

Report from AmSECT’s International Consortium for Evidence-Based Perfusion: American Society of ExtraCorporeal Technology Standards and Guidelines for Perfusion Practice: 2013

Robert A. Baker, PhD, Dip Perf, CCP (Aus);* Shahna L. Bronson, CCP;†
Timothy A. Dickinson, MS;‡ David C. Fitzgerald, CCP;§ Donald S. Likosky, PhD;||
Nicholas B. Mellas, CCP;¶ Kenneth G. Shann, CPP** on behalf of the International Consortium
for Evidence-Based Perfusion for the American Society of ExtraCorporeal Technology

*Cardiac Surgery Research and Perfusion, Flinders Medical Centre and Flinders University, Adelaide, South Australia; †Mayo Clinic, Rochester, Minnesota; ‡SpecialtyCare, Inc., Nashville, Tennessee; §INOVA Fairfax Hospital, Falls Church, Virginia; the ||Section of Health Services Research and Quality, Department of Cardiac Surgery, University of Michigan, Ann Arbor, Michigan; ¶Cardiovascular Perfusion, Montefiore–The University Hospital, Albert Einstein College of Medicine, Bronx, New York; and **Perfusion Services, Massachusetts General Hospital, Boston, Massachusetts

Abstract: One of the roles of a professional society is to develop standards and guidelines of practice as an instrument to guide safe and effective patient care. The American Society of ExtraCorporeal Technology (AmSECT) first published its Essentials for Perfusion Practice, Clinical Function: Conduct of ExtraCorporeal Circulation in 1993. The International Consortium for Evidence-Based Perfusion (ICEBP), a committee within AmSECT, was tasked with updating this document in 2010. The aim of this report is to describe the method of development and content of AmSECT’s new professional standards and guidelines. The ICEBP committee independently evaluated and provided input regarding the current “Essentials and Guidelines.” Structural changes were made to the entire document, and a draft document was developed, presented, and circulated to the AmSECT Board of Directors and broader membership for comment. Informed by these reviews, a revised document was then presented to the Society for a membership vote. The final document consists of 15 areas of practice covered by 50 Standards and 38 Guidelines (see Appendix 1) with the first standard focusing on the development of institutional protocols to support their

implementation and use. A majority of the membership voted to accept the document (81.2% of the voting membership accepting, 18.8% rejecting). After an audit of the balloting process by AmSECT’s Ethics Committee, the results were reported to the membership and the document was officially adopted on July 24, 2013. The Standards and Guidelines will serve as a useful guide for cardiac surgical teams that wish to develop institution-specific standards and guidelines to improve the reliability, safety, and effectiveness of adult cardiopulmonary bypass. The ICEBP recognizes that the development of a Standards and Guidelines statement alone will not change care. Safe, reliable, and effective care will be best served through the development and implementation of institutional protocols based on these standards. AmSECT’s Standards and Guidelines for Perfusion Practice reflect the changing landscape of our profession as we work toward a safer and optimal provision of cardiopulmonary bypass for all our patients as well as a work environment that is supportive of delivering this care. **Keywords:** standards, guidelines, cardiopulmonary bypass, perfusion, cardiac surgery. *JECT. 2013;45:156–166*

INTRODUCTION/PREAMBLE

The American Society of ExtraCorporeal Technology’s (AmSECT) mission is to “foster improved patient care and safety by providing for the continuing education and

professional needs of the extracorporeal circulation technology community.” In keeping with this mission, AmSECT, through its Perfusion Quality Committee, developed a draft standard for perfusion entitled the “Essentials for Perfusion Practice, Clinical Function: Conduct of ExtraCorporeal Circulation,” which was initially endorsed by the membership in 1993 (1), and reviewed and revised on a number of occasions thereafter (2–4). In 2011 the AmSECT Board of Directors (BOD) asked the International Consortium for Evidence-Based Perfusion (ICEBP) subcommittee to review and update the Essentials and Guidelines (Figure 1).

Address correspondence to: Robert Baker, PhD, Dip Perf, CCP (Aus), Cardiac Surgery Research and Perfusion, Flinders Medical Centre and Flinders University, Adelaide, South Australia. E-mail: Rob.Baker@health.sa.gov.au

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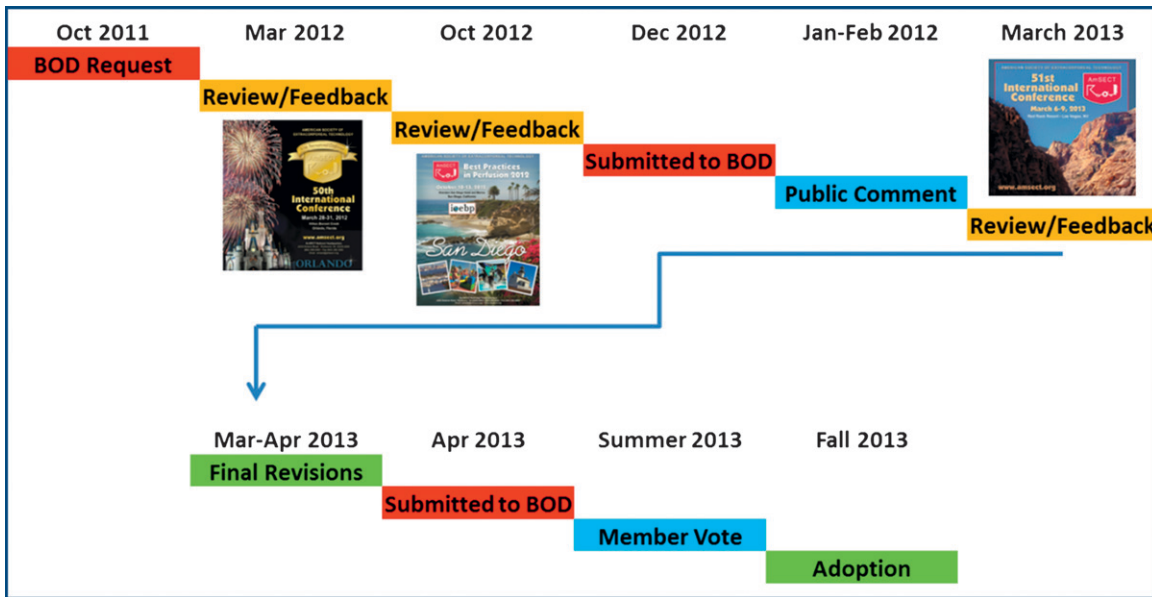


Figure 1. Timeline.

The ICEBP conducted a careful review and critique of AmSECT’s “Essentials and Guidelines” document as well as its relevance and purpose given the focus on patient safety and surgical outcomes. The revised document, “Standards and Guidelines for Perfusion Practice” (Appendix 1), was developed as an outgrowth of marrying evidence-based practices from the literature with an understanding of the context in which care is currently provided. This newly revised document is meant to provide a framework to guide the safe and effective practice of cardiopulmonary bypass in adult patients. AmSECT recommends that clinical teams adopt these standards and guidelines and develop institution-specific protocols to support their use.

The pioneering work to develop statements that guided our profession began with the AmSECT’s Standards of Practice Committee, who developed a guideline for the perfusion record, and with the early work of the American Academy of Cardiovascular Perfusion who developed “standards of practice” (2). The AmSECT Perfusion Quality Committee’s original work was entitled “Essentials for Perfusion Practice, . . .” and consisted of the 12 Essentials, which were later paired with practice guidelines providing supporting statements and information in relation to the individual Essential. The ICEBP has chosen to rename the document, preferring the terminology “Standards and Guidelines” to that of “Essentials and Guidelines.” This terminology is contemporary and coincides with verbiage used by other professional medical societies (5).

The revised document leverages the intent of the definition of a standard by the International Organization for Standardization (ISO) and International Electrotechnical (IEC). According to the ISO/IEC, a standard is “document,

established by consensus and approved by a recognized body, that provides, for common and repeated use; rules, guidelines or characteristics for activities or their results, aimed at the achievement of the optimum degree or order in a given context” (6). To facilitate the understanding of these terms, we have specifically defined them within the Standards and Guidelines (Table 1).

The intent of the Standards and Guidelines is to provide the framework for the practice of cardiopulmonary bypass rather than being beholden to traditional norms that may not maximize patient safety and outcomes. Importantly, the document focuses attention on the role of institutional protocols to dictate how practices should be implemented. We have incorporated the comments and feedback from the membership and secured AmSECT’s legal counsel’s judgment that this document should not impart any adverse

Table 1. Definitions and word use (13).

Standard	Practices, technology, and/or conduct of care that institutions shall meet 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
Shall	In this document, the word shall is used to indicate a mandatory requirement
Should	In this document, the word should is used to indicate a recommendation
Surgical care team	In this document, the term surgical care team is used to indicate the group surgeon, anesthesiologist, perfusionist, nurse, and technicians

impact on our professional conduct. Importantly, feedback from the membership has suggested that the revised document drives our profession forward, which in the end is our collective goal.

GOAL STATEMENT

The goal of this project was to review and update AmSECT's existing Essentials and Guidelines for Perfusion Practice with the intent of providing a standard for the practice of adult cardiopulmonary bypass and a framework for perfusion teams to develop and implement institution-specific standards and guidelines to improve the reliability, safety, and effectiveness of cardiopulmonary bypass.

The rationale for adopting these Standards and Guidelines is multifactorial. Unarguably, they are a reflection of the expectations of our profession. It is important that those who are most familiar with this technology, the professionals that use it everyday, should define the standards rather than it be defined by others. Importantly, the Standards and Guidelines can be used as a tool to garner support for both departmental and multidisciplinary change. Finally, they can and should be used in developing and executing quality assurance and improvement initiatives.

METHOD/PROCESS

The ICEBP developed and sought endorsement (from the AmSECT BOD) of a plan for undertaking the review of AmSECT's "Essentials and Guidelines" document. This plan included: 1) a review of the current Essentials and Guidelines document; 2) proposed changes to the language, use, and value of the document; and 3) request for feedback and endorsement from AmSECT's membership and BOD of a revised document. To achieve these goals, the following steps were undertaken:

1. The members of the ICEBP independently evaluated and provided input regarding the current "Essentials and Guidelines" document based on clinical evidence and current professional norms.
2. Structural changes were made to the entire document based on the individual assessments as follows:
 - o Changing the name to Standards and Guidelines,
 - o Inclusion of a definition of terms table (Table 1),
 - o Increasing the depth and range of topics covered (Table 2), and
 - o Incorporating evidence where applicable into the document.
3. The proposed changes were shared/reviewed at the following meetings and feedback solicited from conference participants:
 - o The 50th AmSECT International Conference, March 2012, and

Table 2. AmSECT Standards for Perfusion Practice.

Standard 1	Development of institutionally based protocols
Standard 2	Qualification, competency, and support staff
Standard 3	Perfusion record
Standard 4	Checklist
Standard 5	Communication
Standard 6	Safety devices
Standard 7	Monitoring
Standard 8	Anticoagulation
Standard 9	Blood management
Standard 10	Gas exchange
Standard 11	Blood flow
Standard 12	Blood pressure
Standard 13	Quality improvement
Standard 14	Maintenance
Standard 15	Duty hours

- o Best Practices in Perfusion, October 2012.
4. After each meeting, the draft document was reviewed and revised.
 5. Additional input was requested through:
 - o Review by AmSECT's BOD and legal counsel in late 2012/early 2013.
 6. The draft Standards and Guidelines were posted on the AmSECT web site for membership and public comment electronically requested in January/February 2013 for a period of 6 weeks.
 7. The draft Standards and Guidelines were revised by the ICEBP working group, incorporating suggestions and changes from each review step.
 8. The draft Standards and Guidelines were shared at:
 - o The 51st AmSECT International Conference in Las Vegas, March 2013.
 9. After final revision by the ICEBP, the Standards and Guidelines were approved by the BOD and legal counsel in May 2013.
 10. The Standards and Guidelines were presented to the membership for electronic voting by the AmSECT membership (June 17 to July 7, 2013).
 11. Ethics committee review of the voting process (July 2013).
 12. Result of ballot announced (July 24, 2013).

The ICEBP recommended that AmSECT review, and update if necessary, the currently endorsed Standards and Guidelines every 2 years or as deemed appropriate by AmSECT's BOD.

On July 24, 2013, AmSECT announced that the Standards and Guidelines (see Appendix 1) had been accepted by the membership (81.2% of the active membership accepting, 18.8% rejecting).

Commentary

AmSECT has a long and rich history of developing statements to guide our profession's conduct and practice (1–4). These statements are developed and implemented

through obtaining consensus of our membership rather than dictated by a small group of individuals. Additionally, these statements serve as a guidepost for our own conduct as well as vectors for securing resources from our institutions or other stakeholders when practices are not aligned with professional norms. In this manner, the revised and approved document, now called “American Society of ExtraCorporeal Technology Standards and Guidelines for Perfusion Practice,” will serve as a useful guide for cardiac surgical teams that wish to develop institution-specific standards and guidelines to improve the reliability, safety, and effectiveness of adult cardiopulmonary bypass (CPB). The most obvious changes to the new document include the name, the focus on protocols, blood management, communication in the operating room, duty hours, and quality assurance and improvement. The focus on these latter areas grew out of professional guideline statements and recognition concerning the role of clinical microsystems and teamwork in maximizing patient safety and outcomes (7–9).

We recognize that the development of a Standards and Guidelines statement alone will not change care. There is a history of professional societies developing clinical practice guidelines, including those derived by the American College of Cardiology/American Heart Association Joint Guidelines Taskforce (10) and Society of Thoracic Surgeons (STS) (11). Indeed, AmSECT has partnered with the STS and Society of Cardiovascular Anesthesiologists (SCA) in developing clinical practice guidelines for cardiopulmonary bypass, with the first such guideline nearly completed which focuses on the systemic inflammatory response. These documents provide invaluable information by synthesizing the evidence (into actionable recommendations) regarding specific topics, including blood management (7). Despite the enthusiasm and energy in producing such documents, our own profession is slow to respond to the translation of knowledge into practice. In the survey sent out to practicing perfusionists and cardiac anesthesiologists, Likosky et al. revealed that 67% of those perfusionists surveyed read all or part of the STS/SCA blood management guidelines published in 2007; however, only 26% of respondents reported one or more changes in response to the guidelines (12). Although there are a number of reasons underlying this reality, one likely culprit is our failure to organize systems of care to ensure that practice is rationally and reliably delivered. With this in mind, the first Standard within the current Standards and Guidelines document is the development of institutionally based protocols. It is our goal and expectation that the development of protocols (at the institutional level) will ensure that care is reliably delivered and in concert with local and professionally based norms. These protocols will be the vector by which other Standards and Guidelines are implemented.

We recognize that clinical and professional practices are supported with varying levels of evidence and consensus. By defining Standards and Guidelines, we are able to build a framework for the use and implementation of the practices defined here. The 15 topics covered by the Standards and Guidelines are whenever possible supported with published peer-reviewed scientific evidence. Each topic contains multiple Standard and Guideline statements that have been carefully vetted by your colleagues and peers. During the conference guideline sessions, we were able to use audience response systems to help us quantify and direct revisions of various elements of the document across the meeting audience. In addition, feedback and commentary were obtained from practicing perfusionists along the way through interaction at meeting sessions, web page-embedded evaluations, and e-mails. In addition, two independent legal reviews were performed to ensure the language and scope of recommendations were considered professionally appropriate. Finally, the AmSECT BOD voted unanimously to approve and forward this document to the membership for formal consideration and ultimately their approval.

AmSECT’s Standards and Guidelines for Perfusion Practice reflect the changing landscape of our profession as we work toward a safer and optimal provision of CPB for all our patients as well as a work environment that is supportive of delivering this care.

ADDENDUM

After completion of the revision of AmSECT’s Essentials and Guidelines and the acceptance by its membership of the new Standards and Guidelines, the ICEBP was made aware of its omission of a previously proposed (in 2004) 13th Essential.

This Essential related to CPB Stand-by procedures, and stated “CPB stand-by procedures, including Off Pump Coronary Artery Bypass (OPCAB), shall have adequate perfusionist preparedness.”

This Essential and its associated Guideline statements reflect on-pump CPB practices, and while not explicitly stated are implicitly covered within the recently endorsed Standards and Guidelines document. Inclusion of a specific statement will be considered when the Standards and Guidelines are next revised.

ACKNOWLEDGMENTS

We acknowledge the feedback from attending delegates at AmSECT’s 2012 International Conference, delegates at AmSECT’s Best Practices in Perfusion 2012 conference, delegates at AmSECT’s 2013 International Conference, and the AmSECT Board of Directors; in addition, we acknowledge the feedback from members who contributed during the commentary period in 2013.

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Appendix 1. American Society of ExtraCorporeal Technology Standards and Guidelines for Perfusion Practice

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:

- o Approved by the Chairman of Cardiac Surgery, or his or her designee, Director of Perfusion or equivalent, and other relevant clinical governance committees if available.

- o Reviewed and revised annually or more frequently when deemed necessary.

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

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 (CPB).¹

Standard 2.2: Perfusionist competency shall be assessed annually 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.²

Standard 2.4: Support staff shall be available on-site to assist the primary perfusionist during CPB procedures.

Guideline 2.1: An individual graduating from an accredited perfusion education program should complete all requirements for American Board of Cardiovascular Perfusion certification within 3 years of graduation.

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

Guideline 2.3: A standardized process to educate, train, and annually evaluate perfusion staff should be developed and followed.

Standard 3: Perfusion Record

Standard 3.1: The perfusion record (written and/or electronic) for each CPB procedure shall be included as part of the patient's permanent medical record. The perfusion record shall be maintained and stored according to institution policy for retaining patient medical records.

Standard 3.2: The record shall include:

- o Patient information including demographics and preoperative risk factors (Appendix A).

¹AmSECT recognizes that individual states may license Perfusionists based on other criteria. These laws supersede this standard.

²American Board of Cardiovascular Perfusion. Available at: www.abcp.org/. Accessed April 18, 2013.

- 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 3.1: The perfusion record should include open text (factual) commentary including supervising physician verbal orders pertinent to the CPB procedure.

Guideline 3.2: The perfusion record should include the signatures of the physician(s) providing oversight for the CPB procedure.

Guideline 3.3: 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 4: Checklist

Standard 4.1: The perfusionist shall use a checklist for each CPB procedure.³

Standard 4.2: Checklists shall be included as part of the patient's permanent medical record.

Guideline 4.1: The perfusionist should use checklists in a read-verify manner where critical steps that should have been performed are confirmed.⁴ 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 intraoperative period.

Guideline 4.2: The perfusionist should use a checklist throughout the entire perioperative period (e.g., setup, pre-bypass, initial onset of bypass, before cessation of bypass, postbypass, and/or any return to bypass).

Guideline 4.3: The perfusionist should use a checklist for other ancillary perfusion services (e.g., cell salvage, intra-aortic balloon pump, extracorporeal membrane oxygenation).

Standard 5: Communication

Standard 5.1: A patient-specific management plan for the CPB procedure shall be prepared and communicated

to the surgical team either during the preoperative briefing or before beginning the procedure.⁵

Guideline 5.1: The use of cellular telephone technology in the operating room should be guided by the principles of the ST-59 Statement on use of cell phones in the operating room written by the American College of Surgeons.⁶

Guideline 5.2: Protocol-driven communication (e.g., closed-loop) should be used to acknowledge verbal commands, verify the content, and reduce ambiguity.⁷⁻⁹

Guideline 5.3: The primary perfusionist should participate in the postprocedure debrief with the surgical team.

Standard 6: Safety Devices

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

- The gross/macrobubble 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 used during CPB procedures using a (hard-shell) reservoir.

- The level sensor shall be either servo-regulated 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 the manufacturer's instructions to allow an appropriate reaction time and a safe operational volume.

³Haynes AB, Weiser TG, Berry WR, et al.; Safe Surgery Saves Lives Study Group. A surgical safety checklist to reduce morbidity and mortality in a global population. *N Engl J Med.* 2009;360:491-9.

⁴Available at: www.commonwealthfund.org/media/Files/Publications/Case%20Study/2011/Mar/1477_McCarthy_VA_case_study_FINAL_March_v2.pdf. Accessed April 18, 2013.

⁵World Health Organization. Available at: www.who.int/patientsafety/safesurgery/ss_checklist/en/. Accessed April 18, 2013.

⁶ST-59 Statement on use of cell phones in the operating room by the American College of Surgeons. Available at: www.facs.org/fellows_info/statements/st-59.html. Accessed April 18, 2013.

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⁹de Vries EN, Prins HA, Crolla RM, et al. Effect of a comprehensive surgical safety system on patient outcomes. *N Engl J Med.* 2010;363:1928-37.

Standard 6.4: Temperature monitoring of the arterial outflow from the oxygenator shall be used during CPB procedures.

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

Standard 6.5: An arterial-line filter shall be used during CPB procedures.

Standard 6.6: A one-way valve in the vent line shall be used during CPB procedures.

Standard 6.7: A method for retrograde flow avoidance when using a centrifugal pump shall be used during CPB procedures.

- At least one method to prevent retrograde flow shall be used for systems using centrifugal pumps for systemic circulation. 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; or
 - A low-speed visual and audible alarm.

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

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

Standard 6.10: A back-up gas supply shall be available during CPB procedures.

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

Guideline 6.1: A ventilating gas oxygen analyzer should be used during CPB procedures.

Guideline 6.2: A level sensor should be used during CPB procedures using 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 used as a surrogate level detector.

Standard 7: Monitoring¹⁰

Standard 7.1: Patient arterial blood pressure shall be monitored continually during CPB.

Standard 7.2: Arterial line pressure shall be monitored continually during CPB.

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

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

Standard 7.5: Patient and device temperatures shall be monitored continually during CPB.

- Patient (e.g., nasopharyngeal, rectal, bladder, esophageal).
- Heart–lung machine (arterial, venous and cardioplegia).
- Heater cooler (H₂O temperature).

Standard 7.6: Blood gas analyses shall be monitored continually or at regular intervals during CPB (Appendix D).

Standard 7.7: Hematocrit (or hemoglobin) shall be monitored continually during CPB.

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

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

Standard 7.10: Venous oxygen saturation shall be monitored continually during CPB.

Guideline 7.1: Carbon dioxide removal should be monitored continually during CPB.

Guideline 7.2: Arterial oxygen saturation should be monitored continually during CPB.

Guideline 7.3: The following patient pressures should be monitored during CPB:

- Central venous pressure; and/or
- Pulmonary artery blood pressure.

Guideline 7.4: Continuous in-line blood gas monitoring should be used during CPB.

Guideline 7.5: Cerebral oximetry should be used during CPB.

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

Standard 8: Anticoagulation

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

¹⁰To be performed in conjunction with Standard 3.

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

Guideline 8.1: The surgical care team should determine the target ACT by considering relevant factors, including variability in the measurement of ACT attributed to the device's performance characteristics.

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

- Weight;
- Dose–response curve (automated or manual);
- Blood volume; or
- Body surface area.

Guideline 8.3: 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;
- Thromboelastograph;
- Thrombin time; and/or
- Anti-Xa.

Guideline 8.4: Additional doses of heparin during CPB should be determined by using an ACT and/or heparin/protamine titration.¹¹

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

Standard 9: Blood Management

Standard 9.1: The perfusionist shall participate in efforts to minimize hemodilution and avoid unnecessary blood transfusions.¹²

Standard 9.2: The perfusionist shall minimize the CPB circuit size to reduce prime volume.¹³

Standard 9.3: The perfusionist shall calculate and communicate to the surgical team before initiating CPB a patient's predicted postdilutional hemoglobin or hematocrit.

Guideline 9.1: Blood management efforts should include the following¹³:

- Participate in preoperative briefings (discussions) with the surgical care team (Standard 5.1) regarding transfusion strategies and target hematocrit values.

¹¹In patients requiring longer CPB times (>2 to 3 hours), maintenance of higher and/or patient-specific heparin concentrations 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). Ferraris et al. 2011.

¹²Ferraris VA, Brown JR, Despotis GJ, 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;91:944–82.

¹³Nichols, JH. Evidence-based practice for point-of-care testing. Guideline 43. 2006 American Association for Clinical Chemistry. Available at: www.aacc.org/SiteCollectionDocuments/NACB/LMPG/POCT/POCT%20Entire%20LMPG.pdf. Accessed December 11, 2012.

- Participation in a multidisciplinary blood management team.
- Minimize hemodilution by:
 - Matching the size of the CPB circuit to the size of the patient;
 - Autologous priming of CPB circuit, including retrograde arterial and venous antegrade priming;
 - Biocompatible coating on the surface of all CPB components;
 - Perioperative blood cell recovery and reinfusion after being appropriately processed; and
 - CPB circuit blood salvage at the end of the procedure.

Guideline 9.2: Point-of-care hemostasis monitoring should be used to minimize blood loss. Monitoring may include:

- International normalized ratio;
- Partial thromboplastin time;
- Prothrombin time;
- Thrombin time;
- Thromboelastography/thromboelastometry;
- Platelet count; and/or
- Platelet function analysis.

Standard 10: Gas Exchange

Standard 10.1: Gas exchange shall be maintained during CPB according to protocol accounting for:

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

Standard 10.2: Devices used to measure gas exchange shall be calibrated according to the manufacturer's instructions for use.

Standard 10.3: Blood gas analysis shall be performed and recorded according to protocol.

Guideline 10.1: Point-of-care testing should be considered to provide accurate and timely information for blood gas analysis.¹³

Guideline 10.2: Oxygen delivery and consumption calculations should be used to evaluate and optimize gas exchange¹⁴:

- Oxygen delivery: $DO_2 = 10 \times CI \times CaO_2$
- Oxygen consumption: $VO_2 = 10 \times CI \times (CaO_2 - CvO_2)$

¹⁴De Somer F, Mulholland JW, Bryan MR, Aloisio T, Van Nooten GJ, Ranucci M. O₂ delivery and CO₂ production during cardiopulmonary bypass as determinants of acute kidney injury: Time for a goal-directed perfusion management? *Crit Care.* 2011;15:R192.

where:

$$\text{CaO}_2(\text{arterial oxygen content}) = (\text{Hb} \times 1.36 \times \text{SaO}_2) + (.0031 \times \text{PaO}_2),$$

and

$$\text{CvO}_2 (\text{mixed venous oxygen content}) = (\text{Hb} \times 1.36 \times \text{SvO}_2) + (.0031 \times \text{PvO}_2)$$

CI = cardiac index

HB = hemoglobin

SaO₂ = arterial oxygen saturation

PaO₂ = partial pressure of oxygen in arterial blood

SvO₂ = venous oxygen saturation

PvO₂ = partial pressure of oxygen in venous blood

Standard 11: Blood Flow

Standard 11.1: Target blood flow rates shall be determined before CPB according to protocol.¹⁵

Standard 11.2: The perfusionist shall work closely with the surgical care team to maintain targeted blood flow rate during CPB.

Guideline 11.1: Variance from intended and targeted blood flow should be communicated to the physician-in-charge.

Guideline 11.2: Appropriate blood flow rate should be determined by evaluation of:

- Acid base balance
 - Base excess;
 - Anesthetic level;
 - Arterial blood pressure;
 - Cerebral oximetry;
 - Lactate burden; and
 - Oxygen delivery and consumption (refer to Guideline 10.2 for formulae).
- Venous pO₂
- Arterial pO₂
- Hemoglobin concentration
- Arterial oxygen saturation
 - Systemic vascular resistance (SVR);
 - Temperature; and
 - Venous oxygen saturation.

¹⁵Body surface area*cardiac index = calculated blood flow rate, where body surface area in square meters = square root of (height*weight/3600), using height in cm and weight in kg.

Standard 12: Blood Pressure

Standard 12.1: The perfusionist, in collaboration with the physician-in-charge, shall define and communicate the intended treatment algorithm for blood pressure management before CPB, including acceptable ranges for blood pressure.¹⁶

Standard 12.2: The perfusionist shall work closely with the surgical care team to maintain blood pressure according to protocol during CPB.

Guideline 12.1: 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.

Standard 13: Quality Assurance and Improvement

Standard 13.1: The perfusionist shall actively participate in both institutional and departmental quality assurance and improvement programs.

Guideline 13.1: The perfusionist should collect data concerning the conduct of perfusion through a clinical registry or database.

Guideline 13.2: The perfusionist should use such data for quality assurance and improvement projects.^{17,18}

Standard 14: Maintenance

Standard 14.1: The perfusionist shall assure that properly maintained and functioning equipment is used in the conduct of CPB, including (but not limited to):

- Heart–lung machine
 - Pumps
 - Timers
 - Pressure monitors
 - Temperature monitors
 - Low-level alarm
 - Air bubble detector(s)
- Blood flow sensors
 - Heater/cooler
 - Anesthetic vaporizer
 - Oxygen blender/flow meter
 - Oxygen analyzer
 - Ancillary equipment

¹⁶In many circumstances, the physician-in-charge may direct the perfusionist to modify the intended blood pressure management to address circumstances occurring during the CPB procedure.

¹⁷Warren CS, DeFoe GR, Groom RC, et al. Variation in arterial inflow temperature: A regional quality improvement project. *J Extra Corpor Technol.* 2011;43:58–63.

¹⁸Baker RA, Newland RF, Fenton C, McDonald M, Wilcox TW, Merry AF. Developing a benchmarking process in perfusion: A report of the Perfusion Downunder Collaboration. *J Extra Corpor Technol.* 2012; 44:26–33.

- Intra-arterial blood pressure
- Vascular assist device
- Cell salvage device

Standard 14.2: Preventive maintenance on perfusion equipment shall be performed and documented on a regularly scheduled basis by the perfusion team and/or appropriately trained and qualified biomedical engineering staff. Any or all of the following may determine the interval of such maintenance:

- Manufacturer recommendations;
- External accrediting agency guidelines; and/or
- Institutional requirements.

Standard 14.3: The organization shall have a written procedure for perfusion equipment failures.¹⁹

Standard 14.4: Appropriate back-up perfusion supplies shall be readily available.

Standard 15: Duty Hours

Standard 15.1: For the perfusionist to ensure proper provision of care, he or she must receive an adequate rest period between scheduled work hours.²⁰

Guideline 15.1: The perfusionist should receive a minimum of 8 hours of rest period for every 16-hour consecutive work period.²¹

RELEVANT PUBLICATIONS

- American Society of Extra-Corporeal Technology. Perfusion practice survey, September, 1993. *Perfusion Life*. 1994;11:42–5.
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- 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. Available at: www.scps.org.uk/index.php?option=com_content&task=view&id=25&Itemid=40. Accessed April 17, 2013.

¹⁹The Joint Commission. 2012 Environment of Care Essentials for Health Care. Available at: www.jointcommission.org/standards_information/standards.aspx.

²⁰10.0 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. Available at: www.scps.org.uk/index.php?option=com_content&task=view&id=25&Itemid=40. Accessed April 17, 2013.

²¹Accreditation Council for Graduate Medical Education (ACGME) Policies for Residents. Available at: www.acgme.org/acgmeweb/GraduateMedicalEducation/DutyHours.aspx.

The Society of Clinical Perfusion Scientists of Great Britain and Ireland and The College of Clinical Perfusion Scientists of Great Britain and Ireland Codes of Practice Document. Available at: www.scps.org.uk/index.php?option=com_content&task=view&id=34&Itemid=40. Accessed April 17, 2013.

The Australian and New Zealand College of Perfusion. Regulations and Guidelines for Perfusionists. Available at: <http://esvc000803.wic050u.server-web.com/Documents/ANZCP%20Regulations.pdf>. Accessed April 17, 2013.

Appendix A. Patient Information

1. Medical record number
2. Patient surname, first name
3. Demographics
 - a. Age (date of birth)
 - 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. Activated partial prothrombin time
 - f. Sodium
 - g. K⁺
 - h. Blood urea nitrogen/creatinine
 - i. Glucose
 - j. Other relevant laboratory values
6. Patient allergies
7. Planned procedure
8. Medical history/risk factors (recommended)
 - a. Cardiovascular
 - b. Pulmonary
 - c. Renal
 - d. Neurologic
 - e. Gastrointestinal/endocrine

Appendix B. Information Sufficient 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. 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 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 cannulae
 - 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. 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. Cardiopulmonary bypass 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
 - d. Cardioplegic solution
 - e. Autologous components
12. Cardioplegia
 - i. Solution (ratio)
 - ii. Route
 - iii. Flow
 - iv. Pressure
 - v. Temperature
 - vi. Volume
13. Output fluid volumes, including:
 - a. Urine output
 - b. Ultrafiltrate
14. Medications and/or inhalational anesthetic agents administered through extracorporeal circuit

Appendix D. Blood Gas, Electrolyte, 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 (ACTs) and/or heparin/protamine assay results and/or thromboelastography results