Recommendations for Standards of Monitoring and Safety during Cardiopulmonary Bypass

Published by the:

Society of Clinical Perfusion Scientists of Great Britain & Ireland

Association for Cardiothoracic Anaesthesia and Critical Care

Society for Cardiothoracic Surgery in Great Britain & Ireland

September 2023

Recommendations for Standards of Monitoring and Safety during Cardiopulmonary Bypass (CPB)

Revision Personnel (2022)

Denise Gonoud	Society of Clinical Perfusion Scientists of Great Britain & Ireland
Noel Kelleher	Society of Clinical Perfusion Scientists of Great Britain & Ireland
Richard Downes	College of Clinical Perfusion Scientists of Great Britain & Ireland
Tony Meakin	College of Clinical Perfusion Scientists of Great Britain & Ireland
Kim Thompson	Society of Clinical Perfusion Scientists of Great Britain & Ireland
Simon Kendall	Society for Cardiothoracic Surgery in Great Britain and Ireland
Phil Botha	Society for Cardiothoracic Surgery in Great Britain and Ireland
Niall O'Keeffe	Association for Cardiothoracic Anaesthesia and Critical Care
Chris Efthymiou	Society for Cardiothoracic Surgery in Great Britain and Ireland
Aamer Ahmed	Association for Cardiothoracic Anaesthesia and Critical Care

This document is available on the following websites:

Society of Clinical Perfusion Scientists of Great Britain & Ireland

www.scps.org.uk

Association for Cardiothoracic Anaesthesia and Critical Care

www.actacc.org

Society for Cardiothoracic Surgery in Great Britain & Ireland

www.scts.org

Table of contents

Definitions and word usage for the purposes of this document

Standard: Practices, technology and/or conduct of care that institutions shall meet in order to fulfil 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 decisions 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.

Point of care testing (POCT): in this document is defined as within or close proximity to the cardiac theatre.

Theatre: any room; cubicle or ward where CPB support is required or on standby

On site facility: in this document is defined as on the hospital site

Primary Clinical Perfusionist is the named person responsible for the operating the heart-lung machine and the conduct of cardiopulmonary bypass

Introduction

This document is intended to improve the reliability, safety and effectiveness of cardiopulmonary bypass (CPB) by setting out the minimum standards of monitoring and safety during CPB for both adult and paediatric cardiac surgery. It is based on informed advice and is considered by the Society of Clinical Perfusion Scientists of Great Britain and Ireland, the Association of Cardiothoracic Anaesthesia and Critical Care and the Society for Cardiothoracic Surgery in Great Britain and Ireland to be the minimal monitoring standards required during CPB. This includes monitoring for the onset of and weaning from CPB, and for confirmation of anticoagulation and ventilation of the lungs.

These standards are for use in conjunction with the Society of Clinical Perfusion Scientists of Great Britain and Ireland Standards of Practice document[1] and local protocols. Relevant local protocols should be informed and guided by this document. Sources of reference include publications from the Society of Clinical Perfusion Scientists of Great Britain and Ireland[1&9], the Association of Anaesthetists of Great Britain and Ireland[2], the American Society of Extra-Corporeal Technology[3] and the Department of Health document – Guide to Good Practice in Clinical Perfusion (GGPCP)[4].

All centres undertaking cardiac surgery involving CPB should plan to institute and implement these standards from receipt of this document. This will be monitored by the College of Clinical Perfusion Scientists (CCPS) unit accreditation process and followed up by the CCPS. Failure to meet any standard set out in this document must be detailed in the Hospital Risk Register with a timetable for urgent resolution noted.

The safe conduct of CPB remains the primary responsibility of the Clinical Perfusion Scientist who must be present (in the operating room) at all times i.e. from heparinisation to decannulation. The management and overall safety of CPB is the joint responsibility of clinical perfusion scientists, surgeons and anaesthetists. It requires a high level of clear

communication between the team members. Whilst it is considered best practice during conduct of CPB for a Consultant Surgeon and Anaesthetist to be present in the operating room at all times during cardiopulmonary bypass, it is recognised that there are circumstances where this may not be essential.

In order to ensure that standards and recommendations are applied in clinical practice, each institution should develop and implement its own locally agreed protocols. These protocols should be ratified by the head clinical perfusion scientist and other relevant clinical governance or patient safety committees within the organisation. (Examples of such locally agreed guidelines, in relation to anaesthetic practice, can be found on the ACTACC website).

Only an accredited clinical perfusion scientist currently registered with the College of Clinical Perfusion Scientists of Great Britain and Ireland shall undertake or supervise the conduct of CPB[1, 4, 5&6]. A named and accredited clinical perfusion scientist without the distraction of other clinical commitments, in close proximity and freely available must supervise a trainee undertaking a CPB[1&9].

General recommendations

Documentation

Adequate records of monitoring should be kept at all times and where a variable is monitored it should be regularly recorded. All units should have electronic acquisition and storage of this data, including the ability to produce a printout[2].

Records should be stored electronically and a summary placed in the patient's notes as per local and NHS/HSE policies. Local policies shall dictate the frequency of recording.

Perfusion CPB records shall monitor and record:

- Patient demographics and pre-operative risk factors.
- Electrocardiogram (ECG), recorded as heart rate.
- Patient systemic arterial blood pressure.
- Patient central venous pressure (CVP).
- Patient body temperature(s).
- Heparin dose/administration (or equivalent) before initiation of CPB.
- Activated clotting time (ACT) before initiation of CPB and at regular intervals during CPB to ensure adequate anticoagulation.
- CPB start/stop times and cumulative elapsed time.
- Aortic cross clamp start/stop times and cumulative ischaemic time.
- Blood flow rate generated by the arterial pump.
- Arterial line pressure(s).

- Cardioplegia line pressure, flows and temperature.
- FiO_2/Gas flow rate.
- Oxygen concentration in the gas delivery line to the oxygenator using an oxygen analyser.
- Anaesthetic agent settings.
- Arterial and venous blood temperatures in the CPB circuit.
- Blood gas data.
- In-line blood monitoring parameters (minimum data set defined below).
- All fluids and drugs administered to the extracorporeal circuit (ECC) pre and peri-CPB.
- Blood products added (type, unit numbers and volumes).
- Drugs administered (type, concentration and volume).
- Cardioplegia type, dose and timing.
- Filtrate volume when using a haemofilter.
- Urine output during CPB.
- Heater/cooler temperature settings.
- Circulatory arrest start/stop times and cumulative elapsed time.
- Route of cerebral perfusion and cerebral perfusion flow rate.
- All hardware and disposables used.
- All hardware shall be easily identifiable and traced back to the patient (e.g. HCU A) and all disposables used should have lot numbers/expiry dates recorded.
- All personnel involved with the CPB should be documented.

- Appropriate checklists completed.
- Signature of any clinical perfusion scientists involved with the procedure and/or other relevant signatures.
- A record of adverse events.

Drug and fluid administration

To enable clinical perfusion scientists to administer fluids and drugs, Patient Specific Directions (PSD) / Patient Group Directives (Wales) should be in place as agreed at local level and, where not forming a part of a CPB record, there should be a document recording those directions for each individual patient and according to guidance in the GGPCP[4]. All departments should be familiar with the GGPCP[4] and this should be readily available for reference. These documents should form part of the local Quality Management Framework.

Display of clinical parameters acquired directly from the patient

During CPB, each unit should aim to have three separate screens for monitoring patient parameters by the clinical perfusion scientist, surgeon and anaesthetist.

The parameters that should be continuously displayed are:

- Electrocardiogram (ECG).
- Intravascular pressures.
- Patient body temperature(s).
- Pulse oximetry when there is a spontaneous pulsatile circulation.
- Expired carbon dioxide tension/concentration when the lungs are being ventilated.

Additional monitoring considerations

Depth of anaesthesia monitoring such as bispectral index (BIS) or patient state index (PSI) should be considered by anaesthesia, particularly in the presence and use of volatile and intravenous anaesthetic agents during CPB.

The use of near infrared spectroscopy (NIRS) for regional cerebral oximetry (RSO_2) monitoring should also be considered for certain procedures requiring CPB, e.g. aortic root/arch surgery, in patients with cerebrovascular or carotid disease, procedures involving the use of retrograde arterial flow, use of regional cerebral perfusion or deep hypothermic circulatory arrest (DHCA) etc. (This list is not exhaustive and intended only as a guide).

Consideration should be given to measuring and monitoring the following:

- Heparin dose titration and levels during CPB.
- Platelet function.
- Patient coagulation profiles (e.g. thromboelastography (TEG), rotational thromboelastometry (ROTEM)).

All monitors and alarms used should be calibrated and maintained regularly according to the manufacturer's instruction and the recommended service schedule. All equipment must be checked before use.

A comprehensive record of all servicing, maintenance, modifications and faults must be maintained and audited.

All departmental team members should receive in-service training on any device or equipment to be used with the manufacturer's instructions for use (IFUs) forming an integral part of that training and a record of training kept accordingly.

N.B: It is accepted that special clinical circumstances, for example, emergency surgery or failure to insert a urinary catheter may, on some occasions, preclude complete monitoring.

Checklists

- The clinical perfusion scientist shall utilise a pre-operative checklist for each CPB procedure and this should form part of the patients' medical record.
- A checklist should verify that all relevant information has been obtained and that all critical safety checks have been completed prior to initiating CPB.
- Completion of a checklist should be performed by two clinical perfusion scientists, one of whom shall be the primary clinical perfusion scientist responsible for operating the heart-lung machine.
- Where a trainee clinical perfusion scientist is conducting a procedure, primary responsibility for the procedure, and therefore the checklist, is with the accredited clinical perfusion scientist[1]. Locally agreed policies will dictate the content of the checklist(s) and set competencies for when it is appropriate for a trainee to carry out a second check.

  *For the SCPS practical examination, the trainee is accepted as the primary clinical perfusion scientist for the procedure.
- A separate handover checklist should be employed if there is a change in clinical perfusion scientist[12].
- Consideration should be given to the use of a weaning checklist[13]
- Consideration should also be given to the use of a CPB re-initiation checklist.

Monitoring and safety devices associated with cardiopulmonary bypass equipment

Local protocols for the conduct of cardiopulmonary bypass (CPB) should be formulated by all hospitals undertaking cardiac surgery using CPB. The following recommendations are considered minimum safety standards only.

Heart-lung machine (HLM)

The number of HLMs available for use shall be N+1, with N being the number of theatres in concurrent use. Theatres with off-pump/pump standby cases should be included within N. The '+1' HLM allows provision for emergencies, or change out of the pump or individual components in the event of equipment failure. This HLM shall be in possession of the full complement of supporting equipment, so that it is ready for immediate use.

All equipment must be serviced and maintained as per manufacturer recommendations.

Blood pumps

- Arterial pumps used for CPB should have a safety mechanism that stops flow. A retrograde flow alarm and/or occlusion device is essential when using centrifugal pumps as a means to prevent retrograde arterial blood flow.
- Pumps for administration of cardioplegia should be linked to the main arterial pump to ensure that the cardioplegia flow does not exceed the blood flow to the patient.
- Pumps shall have a power failure alarm with battery powered back-up in the event of a loss of power supply. The battery capacity must be checked during set-up.

- In the event of a pump malfunction or power supply issue, pumps shall be capable of manual operation by separate hand cranks. Hand cranks shall be kept with the HLM.

Gas supply

- Continuity of fresh gas flow to the oxygenator confirmed by use of flow meter or rotameter[2].
- The gas supply line from a gas blender or flow meter, should incorporate an oxygen analyser to 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 distal to the gas blending compartment and vaporiser if used[2]. This analyser shall be in continuous use when oxygen gas flow is initiated and shall include an audible alarm to warn of low concentrations.
- The gas supply tubing to the oxygenator shall incorporate an appropriate gas filter.
- Audible alarms should be used on gas blenders.
- A back-up blender or supply of gas shall be available in the event of a mechanical/power failure. A spare blender/gas supply for all HLMs in use should be readily available and in close proximity.
- If using volatile anaesthetic agents, a scavenging system for waste gases from the oxygenator shall be installed and maintained[8].

Heater-cooler units (HCU)

- Manufacturer's instructions for use (IFU), cleaning and maintenance should be followed and appropriate records maintained.

- Heater Cooler Units should have safety alarms to indicate when variables are outside expected limits. Alarms should also indicate water pump failure and low water levels.
- HCU's shall have a unique identifier allocated and recorded for each case.
- The number of HCUs available for use shall be N+1, with N being the number of theatres in concurrent use. Theatres with off-pump/pump standby cases should be included within N. The '+1' HCU allows provision of equipment for emergencies, or change out in the event of equipment failure. This HCU shall be in possession of all required additional components, so that it is ready for immediate use.

Venous reservoir low level alarms

- Shall be used for all CPB procedures using hard shell reservoirs.
- Shall be positioned no lower than the venous reservoir's minimum operating level.
- Shall be linked to the arterial pump for an alarmed automatic cut out facility.

Pressure monitoring

- Arterial line pressure shall be monitored continuously with an overpressure alarm on the arterial limb of the CPB circuit with automatic pump cut out/flow reduction facility.
- Cardioplegia line pressure shall be monitored continuously with an overpressure alarm on the post pump aspect of the cardioplegia circuit with automatic pump cut out/flow reduction facility.
- Electronic transducer-based pressure monitoring systems shall be employed at all times to monitor all pressures. They should

incorporate both auditory and visual alarms, set at appropriate levels to alert the clinical perfusion scientist to out of range pressures. A warning alarm should also be incorporated.

- An analogue gauge will allow rapid identification of pressures and allow clear determination of a pulsatile 'swing' during aortic cannulation.
- During retrograde cardioplegia delivery, pressure shall be monitored directly within the coronary sinus.
- When using vacuum assisted venous drainage (VAVD), both positive and negative pressures should be measured and monitored. Warning alarms should be incorporated to alert to out of range pressures.

Bubble detectors

- A minimum of two bubble detectors shall be used during every CPB procedure:
    - Arterial return line
    - Cardioplegia delivery line
- The bubble detectors shall be linked to the appropriate blood pump to enable an alarmed automatic pump cut-out facility.
- The bubble detector must incorporate both auditory and visual alarms.

Continuous in-line/ on-line monitoring

Continuous live monitoring shall be used for each CPB case.

The minimum parameters required are:

Hb or Hct, venous SO_2 and arterial SO_2 or arterial pO_2.

The following should also be considered: glucose, lactate, potassium, calcium, arterial pCO_2, VO_2 and DO_2.

Additional safety guidance:

Suckers and vents

- All suckers and vents shall be checked by the clinical perfusion scientist to confirm correct function, direction and position to aspirate blood and air away from the heart or surgical site.
- Local protocol must include a compulsory occlusion method along with standard directional confirmation of all pumps.
- This must be recorded as double checked via a pre-bypass checklist and confirmed by a circulating/N+1 clinical perfusion scientist.
- One-way pressure relief valves in ALL suckers and vents shall be used as standard.
- "Wet-testing" may also be used in conjunction with checks recorded in line with local policy.

Monitoring and reversal of anticoagulation

- Local protocol shall determine the appropriate level and frequency of measurement of anticoagulation before commencement and during CPB.
- Equipment capable of measuring ACT should be available on an 'N+1' basis.

Protamine administration

The risk of Protamine administration during CPB should be discussed with anaesthesia. Anaesthesia should consider not drawing up Protamine until it is requested by the surgeon.

There should be clear, closed loop communication between the clinical perfusion scientist, surgeon and anaesthetist confirming the intent to administer Protamine, and all aspirating lines i.e. suckers, vents and

venous line(s) have been confirmed as off and removed from the surgical field.

Termination of CPB

Termination of CPB shall only be considered once ventilation has been confirmed between the clinical perfusion scientist and anaesthetist.

Protocols

Emergency equipment failure protocols and critical incident protocols (e.g. massive air embolism) should be in place and confirmed current annually. Emergency procedures shall be practiced and documented at least annually[9].

Staffing

Appropriate staffing levels should be in place in line with the SCPS Code of Practice [4, 9&10]. The minimum safe number of accredited clinical perfusion scientists to cover operating theatres for any CPB procedure is deemed as N+1, where N equals the number of operating theatres in use at any given time on a single site. The plus one shall be available onsite. Trainees must not be included in the minimum safe number. Individual sites, buildings and specialities should be staffed independently[9]. Consideration should be given to situations where 4 OR MORE theatres are in concurrent use, as N+2 may be more appropriate.

On call commitment should be no more frequent than a 1 in 4. On call more frequent than 1 in 3 is considered to be too onerous.

The rota should reflect N+1 at all times. Ideally N+2 etc based on the number of areas/theatres covered.

On-call sessions should not be routinely scheduled before a day off as part of regular workforce planning.

Multi-discipline team training

All those involved in cardiac surgery should undergo training in teamwork, human factors[9] and process design. The team should have regular briefings and reviews, including self-assessment of team climate with clear strategies to improve and monitor any areas of concern. Root cause analyses must be undertaken in any cases where a mishap or "near-miss" event has occurred and outcomes and recommendations implemented.

References

1. Standards of Practice. Society of Clinical Perfusion Scientists of Great Britain and Ireland, London 1999 (Updated April 2019). **https://www.scps.org.uk/society/society-documents**

2. Recommendations for Standards of Monitoring during Anaesthesia and Recovery. The Association of Anaesthetists of Great Britain and Ireland, London 2016 **https://www.actacc.org/node/65**

3. AMSECT Guidelines for Perfusion Practice. The American Society of Extra-Corporeal Technology, 2017. **https://www.amsect.org/page/perfusion-practice-guidelines**

4. Guide to Good Practice in Clinical Perfusion. DH, London 2009 **https://webarchive.nationalarchives.gov.uk/20130123200230/http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_103182**

5. Guidelines for the Provision of Anaesthetic Services. The Royal College of Anaesthetists, London. 2019. **https://www.rcoa.ac.uk/safety-standards-quality/guidance-resources/guidelines-provision-anaesthetic-services**

6. The Employment of Clinical Perfusionists in the NHS, The Department of Health's guidance on best practice for the employment of clinical perfusionists in the NHS, December 1999.

7. Five Steps to Safer Surgery. National Patient Safety Agency, December2010. **https://www.patientsafetysolutions.com/docs/January_11_2011_NPSA_UK_How_to_Guide_Five_Steps_to_Safer_Surgery.htm**

8. Health Services Advisory Committee. Anaesthetic Agents: Controlling Exposure under COSHH. London: HMSO, 1995. **https://www.cdc.gov/niosh/docket/archive/pdfs/niosh-064/0064-010195-McGregor_Ref1.pdf**

9. Code of Practice. Society of Clinical Perfusion Scientists of Great Britain and Ireland, review 2019. **https://www.scps.org.uk/society/society-documents**

10. Independent Root Cause Analysis Report. Mr.M.Gritten, October 2007. **www.scps.org.uk/pdfs/GrittenReport.pdf**

11. World Alliance for Patient Safety. **WHO Surgical Safety Checklist**. Geneva, Switzerland; World Health Organization; 2008. Accessed Jan 2021. **https://www.who.int/patientsafety/topics/safe-surgery/checklist/en/**

12. AMSECT Handover Checklist. Accessed Jan 2021. **https://www.amsect.org/page/perfusion-safety**

13. 2019 EACTS/EACTA/EBCP Guidelines on Cardiopulmonary Bypass in Adult Cardiac Surgery. British Journal of Anaesthesia, **123 (6):** 713e757. https://www.bjanaesthesia.org/action/showPdf?pii=S0007-0912%2819%2930687-7