Regulations and Standards concerning Clinical Practice

Approved 2009, currently under revision 30/4/2021

The Regulations set out in this section are to be regarded as minimum standards for practising Perfusionists.

9.1 Range of Perfusionists' duties

1. A wide spectrum of procedures and services can be carried out by Perfusionists. The actual procedures and services undertaken vary, depending on hospital or institution policy, and all are undertaken upon the prescription or direction of a Medical Practitioner.

2. The procedures and services which can be provided by Perfusionists include, but are not limited to, the following:

    a) Cardiopulmonary Bypass
    b) Extra Corporeal Life Support
    c) Extracorporeal Membrane Oxygenation
    d) Mechanical Circulatory Support / Ventricular-Assist Device
    e) Induction of hypothermia / hyperthermia with reversal
    f) Haemodilution
    g) Haemofiltration / plasmapheresis
    h) Administration of cardioplegia
    i) Anticoagulation monitoring
    j) Blood conservation techniques / autotransfusion
    k) Blood gas / biochemistry monitoring
    l) Physiological monitoring
    m) Intra Aortic Balloon Counter-pulsation
    n) Isolated limb / organ perfusion
    o) Organ preservation
    p) Total body washout
    q) Dialysis
    r) Administration either from medical directives or departmental protocols, via the extra-corporeal circuit, of:
        (i) prescribed medications
        (ii) blood components
        (iii) anaesthetic agents
    s) Platelet sequestration
    t) Full clinical documentation of duties carried out
    u) Administration
    v) Continuing education
    w) Quality control

9.2 Regulations for the Conduct of Perfusion

1. Cardio-pulmonary bypass should only be conducted by specialist individuals who have undergone recognised training and certification in Perfusion. Only Perfusionists certified by the Australasian Board of Cardio-Vascular Perfusion, Registered by the Perfusionists Registration Board and approved by the Cardiac Surgeon in charge of the patient should take responsibility for the conduct of cardio-pulmonary bypass.

2. Trainees in a recognised training programme may only conduct cardio-pulmonary bypass under the supervision of a certified perfusionist, as prescribed in Section 5. This supervision should be

DIRECT supervision for the initial months of training, and should be direct supervision where ever possible thereafter, for the duration of training.

3. The perfusionist should monitor and maintain an appropriate anticoagulation status for the patient during cardio-pulmonary bypass.
4. All measures should be taken to maintain appropriate gas exchange, adequate blood flow and blood pressure during cardio-pulmonary bypass.
5. During cardio-pulmonary bypass the perfusionist should, at all times, be able to comfortably see a monitor or monitors displaying mean arterial pressure and arterial wave-form; ECG; patient core temperature; and venous pressure.
6. Safety glasses and protective gloves should be worn by all personnel involved in cardio-pulmonary bypass who might be at risk of contact with blood or blood products.

9.3 Standards of Perfusion Practice

1. The perfusionist should seek to continually improve the quality of perfusion care.
2. The perfusionist should utilise properly maintained equipment in the conduct of cardio-pulmonary bypass. The equipment should 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).
3. All non-disposable equipment should undergo preventative maintenance examinations as prescribed by its manufacturer. These preventative maintenance examinations should be performed by appropriately qualified people. Dates and details should be documented, and records kept, within the Perfusion Unit.
4. Devices used to monitor or assay parameters measured during cardio-pulmonary bypass should be calibrated and verified for performance and accuracy, at the intervals prescribed by the manufacturer.
5. Regular cleaning and housekeeping routines should be established for the care of all equipment used by the perfusionist in cardio-pulmonary bypass.
6. Major incidents, involving any aspect of the cardiopulmonary bypass (either with or without patient involvement), and including device and product failures, should be fully documented, with written, detailed descriptions of the nature of the incident, causes or possible causes, results, action taken and recommendations arising.
7. Incident reports should be filed within the Perfusion Unit, and reviewed as part of continuing education, staff training, and unit review. In addition, these reports should be filed in accordance with the protocols within each individual Institution or Hospital. It is recommended that incidences be forwarded onto PIRS (Perfusion Incident Reporting System) via the College website. Failure of hardware or disposable should be reported to the TGA (Therapeutic Goods Authority) in Australia and the Medsafe in New Zealand.
8. All Perfusionists should attend a BASIC LIFE SUPPORT course and participate in an accredited ADVANCED CARDIAC LIFE SUPPORT program.
9. The perfusionist should make responsible efforts at cost containment and should uphold the highest professional standards when involved in the purchase of goods and services on behalf of the Institution or Hospital.
10. It is recommended that the Hospital or service provider be able to provide adequate equipment to cover emergency contingences.
11. It is recommended that the Hospital or service provider employ an adequate number of perfusionists to cover all likely situations, so that, when possible, a second perfusionist can be made available to assist in the event of an emergency.
12. Recommended guidelines for the design of theatres and perfusion areas required for Extracorporeal Services.

The Perfusion Room and Operating Theatres should be in close proximity to each other. There should be minimal moving of the heart lung machine as it is heavy and difficult to manoeuvre.

Theatre

1. Doorway (either sliding or swing) from perfusion room into theatre must be at least !.5m wide and the door to remain open long enough (via a touch pad or equivalent) to wheel equipment through.

2. A perfusion pendant to at minimum include the following;
   2 x suction
   2 x air
   2 x oxygen
   16 x power points
   2 x LAN connections
   1 x carbon dioxide

3. A required area of at least 2.0m by 1.5m next to the operating table and the perfusion pendant to accommodate the heart lung machine and any extra safety equipment.

4. A bench/desk for patient history and record keeping.

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

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

Perfusion Room

1. A space of around 40 square metres is required.

2. The area needs to be a low traffic area so that emergency equipment with sterile circuits may be left set up in the area for 24hrs.

3. The area should include the following;

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

   b) An area that can double as a wet lab to test equipment.

   c) A sink with cupboards above and below.

   d) 16 x power points to charge or run equipment

   e) 2 x oxygen outlets

   f) 2 x air outlets

   g) 1 x carbon dioxide gas outlet

   h) Storage/shelving facilities to accommodate sterile stock

   i) Storage area for Heart Lung Machine’s, Intra-aortic Balloon Pump’s, Heater Coolers and Emergency ECLS equipment.

   j) A lockable cupboard for drugs and other equipment.

   k) A long workbench for computers, printers, telephones etc.

   m) Shelving for service manuals.

9.4 Hardware Equipment for Perfusion

9.4.1 Heart-Lung Bypass Machine – General

1. The heart-lung bypass machine consists of either a pump console with integrated pumps, or modular pumps mounted on a console base. These pumps may be either positive displacement - roller pumps; or constrained vortex/centrifugal pumps. Additional equipment includes (but is not limited to) pressure controllers; air emboli detectors; low level alarms; gas flow meters and blenders; and light sources, may be integrated or modular.
2. The heart-lung bypass machine should meet the current Australian and/or New Zealand Electro-medical Specifications for Electrical Safety for a Cardiac Protected procedure. The heart-lung machine must meet other Standards, as specified herein.
3. All roller pump modules should have electronic "runaway" control protection, as part of its standard circuitry.
4. Controls for reversal of pump flow should be locked or disarmed. Initiation of pump reversal should require two actions to prevent inadvertent operation. In the case of constrained vortex pumps a safety device should be used where possible.
5. Each pump module should clearly display either pump flow, or ‘revolutions per minute’.
6. The occlusion mechanism of each roller pump on the heart-lung machine should be secure and protected from inadvertent movement.
7. Arterial roller pumps, or roller pumps being used for the delivery of cardioplegia should be capable of being controlled by:
    a) Low level alarm systems;
    b) Arterial or cardioplegia delivery line pressure alarm systems;
    c) Air emboli detecting devices.
8. All roller pump systems should include a manual override, which inhibits control of the pump by external control systems.
9. The perfusionist should have a dedicated light source available, for general illumination of the oxygenator and blood-path; and for use in situations involving loss of lighting to the operating room. This light source may either be an integral part of the heart-lung machine, or be a portable, battery-powered source.
10. A minimum of two pump heads should have separate crank handles, for manual pump operation, in cases of power or pump failure. These crank handles should be stored adjacent to the pump.
11. Either auxiliary or battery power should be available to provide emergency power for at least one hour for the main arterial pump and for the light source.

9.4.2 Heart-Lung Bypass Machine – Gas Supply system

1. Gas flow meters, air-oxygen blenders and anaesthetic vaporisers should meet Australian and New Zealand Standards.
2. The heart-lung machine should only be connected to a gas specific connection system supplying medical gases to the operating-room, or connected using gas specific connectors to a portable cylinder.
3. The gas supply line, from a blender or flow meter, should incorporate a device to both warn of low oxygen concentration and to validate the actual oxygen concentration immediately proximal to the oxygenator. This oxygen analyser should be sited proximal to the oxygenator and there should not be any other gas line inlets between this device and the oxygenator. This device should be in continuous use whilst the heart-lung machine is in use, and should be fitted with an audible alarm to warn of a low oxygen concentration.

4. The gas supply to the oxygenating device should be filtered or guaranteed free of particulate matter.
5. If an air-oxygen blender is to be used, it should incorporate an audible alarm device which will activate if the gas source pressures differ significantly.
6. A reserve supply of oxygen, for the sole use of the heart-lung machine should be available at all times. If an air-oxygen blender is being used, a supply of medical air, for the sole use of the heart lung machine, should also be available at all times. These reserve supplies should be checked weekly, and should be checked after each use.
7. A spare gas flow meter and/or air-oxygen blender should be readily available, in close proximity to the site of the procedure.
8. Provision should exist for scavenging waste anaesthetic gases from the oxygenating device.

9.4.3 Heart-Lung Bypass Machine – Heater-Cooler system

1. The heart-lung heater-cooler system can either be a self-contained system or utilise the hospital's hot and cold water system through a mixing valve. A spare unit or system should be available, for the event of the primary system failing.
2. Self-contained heater/coolers should have dual temperature safety devices and a heater-cooler system utilising hot and cold water from the hospital supply should have temperature safety devices to prevent the water temperature from exceeding 42 degrees Celsius or dropping below 3 degrees Celsius.
3. The water flow and pressure from the heater-cooler unit should not exceed the manufacturer recommended limits for the heat exchanger.
4. The heater-cooler system should incorporate safety alarms and override facilities for overpressure and temperature, and should indicate water pump failure and low water levels.
5. The system should meet the Australian or New Zealand Standards for electrical safety.

9.4.4 Heart-Lung Bypass machine – Associated equipment

9.4.4.1 Low-level detection devices

1. Low-level detection devices are safety devices mounted on, or secured to the reservoir of the cardio-pulmonary bypass circuit that will alert the perfusionist to a low level in the reservoir.
2. A low-level detection system should be used during the conduct of every cardio-pulmonary bypass procedure utilising a reservoir.
3. The sensor of the low-level detection system should be able to control the arterial roller pump.
4. The low-level detection system should incorporate both audible and visual alarms, to alert the perfusionist of a low blood level in the reservoir of the cardio-pulmonary bypass circuit.
5. The sensor should be sited no lower than the minimum operating level recommended for the oxygenator or reservoir. The perfusionist should allow a reaction time commensurate with the flows expected throughout the procedure.

9.4.4.2 Line Pressure monitoring devices

1. Line pressure monitoring devices are safety devices that give an indication as to the pressure being developed in all delivery lines to the patient, i.e., including, but not limited to, the arterial delivery line, cardioplegia delivery lines (ante grade and retrograde), retrograde cerebral or antegrade cerebral delivery lines and haemofiltration.

a) Electronic transducer-based pressure-monitoring systems should be used at all times to monitor all delivery lines to the patient. They should incorporate both an audible and visual alarm, set within the manufacturer's specifications, to alert the perfusionist to excessive pressures. They should be servo-linked to the delivery system. A variable delay should be an integral part of these systems to avoid "spike transient" false alarms.

9.4.4.3 Air-Emboli detection devices

1. An air-emboli detector is a safety device, which will indicate the presence of gaseous emboli passing the site of the detector.
2. An air-emboli detector should be used during the conduct of every cardio-pulmonary bypass procedure.
3. The sensor of the air-emboli detector system should be able to control the arterial pump.
4. The air-emboli detector system should incorporate both audible and visual alarms, which would alert the perfusionist to the presence of air in the circuit, at the site of the air-emboli sensor.
5. The air-emboli sensor should be positioned at a site that will allow the perfusionist to quickly, and safely remove any air, with a minimum effect on the patient.
6. With respect to Standard number 9.4.4.1 (Low level detection devices) and standard number 9.4.4.3. (Air-emboli detection devices) - BOTH of these systems should be in use during a cardio-pulmonary bypass procedure utilising a reservoir.

9.4.4.4. O_2 Saturation and CO_2 Removal

7. The oxygen saturation of the venous blood should be monitored routinely as a minimum standard.
8. An end-tidal carbon dioxide monitor should be used on the gas outlet port of the oxygenator, especially when carbon dioxide flooding of the surgical field is practised, - OR:-
9. When carbon dioxide is used to flood the surgical field, its levels should be monitored, using either end-tidal CO2 monitoring or more frequent blood gas analysis.

9.4.4.5 Monitoring of Temperatures

10. The following temperatures should be monitored, as a minimum standard for every procedure:
    a) Heater-cooler
    b) Oxygenator arterial blood outlet
    c) Patient (e.g. nasopharyngeal, bladder, and rectal)

9.5 Disposable Equipment for Perfusion

1. The perfusionist should be satisfied that each item has been inspected. Records relating to the device history and sterility must be kept. All lot/batch numbers of oxygenators, tubing packs, haemofilters and cell saving equipment disposables must be stored.
2. All sterile perfusion items should be examined for intact packaging prior to use, and indicators realising sterility should be noted prior to use.
3. All items should be used as per the manufacturer's specifications and instructions for use, including instructions relating to re-use and re-sterilisation, and to use-by and expiry dates.
4. All disposable items used in cardio-pulmonary bypass should be stored in areas meeting manufacturer's standards with respect to ultra-violet light, temperature, humidity, moisture and environmental extremes.

9.6 Pre-Operative Patient Assessment

1. In order to assess the patient for cardio-pulmonary bypass, a pre-operative evaluation of the patient and his/her related parameters, including the following details, should be noted:
    a. Name
    b. Unit record number
    c. Age and date of birth
2. The following patient parameters should be evaluated:
    a. Weight
    b. Height
    c. Recent full blood examination
    d. Recent clotting profile
    e. Pathology and aetiology of the cardiac disease
    f. Other patient pathology and serology
    g. Current medications
    h. Operative procedure planned

9.7 Setting Up / Protocols / Check Lists

9.7.1 Setting Up

1. The oxygenator, tubing and all other devices to be used in setting up for the cardio-pulmonary bypass procedure should be visually inspected by the perfusionist with responsibility for the procedure. The perfusionist should be satisfied that all components and devices are sterile, and not compromised in any way.
2. Assembly of the circuit should be performed in an aseptic manner, as prescribed both by the manufacturer of any device utilised, and by the Hospital or Institution.
3. Instructions accompanying any device should be available for reference during the procedure.
4. Replacement or spare components should be available in close proximity to the site of the procedure.

9.7.2 Protocols

1. Written protocols for the set-up and conduct of cardio-pulmonary bypass should be available.
2. Written protocols covering the management of, and the training for, "catastrophic events" that may occur during cardio-pulmonary bypass should also 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

9.7.3 Check Lists

1. A written, or computer-generated, check list should be completed for every procedure and should cover the following:
   a) Verifying the integrity of the heat exchanger.
   b) Verifying the gas supply and connection to the oxygenator.
   c) Verifying the patient identification.
   d) Checking blood group and availability.
   e) Preparing and verifying all prime constituents and additives.
   f) Verifying all tubing connections secure.
   g) Verifying desired occlusion and direction of ALL pumps.
   h) Verifying calibration of arterial and cardioplegia delivery pumps.
   i) Verifying arterial-line pressure and cut-off limits.
   j) Verifying cardioplegia delivery-line pressure alarm and cut-off (if applicable).
   k) Attaching and verifying operation of the level sensor.
   l) Attaching and verifying operation of the air-emboli detector.
   m) Attaching and verifying operation of the oxygen saturation monitor.
   n) Checking "EMERGENCY EVENT" supplies, which should include: hand cranks, an auxiliary light/torch, sterile tubing, scissors, sterile blades, tubing clamps, etc.
   o) Confirming administration of the loading dose of heparin to the patient.
   p) All check lists should be signed and dated and should accompany the Patient Perfusion Parameter Sheet into the Patient Unit Record/Medical History.

9.8 Cardio-pulmonary Bypass Records

1. Details relating to the patient and to the procedure should be documented electronically on a Computer Generated Record Sheet, or annotated on a Perfusion Record Sheet.
2. A record of the patient's haemo-dynamic and perfusion parameters during cardio-pulmonary bypass should be documented on a Computer Generated Record Sheet, or annotated on a Perfusion Record Sheet.
3. Adequate space for comments should be available on all Perfusion Record Sheets.
4. The Perfusion Record Sheet or Computer-Generated Record should be signed and dated by the Perfusionist performing the procedure and placed in the patient history.

9.9 Off-Pump Surgery

1. Off-pump surgery is carried out when the Surgeon decides that it is in the best interests of the patient to perform a corrective procedure without the use of cardiopulmonary bypass.

2. A Perfusionist should be available during the procedure to assist the Surgeon, in case the use of cardiopulmonary bypass is required. The Perfusionist should be present in the operating room throughout the procedure.

3. A circuit should be available or set up in the operating room, in case an emergency arises necessitating the institution of cardiopulmonary bypass.

4. The procedure should be fully documented and recorded.

9.10 Extra-corporeal Life Support (ECLS)

1. Extracorporeal Life Support is a method for providing life support to patients with cardiac and/or respiratory disease. The support is generally provided for patients with reversible conditions; however it can also be used as a bridge to organ transplantation.

2. Patients will either be categorised as ambulatory or non-ambulatory, depending upon the type of device inserted. The patients may have to meet certain institution-based criteria before ECLS can be instituted.

3. Priming of all extracorporeal circuits should be carried out by a Perfusionist.

4. For all patients, a Perfusionist should:

   a) be involved in the decision to offer ECLS;

   b) be responsible for the setting up and institution of the ECLS device;

   c) be an integral part of the management of the patient;

   d) be responsible for the training of appropriate personnel in the management of the patient on ECLS.

5. Spare pumps and disposable equipment should be available at all times and emergency kit for change out of failing components.

6. A Perfusionist should accompany the transport of any patient on ECLS.

7. Patients on ECLS in the operating theatre require an appropriately trained and experienced Perfusionist to supervise the ECLS circuit.

9.11 Ventricular-Assist Devices (VADs)

1. *Description.* Ventricular-assist devices provide support to patients with decreased cardiac function. The specific device will be selected on the basis of whether the support is intended to be short term (i.e. days to weeks), intermediate to long term (i.e. weeks to months), or permanent (i.e. destination therapy).

2. *Device Selection.* The device selected for support of these patients will be at the discretion of the Surgeon, and will be dependant on the patient's pathology and prognosis.

3. *Bridge to Recovery.* If the pathology is reversible, the device may be used to support the patient until heart function recovers.

4. *Bridge to Transplant.* If the pathology is irreversible and the patient is a suitable candidate for transplantation the device may be used to support the patient until a suitable organ becomes available.

5. *Destination Therapy (Alternative to Transplant).* If the patient has irreversible pathology and is deemed to be unsuitable for transplantation the device may be used to support the patient permanently.

6. General principles.

   a) For all patients, a Perfusionist should assist in the priming and setting up of the driver and in the institution of ventricular support.

b) Perfusionists should be an integral part of the management of the patient and the VAD.

c) Perfusionists should be responsible for the training of personnel for the management of the equipment

d) Spare equipment should be available at all times and an emergency kit for change out of failing components.

7. *Transport of Patients on VAD.* For some VAD's, the presence of an appropriately trained Perfusionist to accompany the device during transport is required.

8. *Non-Cardiac Surgical Procedures on VAD patients.* Patients on VAD in the operating theatre require an appropriately trained Perfusionist to operate the VAD.