
  - ☐ Anesthetic gas scavenge line operational
- **COMPONENTS**
  - ☐ ***System debubbled and operational***
  - ☐ ***Connections / stopcocks / caps secure***
  - ☐ ***Appropriate lines claimed / shunts closed***
  - ☐ ***Tubing direction traced and correct***
  - ☐ ***Patency of arterial line / cannula confirmed***
  - ☐ No tubing kinks noted
  - ☐ One-way valve(s) in correct direction
  - ☐ Leak-free after pressurization
- **SAFETY MECHANISMS**
  - ☐ ***Alarms operational, audible and engaged***
  - ☐ ***Arterial filter / bubble trap debubbled***
  - ☐ ***Cardiotomy / hardshell venous reservoir(s) vented***
  - ☐ ***Vent(s) tested***
  - ☐ Venous line occluder(s) calibrated and tested
  - ☐ Devices securely attached to console
- **ASSISTED VENOUS RETURN**
  - ☐ ***Cardiotomy positive-pressure relief valve present***
  - ☐ ***Negative- pressure relief valve unobstructed***
  - ☐ Vacuum regulator operational
- **MONITORING**
  - ☐ ***Circuit / patient temperature probes placed***
  - ☐ Pressure transducers / monitors calibrated and on proper scales
  - ☐ Inline sensors calibrated
  - ☐ Oxygen analyzer calibrated
- **ANTICOAGULATION**
  - ☐ ***Heparin time and dose confirmed***
  - ☐ Anticoagulation tested and reported

- **TEMPERATURE CONTROL**
  - ☐ ***Water source(s) connected and operational***
  - ☐ Temperature range(s) tested and operational
  - ☐ Water lines unobstructed
- **SUPPLIES**
  - ☐ ***Tubing clamps available***
  - ☐ Drugs available and properly labeled
  - ☐ Solutions available
  - ☐ Blood products available
  - ☐ Sampling syringes / laboratory tubes available
  - ☐ Anesthetic vaporizer correct
  - ☐ Vaporizer operational and filled
- **BACKUP**
  - ☐ ***Hand cranks available***
  - ☐ ***Duplicate circuit components / hardware available***
  - ☐ Emergency lighting / flashlight available
  - ☐ Backup full oxygen tank with flow meter available
  - ☐ Ice available
- **EMERGENT RESTART OF BYPASS**
  - ☐ ***Heparin time and dose confirmed***
  - ☐ ***Components debubbled***
  - ☐ ***Gas flow confirmed***
  - ☐ ***Alarms reengaged***
  - ☐ ***Water source(s) connected***
- **TERMINATION CHECKLIST**
  - ☐ ***Venous assist off / cardiotomy / venous reservoirs vented***
  - ☐ ***Shunt(s) closed***
  - ☐ ***Vent(s) clamped / removed***
- **POSTBYPASS CHECKLIST**
  - ☐ ***Announce bypass terminated***
  - ☐ ***Arterial and venous lines clamped***
  - ☐ ***Arterial circuit bubble-free before transfusing perfusate***
  - ☐ ***Pump suction(s) off***

Comments:

Signature: _____

Date: _____ Time: _____

These perfusion checklists, or a reasonable equivalent, should be used in perfusion practice. This is a guideline, which perfusionists are encouraged to modify to accommodate differences in circuit design and variations in institutional clinical practice. Users should refer to manufacturers' information, including Instructions for Use, for specific procedures and/or precautions. AmSECT disclaims any and all liability and responsibility for injury and damages resulting from following this suggested checklist. Origination 1990; revision 2004 by AmSECT Quality Committee.