The Canadian Society of Clinical Perfusion

La Société Canadienne de Perfusion Clinique

cscp.ca

STANDARDS OF PRACTICE OF CLINICAL PERFUSION

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MISSION

The mission of the Canadian Society of Clinical Perfusion (CSCP) is to encourage and continually foster the evolution of Clinical Perfusion through advocacy, education, and certification, optimizing patient care.

VISION

Our vision is to promote the highest standards of safe health care in clinical perfusion.

OBJECTIVES

The primary objective of the CSCP is to promote high standards of professional skill and knowledge among healthcare practitioners known as Clinical Perfusionists, who are responsible for providing safe, efficient, and effective Extracorporeal Circulation and other related procedures.

The goals of the CSCP are to:

1. Promote a high standard of professional skill and knowledge. Measures will include maintaining standards of practice, certification by examination, and recertification processes.

2. Provide leadership within the discipline as well as with other health care professionals.

3. Promote accredited perfusion education training programs and continuing education for practicing perfusionists.

4. Promote communication among the members, other perfusion organizations and health care professionals.

5. Promote preparation, presentation and submission of teaching materials and scientific documents.

6. Promote professional responsibility and accountability to the patient, the team and the employer.

The specific criteria developed in this Standards document shall provide the means by which the clinical perfusionist will participate in delivering safe, high-quality care to the patient.

These Standards will assist the perfusionist in evaluating the performance and patient care outcomes in relation to perfusion practice.

SCOPE OF PRACTICE OF THE CLINICAL PERFUSIONIST

In the multifaceted landscape of cardiovascular surgery and critical care, the Clinical Perfusionist emerges as a cornerstone of patient care, wielding expertise that extends far beyond the confines of mechanical operation. Tasked primarily within the realm of Cardiovascular Surgery, their role encompasses a spectrum of responsibilities critical to the successful outcome of surgical interventions. From managing extracorporeal circulation to navigating the complexities of mechanical support devices, their contributions are integral to the fabric of modern healthcare.

Embedded within the essence of perfusion practice lies a commitment to excellence that transcends mere technical proficiency. It is incumbent upon each perfusionist to continuously pursue and maintain a high level of current knowledge and technique through accredited academic and clinical education and practice. This commitment ensures proficiency and fosters collaboration with allied healthcare practitioners in delivering comprehensive patient care.

A profound understanding of extracorporeal physiology, spanning both adult and pediatric populations, forms the bedrock of perfusion practice. Complementing this expertise are foundational proficiencies in infection control, hemodynamics, biochemical principles, and pharmacology—all indispensable for navigating the complexities of patient care. Furthermore, the exigencies of the profession demand unwavering resilience as perfusionists operate under intense stress, often necessitating acute decision-making and unwavering focus on patient safety.

Effective communication emerges as a linchpin in the seamless orchestration of care, with perfusionists adeptly liaising with multidisciplinary teams and exercising discernment in critical decision-making junctures. Their role extends beyond technical execution to encompass a realm of professional consultation and advisement, wherein their insights guide physicians toward the most efficacious and prudent courses of action.

Concomitant with their clinical responsibilities, perfusionists navigate a landscape fraught with legal and ethical considerations, underscoring the need for unwavering diligence and awareness. Theirs is a profession characterized not only by technical prowess but by a profound sense of duty, accountability, and unwavering commitment to the highest standards of care.

The establishment and adherence to clinical standards are imperative in ensuring the consistent delivery of safe, effective, and high-quality care. These standards serve as guiding principles, providing a framework for best practices, promoting patient safety, and upholding professional integrity within the field of clinical perfusion. Through adherence to established standards, clinical perfusionists can maintain uniformity in practice, minimize variability, and ultimately optimize patient outcomes.

DEFINITIONS

Standard: Practices, technology, and/or conduct of care that institutions shall meet to fulfill the minimum requirements for CPB procedures.

Guideline: Recommendations that should be considered and may assist in developing and implementing protocols.

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

Shall: Indicates a mandatory requirement.

Should: Indicates a recommendation.

Clinical Team: Refers to the group comprising Surgeons, Anesthetists, Perfusionists, Nurses, and Technicians.

CLINICAL PERFUSIONIST'S STANDARDS OF PRACTICE

STANDARD 1
DEVELOPMENT AND IMPLEMENTATION OF INSTITUTION-SPECIFIC PROTOCOLS

Standard 1.1. Institutional protocols (operating procedures) shall be established for each clinical practice to ensure each standard is applied to clinical practice effectively.

Standard 1.2. Institutional Protocols shall have:

1. Approval by the Director of Cardiac Surgery or their designee, Perfusion Supervisor, or equivalent, and other relevant clinical governance committees, if applicable.
2. Regular review and update at least annually or more frequently as needed.

Standard 1.3. Written protocols shall be in place for managing and training personnel in handling "catastrophic events" during cardio-pulmonary bypass, including but not limited to: [1]

a. Massive air embolism
b. Oxygenator failure
c. Tubing rupture
d. Power failure
e. Pump failure
f. Heater-cooler failure

Guideline 1.1. Deviation from protocols may be permitted at the discretion of the clinical team, with documentation in the perfusion record.

[1] Amsect Standards and Guidelines for Perfusion Practice. Accessed via AmSECT_Perfusion_S&G_2023 Ratified 021023_Digital edition.pdf

STANDARD 2
QUALIFICATION AND COMPETENCY

Standard 2.1. Only qualified Perfusionists, certified by the Canadian Society of Clinical Perfusion (CSCP), or eligible for certification, shall conduct cardiopulmonary bypass (CPB) procedures in Canada.

Standard 2.2. The Perfusionists shall actively engage in perfusion-related education and training, fulfilling all requirements for recertification set forth by the CSCP on an annual basis.[2]

Standard 2.3. The Perfusionist shall abide by the code of ethics, bylaws, regulations, and standards as set out by CSCP. [2]

Standards 2.4. The perfusionist respects the confidences of the patient and follows legislative requirements for privacy of information.

Standard 2.4. During CPB procedures, designated support staff, including Perfusionists, nursing, technical, or non-technical personnel, shall be available on-site to assist the primary perfusionist.

Standard 2.5. Trainees enrolled in a CSCP recognized training program are permitted to perform CPB procedures under the direct supervision of a Canadian Certified Perfusionist (CPC). Supervision shall be continuous in the operating theater until trainees achieve clinical competency, with ongoing supervision provided as needed throughout the training period.

[2] Bylaws, Canadian Society of Clnical Perfusion. Accessed via Microsoft Word - CSCP Bylaws_ENv2019NEW.docx

STANDARD 3
EFFECTIVE COMMUNICATION

Standard 3.1. Prior to commencing CPB, a patient-specific management plan shall be formulated and communicated to the surgical team. This communication may occur during the pre-operative briefing, prior to the procedure commencement, or during the surgical "time out."[3]

Standard 3.2. In the operating theater, protocol-driven communication methods, such as closed-loop communication, shall be consistently employed to acknowledge verbal commands, verify information, and minimize ambiguity.[4][5]

Standard 3.3. When transitioning the management of a case to a second Perfusionist, the primary Perfusionist shall utilize a standardized handoff protocol, such as SBAR (Situation, Background, Assessment, Communication).[6]

Standard 3.4. The use of cellular telephone technology within the operating room shall adhere to institutional protocols governing cell phone usage.

Guideline 3.1. Following the procedure, the primary Perfusionist should actively participate in a post-procedure debrief with the surgical team. Discussion topics may include communication effectiveness, additional training needs, equipment or disposables concerns, post-operative instructions, constructive feedback (when applicable) and any safety incidents.

Guideline 3.2. Any deviations from the intended treatment care plan should be documented and promptly communicated to the clinical team, facilitating adjustments to the management plan as necessary.

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[3] World Health Organization surgical safety checklist and implementation manual. World Health Organization, http://www.who.int/patientsafety/safesurgery/ss_checklist/en/

[4] Merry AF, Weller J, Mitchell SJ. Teamwork, communication, formula-one racing and the outcomes of cardiac surgery. J Extra Corpor Technol. 2014 Mar;46(1):7-14. PMID: 24779113; PMCID: PMC4557515.

[5] Wadhera RK, Parker SH, Burkhart HM, Greason KL, Neal JR, Levenick KM, Wiegmann DA, Sundt TM 3rd. Is the "sterile cockpit" conceptapplicable 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.

[6] The Joint Commission. Hot Topics in Health Care. Transitions of Care: The need for a more effective approach to continuing patient care.http://www.jointcommission.org/assets/1/18/hot_topics_transitions_of_care.pdf

STANDARD 4
COMPREHENSIVE DOCUMENTATION: PERFUSION RECORDS AND CHECKLIST

Standard 4.1. A comprehensive and accurate record of all perfusion-related activities shall be maintained for each patient undergoing CPB procedures (*Appendix i*).

Standard 4.2. Perfusion records shall include but not be limited to:

a. Patient information, including demographics, pre-operative risk factors, and planned procedure.
b. Completed Checklist
c. Perfusion circuit details, equipment setup
d. Medication administration records
e. Physiological parameters monitored during the procedure
f. Any deviations from the established protocols or treatment plans
g. Intraoperative complications or adverse events
h. Signature or electronic equivalent of the Perfusionist performing the procedure.

Standard 4.3. The electronic health record system utilized for perfusion documentation shall comply with institutional policies and regulatory requirements governing data security, privacy, and confidentiality.

Standard 4.4. The checklist should be utilized for every procedure where Perfusion services are involved. The Perfusionist shall use checklists in a read-verify manner where critical steps that shall have been performed are confirmed (*Appendix ii*).[7]

Guideline 4.1. A standardized format for perfusion documentation should be established to ensure consistency and facilitate comprehensive recording of essential information throughout the perioperative period.

Guideline 4.2. Depending on institutional protocols, two individuals should complete the checklists, with one person designated as the primary Perfusionist responsible for operating the heart-lung machine.

[7] 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 globalpopulation. N Engl J Med. 2009 Jan 29;360(5):491-9. doi: 10.1056/NEJMsa0810119. Epub 2009 Jan 14. PMID: 19144931.

STANDARD 5
OPERATING OF SAFETY DEVICES

Standard 5.1. During CPB procedures, safety devices shall remain armed unless overridden due to device failure.

Standard 5.2. Arterial blood flow should be controlled by the following safety devices:

a. Pressure monitoring in all delivery lines to the patient, including arterial, cardioplegia (antegrade and retrograde) and cerebral (antegrade or retrograde)

b. A Bubble detector (positioned according to manufacturer instructions)

c. A level sensor (positioned according to manufacturer instructions to allow an appropriate reaction time and a safe operational volume)

All the above safety devices should be able to servo-regulate or interrupt arterial blood flow and should be equipped with both audio and visual alarms.

Standard 5.3. Temperature monitoring of arterial outflow from the oxygenator shall be employed and include audible and visual alarms to prevent high temperatures.[8]

Standard 5.4. An arterial-line filter, external or integrated, shall be used during CPB procedures.

Standard 5.5. A one-way valve in the vent line shall be employed during CPB procedures.

Standard 5.6. When using a centrifugal pump for CPB procedures methods preventing arterial retrograde flow shell be employed. Examples:

- One-way flow valves
- Electronically activated arterial line clamps
- Hard stop detent controls to prevent accidental reduction in pump speed
- Low speed visual and audible alarm.

Standard 5.7. A ventilating gas oxygen analyzer should be used during CPB procedures.

Standard 5.8. An anesthetic gas scavenge line shall be employed when inhalation agents are introduced into the circuit.

Standard 5.9. A backup gas supply shall be accessible during CPB procedures.

Standard 5.10. Hand cranks shall be readily available during CPB procedures.

Standard 5.11. The heart-lung machine shall have a backup power source for uninterrupted supply and shall be plugged into a power supply meeting electrical safety standard.

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[8] Engelman R, Baker RA, Likosky DS, Grigore A, Dickinson TA, Shore-Lesserson L, Hammon JW. The Society of Thoracic Surgeons, The Society ofCardiovascular 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
CONTINUOUS PATIENT MONITORING

Standard 6.1. Patient's blood pressure shall be monitored continuously during CPB procedures, including but not limited to:

- Invasive arterial pressure
- Central venous pressure
- Pulmonary artery blood pressure, if available
- Coronary sinus pressure during retrograde cardioplegia delivery

Standard 6.2. Arterial blood flow shall be monitored continuously at a point in the CPB circuit where it accurately reflects the flow delivered to the patient during CPB procedures (e.g., distal to intra-circuit shunts).

Standard 6.3. Cardioplegia dose, delivery method, line pressure, coronary sinus pressure (for retrograde), and ischemic intervals shall be monitored continually and reported to the surgical team as necessary during CPB procedures.

Standard 6.4. Patient and device temperatures shall be monitored continuously during CPB procedures.

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

Standard 6.5. Arterial oxygen saturation, pH, carbon dioxide and oxygen partial pressures, potassium and bicarbonate concentration, shall be monitored continuously if using in-line blood gas monitoring or continually if using intermittent blood gas analysis (point of care) during CPB procedures.

Standard 6.6. Venous saturation/Hematocrit (or hemoglobin) shall be monitored continuously if using in line blood gas monitoring or via blood gas sampling and analysis shall be at regular intervals during any ECLS procedures.

Standard 6.7. Oxygen fraction and gas flow rates shall be monitored continuously during CPB procedures.

Standard 6.8. Venous and/or Arterial line occlusion shall be monitored continuously during CPB procedures if utilized.

Standard 6.10. Carbon dioxide removal or concentration shall be monitored continuously if using exhaust capnography during CPB procedures.

Guideline 6.1. Continuous in-line blood gas monitoring should be used during CPB procedures, including DO2i, if possible.

Guideline 6.2. Cerebral oximetry should be used during CPB procedures.

Guideline 6.3. For Aortic surgeries requiring Antegrade cerebral perfusion pre and post clamp invasive arterial monitoring should be established during CPB procedures.

STANDARD 7
MANAGEMENT OF ANTICOAGULATION

Standard 7.1. The Perfusionist, in collaboration with the clinical team, shall establish the anticoagulation management plan, defining:

- Target and acceptable range for activated clotting time (ACT), considering device performance variability.[9]
- Monitoring and treatment of anticoagulation status before, during, and after CPB
- at specified intervals.
- Patient-specific initial heparin dosage, determined by weight, dose-response curve (automated or manual), blood volume, or body surface area.
- Preparation of alternative anticoagulation methods when heparin is unsuitable.

Standard 7.2. Anticoagulation monitoring should encompass ACT testing. Additional tests may include:

- Heparin level measurement (heparin/protamine titration or unfractionated heparin level)
- Partial Thromboplastin Time
- Thromboelastography
- Thrombin Time
- Anti Xa

Standard 7.3. Additional anticoagulant doses during bypass procedures should be guided by appropriate tests.[10]

Standard 7.4. Protamine administration for heparin reversal should minimize over-exposure, confirmed by ACT and/or heparin/protamine titration or thromboelastography.

Standard 7.5. Cardiotomy suction shall be discontinued at the onset of protamine administration to avoid clotting within the extracorporeal circuit. [11]

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

[10] In patients requiring longer cardiopulmonary bypass (CPB) times (>2 to 3 hours), maintenance of higher and/or patient-specific heparinconcentrations during CPB 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

[11] Jansa, L., Fischer, C., Serrick, C., Rao, V. Protamine Test Dose: Impact on Activated Clotting Time and Circuit Integrity.
https://doi.org/10.1016/j.athoracsur.2021.04.059Protamine

STANDARD 8
GAS EXCHANGE MANAGEMENT

Standard 8.1. Gas exchange shall be maintained during CPB procedures according to protocol, accounting for individual patient needs.

Guideline 8.1. Indexed oxygen delivery (DO2) and consumption (VO2) calculations should be utilized to evaluate and optimize gas exchange.[12][13][14]

Guideline 8.2. Point-of-Care testing should be considered to provide accurate and timely information for blood gas analysis.[15]

[12] de Somer F, Mulholland JW, Bryan MR, Aloisio T, Van Nooten GJ, Ranucci M. O2 delivery and CO2 production during cardiopulmonary bypass asdeterminants 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

[13] 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.

[14] 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. JThorac Cardiovasc Surg. 2018 Nov;156(5):1918-1927.e2. PMID: 29778331.

[15] Nichols, JH. Laboratory Medicine Practice Guidelines. Evidence-based practice for point-of-care testing. American Association for ClinicalChemistry Press. 2006. https://www.aacc.org/science-and-research/practice-guidelines/point-of- care-testing (accessed December 4, 2022)

STANDARD 9
BLOOD FLOW MANAGEMENT

Standard 9.1. Blood flow rates must be established as per protocol before initiating CPB.

Standard 9.2. The Perfusionist, in collaboration with the clinical team, is responsible for maintaining the targeted blood flow rate during the CPB procedure.

Standard 9.3. The Perfusionist, in collaboration with the clinical team, shall define and communicate the intended treatment algorithm for blood pressure management prior to cardiopulmonary bypass, including acceptable ranges for blood pressure.

Standard 9.4.: The following should be used to determine the adequacy of blood flow rate:

- Acid-base balance
- Anesthetic depth
- Arterial blood pressure
- Cerebral oximetry
- Lactate levels
- Oxygen delivery and consumption
- Venous pO2
- Arterial pO2
- Hemoglobin concentration
- Arterial oxygen saturation
- Temperature
- Venous oxygen saturation

STANDARD 10
COMPREHENSIVE BLOOD MANAGEMENT

Standard 10.1. The Perfusionist shall participate in a comprehensive multimodality blood conservation and management program led by a multidisciplinary team of healthcare providers to limit the utilization of blood resources, decrease the risk of bleeding, optimize hemostasis, and minimize blood loss to improve patient outcome.[16]

Standard 10.2. The CPB circuit shall be minimized to reduce prime volume.

Standard 10.3. The Perfusionist shall calculate, prior to induction, and communicate to the clinical team prior to initiating CPB, a patient's predicted post-dilutional hemoglobin or hematocrit.

Guideline 10.1. Blood management efforts should include:[16]

1) Participation in multidisciplinary blood management strategy
2) Adoption of case-specific strategies to minimize hemodilution by:
    i. Optimizing circuit priming volume
    ii. Match the circuit size with the size of the patient
    iii. Biocompatible surface coating on all surfaces of the CPB circuit
    iv. Autologous priming of the circuit, including retrograde arterial and venous antegrade priming.
    v. Ultrafiltration
    vi. Perioperative blood cell recovery and reinfusion.
    vii. CPB circuit blood salvage at the end of the procedure
    viii. Anesthetic volume loading

[16] Budak AB, McCusker K, Gunaydin S. A Cardiopulmonary Bypass Based Blood Management Strategy in Adult Cardiac Surgery. Heart Surg Forum. 2017 Oct 24;20(5):E195-E198. doi: 10.1532/hsf.1792. PMID: 29087283.

STANDARD 11
PREPAREDNESS FOR HIGH-RISK PROCEDURES THAT MAY REQUIRE CPB

Standard 11.1. Procedures identified preoperatively to be at elevated risk of requiring conversion to CPB procedure shall have a protocol for transition to such procedures.

Standard 11.2. A Perfusionist shall be assigned for each such standby procedure.

Standard 11.3. A heart-lung machine and extracorporeal set-up with ancillary equipment shall be readily available for the procedure.

Standard 11.4. Assembly and maintenance of the ECLS circuit shall be regulated according to institutional protocol in collaboration with infection control.[17]

[17] 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 (accessed March 20, 2022)

STANDARD 12
STAFFING, ON-CALL AVAILABILITY, AND DUTY HOURS MANAGEMENT

Standard 12.1: The Hospital or service provider shall employ an adequate number of perfusionists to cover all operational situations, so that a second perfusionist can be made available to assist in the event of an emergency.

Standard 12.2: The "n+1" staffing model should be always utilized, where "n" equals the number of operating/procedure rooms requiring perfusionist support at any given time at a single site.[18]

Standard 12.3: An on-call Perfusionist shall be present and clinically ready for unscheduled and emergency procedures within the institutional protocolized time.

Standard 12.4: For the Perfusionist to ensure proper provision of care, the Perfusionist should receive a minimum of 8 hours of rest period for every 16-hour consecutive work period.

Standard 12.4. For new staff (new hire or Locum) an "on-boarding" process shall be developed for appropriate integration into the clinical environment, with access to protocols and hospital policies (*Appendix iii*).

[18]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 March 6, 2021). (Ref; AMSECT Standards and guidelines; https://www.amsect.org/policy-practice/amsects-standards-and-guidelines accessed April 21, 2023)

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.

STANDARD 13
SAFETY AND INCIDENT REPORTING

Standard 13.1. Incident and safety reporting shall be initiated as per hospital required mandatory reporting for all incidents with or without patient involvement.[19]

Standard 13.2. All Perfusionists shall practice emergency procedures as part of routine safety culture.

Guideline 13.1. Incident reports should be submitted to the Perfusion Improvement Reporting System II (PIRS II) using the web portal of the Canadian Society of Clinical Perfusion. https://www.cscp.ca/resources/pirs

Guideline 13.2. Perfusion simulation should be undertaken to maintain competency in low-incidence, high-risk potential events.

[19] MacGillivray TE. Advancing the Culture of Patient Safety and Quality Improvement. Methodist Debakey Cardiovasc J. 2020 Jul-Sep;16(3):192-198. doi: 10.14797/mdcj-16-3-192. PMID: 33133354; PMCID: PMC7587327.

STANDARD 14
COMMITMENT TO QUALITY ASSURANCE, IMPROVEMENT, AND RESEARCH

Standard 14.1. The Perfusionist shall actively participate in both institutional and departmental quality assurance and improvement programs, and safety reporting systems.

Standard 14.2. The Perfusionist shall collect data concerning the conduct of perfusion via a clinical registry or database to advance quality and safety.

Guideline 14.1. The Perfusionist shall remain current with literature on quality assurance activities that improve patient care and perfusion practice.

Guideline 14.2. The Perfusionist should support, conduct and participate in research within the field of perfusion science.

STANDARD 15
EQUIPMENT MAINTENANCE, MANAGEMENT, AND FACILITY REQUIREMENTS

Standard 15.1. The Perfusionist shall ensure that equipment used in the conduct of CPB is properly maintained and functioning.

Standard 15.2. Preventive maintenance of perfusion equipment shall be performed by appropriately trained and qualified manufacturer technicians, representatives, or Biomedical technicians. Regularly scheduled maintenance shall be documented by the perfusion department and/or Biomedical engineering staff. The interval of such maintenance shall be consistent with manufacturer recommendations, applicable external accrediting agency guidelines and institutional requirements.

Standard 15.3. The organization shall follow a protocol for perfusion equipment failures.[20]

Standard 15.4. Appropriate backup perfusion supplies and equipment shall be readily available.

Standard 15.5. The organization shall follow a protocol for acknowledging and addressing perfusion equipment notices (e.g., recalls, warnings, and advisories)

Standard 15.6. Maintenance of all heater-cooler devices (utilizing water) which are used in extracorporeal support procedures shall undergo routine cleaning, disinfection and routine testing as per the manufacturer's instructions for use. These procedures should be logged and documented.

Standard 15.7 Each disposable item used in the extracorporeal support circuit and other ancillary devices shall be inspected for integrity and sterility. Records relating to the device history and sterility must be kept. Lot/batch numbers of disposables shall be recorded.

[20] Overview of Vanessa's Law Accessed via https://www.canada.ca/en/health-canada/services/drugs-health-products/legislation-guidelines/overview-vannessa-law-protecting-canadians-unsafe-drugs-act-vanessa-law-amendments-food-drugs-act.html Sept 05, 2024.

STANDARD 16
CRISIS MANAGEMENT

Standard 16.1. 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.[21]

Guideline 16.1. Alternate vendors for vital equipment should be identified to address supply chain interruptions.

Guideline 16.2. Alternate storage and staging areas should be identified in the event primary/routine areas are compromised.

Guideline 16.3. Perfusionists should have a working knowledge of the institution's infrastructure to identify operating room facilities suitable for CPB procedures when routine surgical suites are unavailable.

Guideline 16.4. Clinical personnel should have a procedure for patient evacuation and potential support for patients committed to CPB while evacuations are in progress.

Guideline 16.5. Clinical expertise, education, and proper role assignment should be considered if Perfusion staff repurposing is required.

[21] Sergeant M, Hategan A. What healthcare leadership can do in a climate crisis. Healthc Manage Forum. 2023 Jul;36(4):190-194. doi: 10.1177/08404704231157035. Epub 2023 Mar 23. PMID: 36951255; PMCID: PMC10291484.

APPENDIX i

GUIDELINES FOR PERFUSION RECORD

Please refer to the Policy and Procedures Manual for Clinical Perfusion Technology at your Institution for further and more specific information.

The perfusion record is utilized during cardiopulmonary bypass, and it should be developed in a format that is approved by the institution and should contain the following as a minimum standard:

For example only, each institution will tailor to local requirements and practice needs

A. Patient information, including demographic and preoperative risk factors.
1. Medical Record Number
2. Patient Surname, first name
3. Demographics
    a. Date of birth
    b. Gender
    c. Ethnicity
    d. Height
    e. Weight
    f. Body surface area
4. Blood Type
5. Laboratory Data
    a. Hemoglobin/hematocrit
    b. Predicted hematocrit on bypass
    c. Platelet count
    d. APTT
    e. Na
    f. K+
    g. Creatinine
    h. Glucose
    i. Lactate
    j. Other relevant laboratory values
6. Patient Allergies
7. Planned Procedure
8. Medical History/Risk Factors

a. Cardiovascular
    b. Pulmonary
    c. Renal
    d. Neurologic
    e. GI/Endocrine

B. Information to accurately describe the procedure, personnel, and equipment.

1. Date of Procedure
2. Type of Procedure
3. Perfusionist(s) names
4. Surgeon(s) name
5. Anaesthetist(s) name
6. Nurse(s) name
7. Operating Room number
8. Comments/Events (recommended)
9. Equipment
    a. Heart lung machine
    b. Autotransfusion device
    c. Heater/cooler

Note: Items a-c are often 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.

11. Performance and completion of checklists

C. Patient physiological parameters documented at a frequency determined by institutional protocol

1. Blood Flow Rates (RPM)
2. Arterial Blood Pressure
3. Arterial Line Pressure
4. Central Venous/Pulmonary Artery Pressure
5. Vacuum Assist Venous Return (VAVR)
    a. VAVR 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. Myocardium

9. CPB temperatures:
i. Venous return blood
ii. Arterial blood inflow

b. Optional
i. Water bath(s)

10. Oxygenator gases, including gas flow rate and concentration (s)
11. Input fluid volumes including:
a. Prime
b. Blood Products
c. Asanguineous Fluids (e.g. RAP)
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:
a. Urine output
b. Ultrafiltrate
14. Medications and/or inhalational anesthetic agents administered via extracorporeal circuit.

D. Blood gas and anticoagulation monitoring results

1. Blood gases
a. pO2
b. pCO2
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 Thromboelastography Results

E. Signature of perfusionist (and relief) performing the procedure

APPENDIX ii

Perfusion Checklist

For example only, each institution will tailor to local requirements and practice needs

1) Perfusionist name, time and date/signed

Priority:

a. Mains power connected
b. Circuit connections checked
c. HC attached and de-aired
d. Cardioplegia pressure monitoring connected
e. Pump + tubing directions correct
f. Vent valve orientation correct
g. Gas supply to oxygenator verified
h. Circuit de-aired
i. Bicarb added
j. Heparin added
k. Albumin added

2) System Activation:

a. Level detector function verified
b. Bubble detector function verified
c. Pressure alarm verified
d. Temperature probes connected
e. Times and cardioplegia volumes reset
f. Venous occluder calibrated
g. Touch screens locked
h. Cardiac index data entered
i. HLM time synced to PC
j. FiO2 verified

3)Patient:

a. Patient notes and ID checked
b. CPB Hb calculated
c. Blood ordered
d. RAP discussed with anesthetist
e. Pre-op blood samples sent to lab

4)HLM& Circuit:

a. Cardioplegia High K selected
b. All arterial luer lock connections checked
c. Tubing clamps (correct #)
d. Volatile gas vaporizer filled
e. Data collection verified
f. Gas scavenger attached
g. Vacuum if required and tubing

h. CO2 flushing lines if required

5)Perfusionist rotation:

a. Last ACT/additional heparin requirement
b. Current Hb
c. CGP time, delivery route, type and flow rate
d. Potassium
e. Glucose/insulin
f. Any volatile gases running
g. Vacuum on / CO2 flushing
h. Inform the surgeon

APPENDIX iii

ORIENTATION PROGRAM CONTENTS

The CSCP expects the clinical perfusionist to be provided with an orientation program upon commencement of employment, which shall include but not be limited to:

1. General orientation to hospital and affiliated facilities.

2. General orientation to surgical suites.

    a) scrub, gown and glove technique
    b) aseptic technique principles
    c) dress codes and regulations
    d) supply management systems
    e) facility policy and procedures
    f) department tour
    g) occupational health support

3. Planned orientation for perfusionist

    a) Department orientation
        i) blood bank
        ii) laboratories
        iii) diagnostic imaging
        iv) cardiovascular laboratories
        v) emergency department
        vi) intensive care units

    b) Orientation to cardiovascular surgeons and anesthetists

        i) bypass methods used
        ii) procedures and techniques
        iii) expectations
        iv) use of blood/blood products and various pharmacological agents

    c) Orientation to consulting physicians

        i) expectations
        ii) use of blood products and various pharmacological agents

    d) Orientation to operating room

i) nursing expectations
ii) policies and procedures relevant to theatre practice
iii) roles and specifications of positions

e) Orientation to infection control practices

i) aseptic techniques
ii) cleaning practices and agents
iii) sterilization practices
iv) sterile storage

f) Orientation to waste management, handling of Bio-hazardous materials

g) Orientation to emergency procedures

i) cardiac/respiratory arrest
ii) fire
iii) threats to life and safety

APPENDIX iv

Additional Resources

1. AmSect Standards and Guildelines for Pediatric & Congenital Perfusion Practice

2. The Society of Clinical Perfusion Scientists of Great Britain and Ireland Standards and Guidelines

3. The Australian and New Zealand College of Perfusion Codes of Practice