Australian and New Zealand College of Perfusionists

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Standards and Guidelines

For

Perfusion Practice

Previously known as **Rules and Regulations** of the Australian and New Zealand College of Perfusionists (ANZCP) originally drafted in 2006.

The Standards and Guidelines for Perfusion Practice of the ANZCP are provided to support Fellows of the ANZCP to deliver the best care and outcomes for patients. To facilitate this teams may leverage these standards and guidelines to develop institution-specific protocols and practices to improve the reliability, safety, and effectiveness of extracorporeal support services. The standard and guidelines are based upon the Regulations and Standards Concerning Clinical Practice (approved 2009) of the ANZCP and the Standards and Guidelines of the American Society of Extracorporeal Technology (2017).

The Standards of the College have been written to demonstrate an evidence based approach to clinical practice and as such have leveraged published Clinical Practice Guidelines where available. Each Standard is supported by standard and/or guideline statements as defined below.

Definitions:

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

***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 a mandatory requirement.

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

Clinical Team: In this document, the term clinical team is used to indicate the group Surgeon, Anesthetist, Perfusionist, Nurse and technicians.

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

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

Disclaimer:
The ANZCP recognizes that individual hospitals may have local policies that may supersede ANZCP's Standards and Guidelines.

The Australian and New Zealand College of Perfusionists

Standards and Guidelines for Perfusion Practice

June 2022

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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 a protocol (operating procedure) for each of the standards.

Standard 1.2: Protocols shall be:

1. Approved by the Director of Cardiac Surgery their designee, Chief of Perfusion or equivalent, and other relevant clinical governance committees if required.

2. Protocols shall be reviewed and revised annually or more frequently when deemed necessary.

Standard 1.3: Written protocols covering the management of, and the training for, "catastrophic events" that may occur during cardio-pulmonary bypass shall be available. Such events include, but are not limited to:

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 protocol may be at the discretion of the clinical team and should be documented in the perfusion record.

Standard 2: Qualification, Competency and Support Staff

Standard 2.1: A Perfusionist, who is a specialist individual whom is Certified by the Australian and New Zealand Board of Perfusion (ANZBP) or who has demonstrated competency through the ANZBP Overseas Trained Perfusionist recognition procedure, shall conduct extracorporeal support procedures.[1].

Standard 2.2: The perfusionist shall participate and engage in perfusion related education and training and shall complete all requirements for the ABCP recertification on a yearly basis.

Standard 2.3: Designated support staff shall be available on site to assist the primary perfusionist during CPB procedures. Support staff may include a Perfusionist, nursing, technical, or non- technical staff.

Standard 2.4: Trainees in an ANZCP recognized training program may only conduct extracorporeal support under the supervision of a Perfusionist. Supervision shall be direct in theatre until clinical competency has been achieved and shall be continued for the duration of training at a level appropriate to provide immediate support if required.

Guideline 2.1: A standardized process should be developed and followed to identify, orient and educate designated 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 extracorporeal support procedures.

[1] *The ANZCP recognizes that overseas trained and certified clinical perfusionists are currently employed within units within Australia and New Zealand, and have developed a process of qualification recognition.*

Standard 3: Communication

Standard 3.1: A patient-specific management plan for the extracorporeal support procedure shall be prepared and communicated to the surgical team either during the pre-operative briefing or prior to beginning the procedure or during surgical "time out".

Standard 3.2: Protocol driven communication (eg closed loop) shall be utilized at all times in the operating theatre to acknowledge verbal commands, verify the content and reduce ambiguity.

Standard 3.3: The primary Perfusionist shall use a set handoff protocol (e.g., SBAR- Situation, Background, Assessment, Communication) when transitioning the management of the case to a second Perfusionist.

Standard 3.4: The use of cellular telephone technology in the operating room shall be guided by institutional protocols on use of cell phones in the operating room.

Guideline 3.1: The primary Perfusionist should participate in the post-procedure debrief with the surgical team. 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.

Guideline 3.2: Deviations from the intended treatment care plan should be documented and communicated to the clinical team to allow for changes in the management plan.

Standard 4: Perfusion Record

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

Standard 4.2: The record shall include (see Appendix A and B for details):

- Patient information including demographics and pre-operative risk factors.
- Information sufficient to accurately describe the procedure, personnel, and equipment.
- Patient physiological parameters documented at a frequency determined by institutional protocol.
- Blood gas and anticoagulation monitoring results.
- Free text commentary of events or verbal orders during support.
- Signature/electronic equivalent of the Perfusionist performing the procedure.

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

Standard 5: Checklist

Standard 5.1: The Perfusionist shall use a checklist for each extracorporeal support procedure. The Perfusionist shall use checklists in a read-verify manner where critical steps that shall have been performed are confirmed. Checklist shall be updated regularly or when new techniques or equipment are added.(appendix C)

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

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

Guideline 5.1: 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 checklists 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).

Standard 6: Safety Devices

Standard 6.1: Safety devices shall not be disarmed during an extracorporeal support procedure, unless to override a device failure.,

Standard 6.2: Line pressure monitoring systems shall be employed during extracorporeal support procedures in all delivery lines to the patient, including but not limited to arterial, cardioplegia (antegrade or retrograde) and cerebral (antegrade or retrograde).

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

Standard 6.3: Pressure monitoring of the venous reservoir (when augmented venous drainage is utilized)

- The pressure monitor shall include an audible and visual alarm
- Positive and negative pressure shall be monitored

Standard 6.4: A bubble detector shall be employed during extracorporeal support 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 6.5: A level sensor shall be employed during extracorporeal support procedures utilizing 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 manufacturer's instructions to allow an appropriate reaction time and a safe operational volume.

Standard 6.6: Temperature monitoring of the arterial outflow from the oxygenator shall be employed during extracorporeal support procedures.
The temperature sensor shall include an audible and visual alarm to prevent high arterial outlet temperatures.

Standard 6.7: An arterial-line filter, external or integrated, shall be employed during extracorporeal support procedures.

Standard 6.8: A one-way valve in the vent line shall be employed during extracorporeal support procedures or the vent line shall be tested prior to bypass for correct flow direction by sucking fluid back from a bowl on the operating table.

Standard 6.9: A method for retrograde flow avoidance when using a centrifugal pump shall be employed during extracorporeal support 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.

Standard 6.10: A ventilating gas oxygen analyzer shall be employed during extracorporeal support procedures.

Standard 6.11: An anesthetic gas scavenge line shall be employed whenever inhalation agents are introduced into the circuit during extracorporeal support procedures.

Standard 6.12: Hand cranks shall be readily available during extracorporeal support procedures.

Standard 6.13: A back-up gas supply shall be available during extracorporeal support procedures.

Standard 6.14: The extracorporeal support machine shall have a backup power source that allows for uninterrupted power supply during extracorporeal support procedures.

Standard 6.15: The heart lung machine shall be plugged into a power supply in theatre to provide emergency power supply to meet current Australian and/or New Zealand electrical safety standards for cardiac protected equipment.

Guideline 6.1: A level sensor should be employed during extracorporeal support 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 used utilized as a surrogate level detector.

Standard 7: Monitoring

Standard 7.1: Patient blood pressure shall be monitored continuously during extracorporeal support procedures, including but not limited to

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

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

Standard 7.4: Cardioplegia dose, delivery method, line pressure, coronary sinus pressure (retrograde), and ischemic intervals shall be monitored continually and reported to surgical team as necessary during extracorporeal support procedures.

Standard 7.5: Patient and device temperatures shall be monitored continuously during extracorporeal support procedures.
Patient (e.g., nasopharyngeal, rectal, bladder, esophageal)
Heart lung machine (arterial, venous and cardioplegia)
Heater cooler (water temperature)

Standard 7.6: Blood gas analyses shall be monitored continuously if using in-line blood gas monitoring or continually if using intermittent blood gas analysis during extracorporeal support procedures.

Standard 7.7: Venous saturation/Hematocrit (or hemoglobin) shall be monitored continuously if using in line blood gas monitoring or continually if using intermittent blood gas analysis during extracorporeal support procedures.

Standard 7.8: Oxygen fraction and gas flow rates shall be monitored continuously during extracorporeal support procedures.

Standard 7.9: Venous line occlusion shall be monitored continuously during extracorporeal support procedures.

Standard 7.10: Venous oxygen saturation shall be monitored continuously during extracorporeal support procedures.

Standard 7.11: Carbon dioxide removal or concentration shall be monitored continuously if using exhaust capnography during extracorporeal support procedures.

Standard 7.12: Arterial oxygen saturation shall be monitored continually during extracorporeal support procedures, if available.

Guideline 7.1: Continuous in-line blood gas monitoring should be used during extracorporeal support procedures

Guideline 7.2: Cerebral oximetry should be used during extracorporeal support procedures.

Standard 8: Anticoagulation and reversal management

Standard 8.1: The clinical team shall define the intended anticoagulation management plan, for anticoagulation management (Heparin) and an alternative plan for when Heparin is not suitable, including acceptable activated clotting time (ACT) ranges.

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

The Clinical team shall define the patient-specific initial heparin dosage using one of the following methods:

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

- The clinical team shall determine the target activated clotting time by considering relevant factors; including variability in the measurement of ACT attributed to the device's performance characteristics.

Standard 8.3: Anticoagulation monitoring shall 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
- Anti Xa

Standard 8.4: Additional doses of heparin during extracorporeal support procedures shall be determined by using an appropriate anticoagulation test.

Standard 8.5: Heparin reversal shall aim to limit over-exposure to protamine and should be confirmed by ACT and/or heparin/protamine titration.

Standard 8.6: Cardiotomy suction shall be discontinued at the onset of protamine administration to avoid clotting within the extracorporeal support circuit.

Guideline 8.1: Blood loss during the period after protamine is administered, should be salvaged via an autotransfusion devices.

Standard 9: Gas Exchange

Standard 9.1: Gas exchange shall be maintained during extracorporeal support procedures according to protocol, accounting for individual patient needs.

Guideline 9.1: Indexed oxygen delivery and consumption calculations should be utilized to evaluate and optimize gas exchange.

Guideline 9.2: Point-of-Care testing should be considered to provide accurate and timely information for blood gas analysis.

Standard 10: Blood Flow

Standard 10.1: Target blood flow rates shall be determined prior to extracorporeal support according to protocol.

Standard 10.2: The Perfusionist shall work closely with the clinical team to maintain targeted blood flow rate during extracorporeal support procedure.

Standard 10.3: The appropriate blood flow rate shall be determined by:

- Acid base balance (base excess)
- Anaesthetic level
- Arterial blood pressure
- Cerebral oximetry
- Lactate burden
- Oxygen delivery and consumption
- Venous pO_2
- Arterial pO_2
- Haemoglobin concentration
- Arterial oxygen saturation
- Systemic vascular resistance
- Temperature
- Venous oxygen saturation

Standard 11: Blood Pressure

Standard 11.1: The Perfusionist, in collaboration with the clinical team, shall define and communicate the intended treatment algorithm for blood pressure management prior to extracorporeal support procedures, including acceptable ranges for blood pressure.

Guideline 11.1: Variance from intended and targeted blood pressure should be documented and communicated to the clinical team.

Standard 12: Blood Management

Standard 12.1: The Perfusionist shall participate in a comprehensive multimodality blood conservation and management program led by a multidisciplinary team of health care providers to limit utilization of blood resources, decrease risk of bleeding, optimize hemostasis, and minimize blood loss in an effort to improve patient outcome.

Standard 12.2: The extracorporeal support circuit shall be minimized to reduce prime volume.

Standard 12.3: The Perfusionist shall calculate, prior to induction, and communicate to the clinical team prior to initiating extracorporeal support, a patient's predicted post-dilutional hemoglobin or hematocrit.

Guideline 12.1: Blood management efforts should include:

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 Extracorporeal support circuit
    iv. Autologous priming of the circuit, including retrograde arterial and venous antegrade priming.
    v. Ultrafiltration
    vi. Perioperative blood cell recovery and reinfusion.
    vii. Extracorporeal support circuit blood salvage at the end of the procedure
    viii. Anaesthetic volume loading

Standard 13: Safety and Incident Reporting

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

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 ANZCP Perfusion Improvement Reporting System II (PIRS II) for the community to document incidents and accidents and share solutions and preventative actions.

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

Standard 14: Level of Readiness for Procedures that may require extracorporeal support

Standard 14.1: Procedures identified preoperatively to be at elevated risk of requiring conversion to an extracorporeal support procedure shall have a protocol for transition to such procedures.

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

Standard 14.3: A heart-lung machine and extracorporeal set-up with ancillary equipment shall be readily available for the procedure.

Standard 14.4: Assembly and maintenance of circuit shall be regulated according to institutional protocol in collaboration with infection control.

Standard 15: Crisis Management

Standard 15.1: 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.

Guideline 15.1: Alternate vendors for vital equipment should be identified in order to address supply chain interruptions.

Guideline 15.2: Alternate storage and staging areas should be identified in the event primary/routine areas are compromised.

Guideline 15.3: Perfusionist should have a working knowledge of the infrastructure of the institution in order to identify operating room facilities that are suitable for extracorporeal support procedures when routine surgical suites are unavailable.

Guideline 15.4: Clinical personnel should have a procedure for patient evacuation and potential support for patients committed to extracorporeal support while evacuations are in progress.

Guideline 15.5: Clinical expertise and proper role assignment should be considered if Perfusion staff repurposing is required.

Standard 16: Staffing and On-call

Standard 16.1: The Hospital or service provider shall employ an adequate number of perfusionists to cover all likely situations, so that, a second perfusionist can be made available to assist in the event of an emergency.

Standard 16.2: An on-call Perfusionist shall be present and clinically ready for unscheduled and emergency procedures within the institutional protocolized time period.

Standard 16.3: "On-boarding" of new staff with a process in place for the integration of a new perfusionist or Locum, into the clinical environment, with access to protocols and hospital policies.

Guideline 16.1: The "n+1" staffing model should be utilized at all times, where "n" equals the number of operating/procedure rooms requiring perfusionist support at any given time at a single site.

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 (i.e. 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 17: Duty Hours

Standard 17.1: A break of at least 12 continuous hours (or a time period as mandated by local or regional awards) must be provided before the next rostered duty, excluding emergency call back.

Guideline 17.1: Perfusionist may regularly work an extended day and be called upon to work into and through the night. In these circumstances in order for the appropriate provision of care, rostering shall occur to provide a minimum break period (as per Standard 1) between scheduled work hours to ensure staff and patient safety.

Standard 18: Quality Assurance, Quality Improvement and Research

Standard 18.1: The Perfusionist shall actively participate in both institutional and departmental quality assurance and improvement programs.

Standard 18.2: The Perfusionist shall collect data concerning the conduct of perfusion via a clinical registry or database to advance quality and safety.

Standard 18.3: The Perfusionist shall support the conduct of research within the clinical team.

Guideline 18.1: The Perfusionist should conduct and participate in the conduct of research specifically within the field of perfusion science and to support the practices of the clinical team.

Standard 19: Equipment and Maintenance

Standard 19.1: The Perfusionist shall ensure that all equipment used in the conduct of extracorporeal support is properly maintained and functioning, and meets the current Australian/New Zealand Standards for Electrical Installations – Patients Areas for cardiac protected procedures. Additional standards as specified herein must also be met.

Standard 19.2: 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 19.3: The Hospital or service provider shall provide adequate equipment to cover emergency contingencies.

Standard 19.4: The organization shall follow a protocol for perfusion equipment failures.

Standard 19.5: Appropriate backup perfusion supplies shall be readily available.

Standard 19.6: The Hospital or service provider shall follow a protocol for acknowledging and addressing perfusion equipment notices (e.g. recalls, warnings, and advisories).

Standard 19.7: 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 manufacturers' instructions for use, and this process logged and documented.

Standard 19.8: The organization shall have in place an established medical equipment and management framework that shall include a plan to decommission and dispose of equipment based upon the principle of its effective life.
The equipment shall be replaced when it can no longer be serviced (i.e. when spare parts are no longer available within 12 months of the last service).

Standard 19.9: The perfusionist shall make responsible efforts at cost containment and shall uphold the highest professional standards when involved in the purchase of goods and services on behalf of the Institution or Hospital.

Standard 19.10: Each disposable item used in the extracorporeal support circuit 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.

Standard 20: Recommended requirements for space and equipment

Guideline 20.1: Recommended guidelines for the design of theatres and perfusion areas required for Extracorporeal Services.

1. The Perfusion Room and Operating Theatres should be in close proximity to each other.
2. There should be minimal moving of the heart lung machine as it is often difficult to maneuver.
3. Ability to see all monitoring that is required for the extracorporeal support procedure.
4. UPS power supply.

Guideline 20.2: Theatre Requirements:

A. Doorway (either sliding or swing) from perfusion room into theatre should be at least 1.5m wide and the door to remain open long enough (via a touch pad or equivalent) to maneuver equipment through.

B. A "perfusion" pendant to at minimum include the following:

3 x suction
2 x air
2 x oxygen
16 x power points
A number of USB outlets
2 x LAN connections
1 x carbon dioxide

C. A required area, free from other equipment, to accommodate the heart lung machine, cell salvage device, point of care monitoring as required to safely perform extracorporeal support should be available adjacent the operating table. An area of at least 2.0m by 1.5m next to the operating table and access to a dedicated perfusion pendant is required.

D. A trolley or cupboard to store spare fluids, drugs, and emergency equipment.

E. The exit doors from theatre need to be 2 metres wide to accommodate largest patient trolley with an ECLS circuit side by side.

Guideline 20.3: Heart Lung Machines and other equipment:
The appropriate number of heart lung machines, autotransfusion devices, point of care testing devices and associated equipment should be available for each theatre, with appropriate levels of back up equipment to provide safe support in the event of equipment failure (n+1) eg:

a) One theatre - two heart lung machines, two heater coolers
b) Two theatres -three heart lung machines and three heater- coolers.

Guideline 20.4: Perfusion Room: A dedicated space, close to the operating room (s) should be provided, the space should be sufficient to allow:

A. A clean area for aseptic set up and assembly of circuits for either a Heart/Lung Machine or ECLS circuit.

B. Storage area for Heart Lung Machines, Intra-aortic Balloon pumps, Heater Coolers and Emergency ECLS equipment.
C. A lockable cupboard for drugs and other equipment.
D. The area should be a low traffic area so that emergency equipment with sterile circuits may be left set up in the area.
E. It should provide the following resources in sufficient number for the size of the perfusion team and the number of theatres supported:
    i. A sink with cupboards above and below.
    ii. A minimum of:
        a. 16 x power points to charge or run equipment
        b. 2 x oxygen outlets
        c. 2 x air outlets
        d. 1 x carbon dioxide gas outlet /cylinder
    iii. Storage/shelving facilities to accommodate sterile stock
    iv. A workbench for computers, printers, telephones etc.
    v. Shelving for service manuals.
    vi. An area that can double as a wet lab to test equipment.

Appendix A *(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 (eg RAP)
    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 anaesthetic 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 B *(example only, each institution will tailor to local requirements and practice needs)*

1. The following shall be monitored continually while a patient is on CPB:
    a. Patient blood pressure
        i. mean arterial pressure
        ii. central venous pressure
        iii. pulmonary artery blood pressure
    b. Arterial line pressure
    c. Arterial blood flow
        i. at a point in the circuit where it accurately reflects the flow delivered to the patient during CPB (ie distal to intra-circuit shunts)
    d. Temperature – both patient and device
        i. patient -nasopharengeal, rectal, bladder, eosphageal
        ii. Heart-lung machine - arterial, venous, cardioplegia
        iii. Heater-cooler – water temperature
    e. Venous saturation
    f. Hematocrit or hemoglobin levels
    g. Carbon dioxide removal
    h. Arterial oxygen saturation
    i. Blood gas and electrolyte analysis, oxygen fraction and gas flows
        a. pO_2
        b. pCO_2 - especially if using CO_2 insufflation of the surgical field
        c. pH
        d. Base excess
        e. Bicarbonate concentration
        f. Venous and arterial O_2 Saturation
        g. Potassium concentration
        h. Ionized calcium concentration
        i. Sodium concentration
        j. Lactate
        k. Glucose
        l. Haemoglobin/haematocrit
        m. Activated Clotting Times (ACT) and/or Heparin/Protamine Assay Results and/or Thromboelastography Results
        n. Cardioplegia dose, ischemic times, line pressure (antegrade) and coronary sinus pressure (retrograde)

Appendix C: Perfusion Checklist *(example only, each institution will tailor checklists to local requirements and individual practice needs)*

Perfusionist name, time and date/signed

Priority:

- Mains power connected
- Circuit connections checked
- HC attached and de-aired
- Cardioplegia pressure monitoring connected
- Pump + tubing directions correct
- Vent valve orientation correct
- Gas supply to oxygenator verified
- Circuit de-aired
- Bicarb added
- Heparin added
- Albumin added

System Activation:

- Level detector function verified
- Bubble detector function verified
- Pressure alarm verified
- Temperature probes connected
- Times and cardioplegia volumes reset
- Venous occluder calibrated
- Touch screens locked
- Cardiac index data entered
- HLM time synced to PC
- FiO_2 verified

Patient:

- Patient notes and ID checked
- CPB Hb calculated
- Blood ordered
- RAP discussed with anesthetist
- Pre-op blood samples sent to lab

HLM& Circuit:

- Cardioplegia High K selected
- All arterial luer lock connections checked
- Tubing clamps (correct #)
- Volatile gas vaporizer filled
- Data collection verified
- Gas scavenger attached
- Vacuum if required and tubing
- CO_2 flushing lines if required

Perfusionist rotation:

- Last ACT/additional heparin requirement
- Current Hb
- CGP time, delivery route, type and flow rate
- Potassium
- Glucose/insulin
- Any volatile gases running
- Vacuum on / CO_2 flushing
- Inform the surgeon

Appendix D: AmSECT Standards and Guidelines for Pediatric and Congenital Perfusion Practice

Please click link:

AmSECT Standards and Guidelines for Pediatric and Congenital Perfusion Practice (2019)