



Guide to Good Practice in Clinical Perfusion

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Guide to Good Practice in Clinical Perfusion

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Foreword



Cardiac surgery has been one of the most progressive and innovative specialties in medicine.

There is strong scientific evidence to show that in the right patients heart surgery not only relieves symptoms but also prolongs life. The success of heart surgery has evolved through the relentless application of basic science and complex technological innovation; but it is also technically demanding surgery requiring intricate and complex teamwork.

In the UK some 40,000 heart operations are performed every year with results that are as good as anywhere in the world. Most of these require that the heart and lungs are stopped during the operation and their function is taken over by a “heart-lung” machine operated by a clinical perfusion scientist.

Given such complexity the safety record of heart surgery is outstanding.

But there have been two reported incidents in England in the last few years where the fluids injected while patients have been dependent on the heart lung machine have resulted in the death of both patients.

These events have been fully investigated and this Good Practice Guide provides a framework for safe administration of fluids and drugs associated with heart-lung bypass.

It has been developed by a Working Group, chaired by the Chief Scientific Officer, with representatives of the Society of Clinical Perfusion Scientists of Great Britain and Ireland, the Society for Cardiothoracic Surgery in Great Britain and Ireland and the Association of Cardiothoracic Anaesthetists. We are very grateful to those representatives for their significant contribution and to their professional societies for their endorsement of the guide.

A handwritten signature in black ink that reads "Bruce Keogh". The signature is written in a cursive style and is underlined with a single horizontal stroke.

Professor Sir Bruce Keogh
NHS Medical Director

Executive Summary

The purpose of this document is to provide guidance on systems and processes which need to be in place to assure safe, high quality clinical perfusion services provided by the NHS and independent sector providers to support cardiopulmonary bypass (CPB) and mechanical circulatory support during cardiac surgical procedures. Whilst it recognises that there are nearly 40,000 cardiac surgical procedures each year involving CPB with few adverse incidents, this document addresses the recommendations for providers of clinical perfusion services of the Gritten Report.¹

The guidance is intended for Trust Boards, Medicines Management Committees, Clinical Governance Departments and Service Commissioners as well as practitioners working in multi-disciplinary cardiac surgical teams. It is a guide to good practice and recommends a Quality Management Framework and System, including a Framework for the Administration of Named Medicines, for good practice in clinical perfusion. If adhered to, this guidance and the recommended frameworks should minimise the risk to Boards and senior executives of being culpable under the Corporate Manslaughter and Homicide Act 2007 (the CMA 2007) (see Annex A).

This document:

- sets the context of the development of heart surgery and clinical perfusion, the current ‘non-statutory’ system of professional registration of clinical perfusionists by the College of Clinical Perfusion Scientists, and DH guidance that employment in the NHS should be limited to those clinical perfusionists registered with the College;
- sets out current medicines legislation and the implications for medicines and fluid administration by clinical perfusionists, who are not yet subject to statutory regulation and who may legally administer prescription only drugs **only** on the specific directions of an ‘appropriate practitioner’ (prescriber), in this case normally a registered medical practitioner (ie surgeon or anaesthetist within the cardiac surgical team);
- discusses the importance of teamwork, an understanding of human factors in the design and delivery of safe cardiac surgery, and the need to design systems to prevent errors, including operation of a new safety checklist for surgical teams, which is used at three stages of an operation;
- describes a framework for, and the principles of, a Quality Management System, and the need for a robust and clear system of Standard Operating Procedures (SOPs) to be in place for all procedures involving CPB (as well as for other procedures involving clinical perfusionists), with separate SOPs for adults and for children;
- suggests a Framework for the Administration of Named Medicines set out at Annex B to be used by clinical perfusion service providers as part of their Quality Management System, with separate clinical perfusion medicines protocols for adults and children, and which should form the basis of patient specific directions which are recorded in the patient’s notes and clinical perfusion record; and

¹ Gritten, M. (2007) *Independent Root Cause Analysis Report into the Adverse Incident that led to the Death of a Paediatric Cardiac Surgery Patient at the United Bristol Healthcare NHS Trust on 27 May 2005*. Bristol: UBHT NHS Trust

- summarises the actions which different organisations and stakeholders would need to take to implement this document's recommendations.

The Department of Health is very grateful to the members of the Clinical Perfusion Working Group for their sustained commitment and significant contribution to the development of this Good Practice Guide and to their professional societies for their endorsement.

Background

Bypass and heart surgery

Heart disease is a major health problem in the UK, and heart surgery is now common for:

- revascularisation in coronary artery disease;
- heart valve repair and replacements; and
- heart and heart-lung transplantation.

This includes surgery for adults with acquired heart disease and corrective and palliative surgery for both children (including neonates and infants) and adults with congenital heart conditions. In England in the NHS in 2007, there were approximately 22,500 coronary artery bypass graft (CABG), operations and just over 11,000 episodes of valve surgery. Whereas the number of CABGs performed has plateaued in recent years, valve surgery has increased at a rate of about 7% each year,² from 2001 to 2006. For congenital heart conditions, the number of episodes of surgery is increasing each year, especially for adults.

Cardiopulmonary bypass (CPB) is a key component of these highly invasive surgical procedures, many of which are complex. CPB takes over the functions of the heart and lungs and maintains blood oxygenation and circulation to the body whilst the heart and lungs are stopped during surgery. In England in the NHS nearly 38,000 CPB procedures are undertaken each year, in a total of 34 NHS tertiary centres (32 Trusts), 3 of which only treat children.³ There is a general trend to more minimally invasive surgery and some surgeons are now using off pump surgery techniques.

Clinical perfusion scientists

Clinical perfusion scientists (clinical perfusionists) are members of the multi-disciplinary cardiac surgical team. They have a clearly defined and uniquely specialised role. They are responsible for all aspects of patient care associated with the use of CPB during cardiac surgery. The safe conduct of CPB requires the clinical perfusionist to measure and control haematological, biochemical and other physiological parameters such as blood temperature, blood gases, pressures and flows in the circuit, during the period of bypass.

Before the start of CPB, the circuit is primed with fluid, to clear all air or any small particles out of the circuit before connecting it to the patient. Any air or small particles from the circuit could cause injury or death to the patient. The prime fluid therefore has to be of a composition and strength which will not harm the patient when it enters their circulation and mixes with their blood. Within the context of the cardiac surgical team, the clinical perfusionist is responsible for this specialist task, working very closely with other members of the team, including the cardiothoracic surgeon, cardiac theatre nurse and cardiothoracic anaesthetists to ensure safe and successful patient outcomes. During surgery, medicines

² Source: Central Cardiac Audit Database (CCAD)

³ 20,774 Coronary Artery Bypass Grafts in 2006/07 (HES data); 8,994 valve replacements in 2005/06 (Cardiac Benchmarking data, on-line HES) 2,909 congenital heart defect repairs in 2005/06 (CCAD- Congenital Heart Disease Website)

and additional fluids are given to the patient through the CPB machine. The clinical perfusionist is also responsible for the safe termination of CPB following the instruction of the surgeon to terminate.

Clinical perfusionists also work in intensive care, the emergency department, non-cardiac theatres and the cardiac catheter laboratory, providing mechanical circulatory support and other specialist services for patients with heart disease and for other procedures, such as liver surgery and cancer chemotherapy.

In 2008 the DH workforce census of the NHS in England identified 158 clinical perfusionists. 151 whole time equivalents were employed in the NHS, but some clinical perfusion services are provided by private companies on contract to the NHS, and staff working in those will not be included in these numbers. As of 31 January 2009, the Register of the Society of Clinical Perfusion Scientists of GB and Ireland has a membership of 319 in England, Scotland and Wales, working in both the NHS and independent sectors.

The government fully recognises the need for this key group of staff to be regulated by statute and has clearly stated that all matters relating to the regulation of the five aspirant groups of healthcare scientists, including clinical perfusionists, who have already been recommended to the Secretary of State for extension of statutory regulation will be resolved as part of a separate consultation.⁴ However, until clinical perfusionists are subject to statutory regulation, this has implications in law for their role in working with medicines (see below).

Assuring the quality of clinical perfusion scientists

The Society of Clinical Perfusion Scientists of Great Britain and Ireland (SCPS) sets the standards of conduct, behaviour and competence of the profession. It issues individuals with a Certificate of Accreditation after written, practical and viva voce examinations. All accredited clinical perfusionists are then eligible for professional (non statutory) registration with the College of Clinical Perfusion Scientists (CCPS). The CCPS also ensures that the standards of registered practicing clinical perfusionists are maintained by ensuring that they undertake a set minimum caseload each year as part of continuous professional development. Failure to achieve these standards can result in limited registration or removal from the CCPS register, which should mean that those clinical perfusionists will not be employed to practice.

The Department of Health has also recognised that, following an earlier clinical perfusion related incident, employment in the NHS should be limited to those professionally registered with the College, and issued a letter to this effect.⁵ All trainee clinical perfusionists need to be supervised by an accredited and registered clinical perfusionist.⁶ The CCPS also accredits Trust clinical perfusion departments for training, but not currently for the quality of service they should provide. In the light of the Gritten Report, the CCPS is developing a process of quality assurance for clinical perfusion services, which should work alongside the clinical governance and quality management systems and processes put in place by providers of clinical perfusion services and any requirements of cardiothoracic specialist commissioners.

⁴Department of Health (2008) *The Future of the Healthcare Science Workforce Modernising Scientific Careers: The Next Steps A Consultation*. London

⁵NHS Executive (1999) *Employment of Clinical Perfusionists in the NHS*. Guidance on Best Practice. Leeds: Department of Health

⁶Gritten *op cit*

The law in respect of the sale, supply and administration of medicines: the Medicines Act 1968

This section sets out in some detail the legal framework for the sale, supply and administration of medicines, as this has major implications for employers and for individual practitioners in respect of the legal and safe delivery of clinical perfusion services and for the role of clinical perfusionists in cardiac surgery. In the context of this guidance, it is necessary only to consider the administration of medicines, and not their sale or supply.

The Medicines Act 1968 and associated secondary legislation⁷ regulates the administration of all medicines available in the UK. Medicines are classified as prescription only medicines (POM), pharmacy medicines or general sale list medicines. As far as POMs are concerned, the general rule, subject to various exemptions, is that only an “appropriate practitioner” may prescribe, administer or give directions for their administration. The term “appropriate practitioner” is used in the legislation but in this document we shall use the term “prescriber”.

The Medicines Act 1968 and the Medicines for Human Use (Prescription Only Medicines) Order 1997 (the POM Order) list these prescribers and, in certain circumstances, the categories of POMs which they can prescribe. All medicines for parenteral⁸ administration are categorised as POM. The rules are that medicines for parenteral administration may only be:

- self administered;
- administered by a prescriber. Currently, legislation provides that doctors, dentists, nurse independent prescribers, pharmacist independent prescribers and, subject to certain limitations, other supplementary prescribers⁹ are prescribers for medicines for parenteral administration; and
- administered by anyone¹⁰ acting in accordance with the patient-specific directions of a prescriber.

There are certain exemptions from these requirements. For example, the POM Order allows any person to administer parenterally, certain medicines where the administration is for the purpose of saving life in an emergency, but none of these exemptions would be relevant to the normal practice of a clinical perfusionist. There are no exemptions in medicines legislation which would enable a clinical perfusionist to administer a medicine parenterally without the direction of a prescriber. Whilst the Medicines Act 1968 does not require directions for administration to be in written form, it is best practice for written directions to be given and signed.

Current medicines legislation¹¹ provides for anyone (eg parent; care home worker) to follow the directions of a prescriber and administer POMs which are for parenteral administration to a named individual: these are sometimes referred to as Patient Specific Directions (PSDs),¹² although that term is not used in the legislation. The term ‘PSD’ will only be used in this Guide in the context of directions for medicines administration which a prescriber can give (either verbally or in writing).

The current legal framework therefore permits clinical perfusionists to follow a prescriber’s directions to administer POMs, including controlled drugs, which are for parenteral administration to a specific

⁷ In particular, the Prescription Only Medicines (Human Use) Order 1997 (“the POM Order”)

⁸ Administration by breach of skin or mucous membrane. For example, by injection, infusion, or implantation

⁹ Registered professions eligible to be designated as supplementary prescribers include: nurses, pharmacists, physiotherapists, chiroprodists/podiatrists, radiographers and optometrists

¹⁰ Including someone who is not a health care professional, eg a carer

¹¹ Section 58(2)(b) of the Medicines Act 1968

¹² It should be noted that the term ‘PSD’ is also used outside this Guide to describe situations not involving administration, for example exemptions under the POM Order which allow for supply on the written directions of a doctor or dentist (or sometimes another prescriber) in certain circumstances. It is sometimes used to describe prescriptions

patient (a PSD). While not required under medicines legislation, it is best practice that those directions are written and signed. Those directions can indicate the administration of medicines within a dosage range. In these circumstances, the clinical perfusionist can exercise his/her professional judgement when acting in accordance with the directions, and refer back to the prescriber for further directions if required. Provider organisations should have arrangements in place which enable these legal requirements to be implemented.

This document gives guidance on policies and procedures which should be in place in clinical perfusion services to meet these legal requirements and standards of best practice. It emphasises the importance of:

- teamwork and human factors training;
- a Quality Management System and Framework;
- agreed Standard Operating Procedures, compliance with which is audited and reported through local clinical governance arrangements; and
- a framework of locally agreed medicines protocols, within which PSDs for individual patients can be determined locally (for example at a pre-operative discussion of the individual case by a consultant or other designated senior members of the surgical team, including the anaesthetist(s) and clinical perfusionist(s) as outlined in Annex B.

The importance of quality at the heart of care

Whilst it is crucial that patient care is delivered within the law, fulfilling legal requirements alone will not be enough to deliver high quality services to local communities, patients and their families. The final report of the Next Stage Review of the NHS, *High Quality Care for All*¹³ reaffirmed the government's commitment to putting quality at the heart of health care, as the organising principle. Three key and equally important dimensions of high quality care are defined as:

- **patient safety**, whereby no harm is done to patients. The healthcare environment is safe and clean, and avoidable errors and rates of infection are reduced;
- **patient experience**, in which there is a high quality of caring by all providing services; patients and their families are treated with compassion, dignity and respect and patient satisfaction is analysed and understood; and
- **effectiveness of care**, in which the success rates of different treatments are understood for different conditions, and the patient's own assessment of the outcome of care is captured and measured.

Whilst this document focuses specifically on systems for patient safety during CPB, it is in the context of recognition that cardiac surgery must ultimately enhance the patient experience and deliver improved quality of life, and use procedures and interventions which are known to be safe and effective.

The importance of leadership and good teamwork

Heart surgery is technologically complex and relies critically on people working well together. Over and above the quality of individual practitioners' skill and expertise, there is strong evidence that effective leadership and good team working offers a better standard of care and reduces the chance of error. The

¹³ Department of Health (2008) *High Quality Care for All*. NHS Next Stage Review Final Report. Cm7432. London: The Stationery Office

team, its members and its leadership create safety in the health care system. Leadership with a purpose to constantly improve the quality of care is needed in all parts of the healthcare workforce: not just in the most senior positions. Practitioners and managers need to feel empowered to make improvements and take decisions at the front line of services which will enhance the quality of patient care, the quality of their own working environment and the quality of their team work. It is vital that practitioners do not wait to be led.

Research on teamwork in the operating theatre has shown that good teamwork is crucial in reducing errors in surgery,¹⁴ and that poor communication is frequently involved in errors.¹⁵ This is acknowledged by both the Royal College of Surgeons and the Royal College of Anaesthetists, each of which has developed training programmes in leadership, teamwork and the avoidance of errors. Good team working cannot be expected to occur spontaneously, but a range of interventions can enable groups of practitioners to develop into a good team. The challenge for NHS employers is to ensure that all staff who may work together in a team in theatre have adequate training, so that they can work effectively in a team, whatever its composition as staff rotas change. Measures which have been found to improve team formation and working include:¹⁶

- **briefings and reviews**, which can improve shared understanding and goals;
- **continuous updates** to all team members of successes and problems; and
- **self-review**, including self assessment of team climate. There are several tools to aid teams in undertaking such reviews.¹⁷

Designing systems to prevent errors

Healthcare will always involve risks, particularly when very complex systems and procedures are involved.¹⁸ The National Patient Safety Agency (NPSA) estimates that around 10% of patients admitted to NHS hospitals have experienced a patient safety incident, and that up to half of those incidents could have been prevented.¹⁹ Research has shown that most untoward incidents are underpinned by failures in the organisational culture, systems and process design within which practitioners work. The best way of reducing error rates is to target the underlying system failures and root causes of incidents, rather than focussing solely on the actions of individual members of staff.²⁰

Active failures by individuals can combine with organisational weakness to produce serious adverse events.²¹ A focus on human factors helps to illuminate how adverse events occur, and enables the design of safe systems to fit the way that people work. Human factors covers:

- why human error is a factor in all accidents;
- why humans make mistakes and proven error prevention techniques;

¹⁴ Carthey, J. de Leval, MR., Wright, DJ., Farewell, VJ., Reason, JT., *Behavioural markers of surgical excellence*. Safety Science 2003; 41:409-425. Healey, AN, Undre S, Vincent CA. Defining the technical skills of teamwork in surgery. Qual Saf Health Care 2006; 15(4):231-234. Thomas EJ, Sexton JB, Lasky RE., Helmreich, RL., Crandell, DS., Tyson, J. *Teamwork and quality during neonatal care in the delivery room*. J Perinatol 2006; 26(3):163-169. Helmreich, RL.. *On error management: lessons from aviation*. BMJ 2000; 320(7237):781-785

¹⁵ Lingard, L., Reznick, R., Espin, S., Regehr, G., DeVito, I. *Team communications in the operating room: talk patterns, sites of tension, and implications for novices*. Acad Med 2002; 77(3):232-237. Rogers, SO., Jr., Gawande, AA., Kwaan, M., Puopolo, AL., Yoon, C., Brennan, TA. et al. *Analysis of surgical errors in closed malpractice claims at 4 liability insurers*. Surgery 2006; 140(1):25-33. Catchpole, KR., Giddings, AE., de Leval, MR., Peek, GJ., Godden, PJ., Utley, M. et al. *Identification of systems failures in successful paediatric cardiac surgery*. Ergonomics 2006; 49(5-6):567-588

¹⁶ <http://www.npsa.nhs.uk/patientsafety/improvingpatientsafety/humanfactors/teamworking/>

¹⁷ eg *The Team Climate Assessment Measure and the Team Self Review*, both developed with support from the National Patient Safety Agency

¹⁸ Department of Health (2001) *Building a Safer NHS for Patients*. London

¹⁹ National Patient Safety Agency (NPSA)(2004) *Seven Steps to Patient Safety. An Overview Guide for NHS Staff*. Available at www.npsa.nhs.uk/sevensteps

²⁰ *Ibid*

²¹ Reason, JT. (1997) *Managing the Risks of Organisational Accidents*. Aldershot: Ashgate Publishing

- how to analyse and identify human errors and the conditions and situations that cause them;
- how weak and deficient policies and procedures can lead to human errors; and
- how to improve and optimise procedures, workplace design and process design to improve human performance.

Team working and communication have been highlighted as essential for patient safety during surgery.²² As part of a major drive to improve the safety of surgery around the world, in June 2008 the World Health Organisation launched its Safe Surgery Save Lives initiative,²³ which has introduced a new safety checklist for surgical teams, to reduce surgical errors and improve patient safety. The checklist, which is being piloted in England at St Mary's Hospital London, identifies three stages to an operation, and a checklist coordinator confirms that specified tasks have been completed, before the team proceeds to the next stage. The three stages are:

- **'Sign In'**, before anaesthesia, in which patient identity and the site of surgery are confirmed and any known risks in terms of allergy, airway or bleeding are confirmed;
- **'Time Out'**, before skin incision, in which all team members introduce themselves by name and role, the patient and site of surgery are again confirmed and any anticipated critical events are identified and discussed; and
- **'Sign Out'**, before the patient leaves the operating room, in which the name of the procedure is recorded, all instruments are accounted for and the team reviews any concerns for recovery and management of the patient.

This approach to safer surgery sets a context in which the safe conduct of CPB within cardiac surgery can be set, and embedded in local practice. In implementing this approach it is critical that senior staff members such as consultants are involved or they clearly designate a team member with an appropriate level of responsibility.

²² Commission for Health Improvement (2000) *The Commission for Health Improvement Investigation into Carmarthen NHS Trust*. Report to the Assistant Minister for Health and Social Services for the National Assembly for Wales; Committee on Orthopaedic Practice and Economics. The Canadian Orthopaedics Association. *Position Paper on Wrong Sided Surgery in Orthopaedics*

²³ <http://www.npsa.nhs.uk/corporate/news/safe-surgery-saves-lives/>

Quality Management System and Framework: Assuring a Safe Service

It is the duty of an NHS Board, whether a commissioner or provider of services, to enable and ensure the delivery of healthcare and health improvement within the law and without causing harm.²⁴ Under the Corporate Manslaughter and Homicide Act 2007 (the CMA 2007), which came substantially into force on 6 April 2008, organisations, including those in the NHS and other public service providers, are explicitly more accountable for deaths caused by their failings, including systems failures (see Annex A).

Commissioners and providers need to provide a framework of good governance within which NHS organisations can thrive and grow. This guide focuses principally on the systems and processes required in the NHS and of any provider organisation providing NHS commissioned care to assure the safest possible clinical perfusion practice, which will give assurance to the patient and members of the cardiac surgery team that the patient is entering a safe system when going on and off CPB. It sets out a quality management framework of operational systems and processes which NHS Boards (or equivalent) should ensure are in place for clinical perfusion services, which needs to be communicated widely and effectively, and both implemented and adhered to.

NHS Trust Board responsibilities

Throughout the provider NHS Trust, from the Board and its Committees, including the Audit Committee, right through to teams, practitioners (including non-clinical staff) and managers working directly with patients and their families/carers, there should be an awareness of all internal controls, particularly risk management and clinical governance.²⁵ NHS Boards need to satisfy themselves that the requisite controls and actions are in place to mitigate risk and improve quality.

As an employer, the NHS provider organisation should, in accordance with the DH letter, require all perfusionists in its employment whether permanent members of staff or locums to be accredited by the SCPS and members of the CCPS professional (non statutory) register. Their qualifications and registration status should be checked (especially at the start of employment) and monitored regularly. The relevant Board, through its executives, should also ensure that staffing levels are appropriate and in line with the SCPS Code of Practice²⁶ and that all clinical perfusionists including locums are appropriately trained (including in the use and safe handling of medicines) and properly inducted in the Quality Management System and its component parts. Appraisals should be undertaken in line with national and local policies and procedures and time needs to be made available for continuing professional development (CPD).

²⁴ Appointments Commission/Department of Health (2003) *Governing the NHS: A Guide for NHS Boards*

²⁵ Appointments Commission. *Governing the NHS: A Guide for NHS Boards*. London

²⁶ For the SCPS Code of Practice, see <http://www.scps.org.uk>. See also SCPS (1999) *Standards of Practice and Society of Perfusionists of Great Britain and Ireland*, London 1999; SCPS, ACTA, SCTS (2007) *Recommendations for Standards of Monitoring during Cardiopulmonary Bypass*. The Society of Clinical Perfusion Scientists of Great Britain and Ireland, Association of Cardiothoracic Anaesthetists, Society for Cardiothoracic Surgery in Great Britain and Ireland. London at <http://www.scps.org.uk>

Governance of clinical perfusion services

The governance of clinical perfusion services should reflect best practice within the provider organisation, and should be monitored and reported through the local clinical governance structures. Clinical perfusionists should have clear job descriptions, with both managerial and professional accountabilities made explicit. The Departmental Head should have a clear line of professional accountability within the cardiac surgical service.

Promotion of a safety culture is paramount. On induction into employment, clinical perfusionists should be trained in critical incident reporting procedures, with a clear culture of alerting and reviewing any significant incidents. The clinical perfusion department should appoint a lead clinical perfusionist for safety who will undertake further training in root cause analysis, risk register maintenance and provide local expertise in incident investigation. High risk or serious untoward incidents in clinical perfusion should be appropriately reported both locally (to the Clinical Governance Committee or equivalent) and to relevant national bodies including the NPSA and the Safety Committee of the SCPS and be fully investigated. The lead clinical perfusionist for safety should understand the assurance reporting mechanisms of the Trust and be confident to raise issues with the Corporate Safety, Assurance and/or Clinical Governance Committees and Patient Safety Lead.

Participation in audit and incident reviews should be mandated for all departments and there should be an annual internal clinical audit review and report of the clinical perfusion service to the Clinical Governance Committee. Any perioperative cardiac mortality reviews should include clinical perfusion input and opinion. The risk register for the cardiac surgery department should include clinical perfusion risks with a clear departmental mitigation strategy. Deaths attributed to clinical perfusion clinical incidents should be reported to the NPSA's National Reporting and Learning System through local protocols.

Quality Management Framework for Clinical Perfusion Services

Based on available evidence and expert professional opinion it is recommended that a Quality Management Framework is implemented for clinical perfusion services which should include the following:

1 Framework document

A Quality Management Framework should be established in the form of a system and a Quality Manual, which meets at least the Standards of Practice and Codes of Practice of the SCPS and is written down, widely available and approved by the Trust Board. The Framework should make it clear that the interests of the patient are paramount at all times, and set out all the controls and procedures which need to be followed to ensure best practice and to minimise risk. It should also set out what the provider organisation expects, as an employer, of its clinical perfusionists in terms of standards of practice and CPD. The Quality Manual should contain separate sections for component parts of the Framework, and should be sufficiently precise and clear to avoid ambiguity. Adherence to the protocols should be regularly audited and be part of the annual report to the Clinical Governance Committee.

The Framework and Quality Manual should include:

2 Standard Operating Procedures (SOPs)

The Standard Operating Procedures (SOPs) should set out:

- their aims and scope;
- responsibility for adherence/compliance;
- frequency of operation;
- safety measures to be taken;
- clear description of the procedure, including equipment and with reference to Annex B the local medicines management agreements on strengths of solutions and drug doses to be used;
- clear definition of who is competent to undertake which procedures, specifically identifying what is within the competence of trainees and roles, responsibilities and accountabilities of the whole clinical perfusion team;
- records to be kept, including that the equipment has been checked, where appropriate calibrated and quality assured as well as the physiological parameters to be monitored, and signed for each procedure; and
- they will be reviewed not less than annually.

There should be robust version control of SOPs, which should be signed off by the Clinical Governance Committee. If there are different clinical requirements (solutions, drugs) for different anaesthetists or surgeons, which should in the interests of safety be minimised, there should be a separate protocol for each, and for each routine or most commonly practiced clinical perfusion procedure. There should be separate SOPs for adult and paediatric patients.

There need to be clear SOPs for different procedures, including (but not limited to):

A Cardiopulmonary bypass (CPB)

- setting up and priming the equipment pre-bypass;
- initiation of CPB (including pre bypass checklist);
- administration of prescribed fluids and drugs during CPB;
- conduct of CPB (including target ranges for physiological parameters, anticoagulation, flow rates);
- cardioplegia (including fluid and medicine volumes and doses);
- haemofiltration;
- hypothermic Circulatory Arrest;
- emergency procedures (including power failure, pump failure, oxygenator failure, massive air embolus); and
- weaning from CPB and resumption of natural circulation.

SOPs need to be in place for the following if practiced by the clinical perfusion department:

B Additional practices

- off pump surgery conversion to CPB;
- autologous blood salvage;
- limb perfusion;
- left heart bypass;
- minimally invasive (percutaneous) bypass;
- miniaturised extracorporeal circulation (minibypass);
- liver perfusion;
- platelet gels;
- retrograde cerebral perfusion; and
- selective antegrade cerebral perfusion.

C Prolonged Mechanical Circulatory Support

- Ventricular Assist Device (VAD);
- Extra Corporeal Membrane Oxygenation (ECMO);
- Extra Corporeal Life Support (ECLS); and
- Intra Aortic Balloon Counterpulsation Therapy (IABP).

3 Risk assessment

Clinical perfusion is a complex practice with recognised inherent risks. Local practices, procedures or circumstances which potentially increase these risks need to be identified, assessed and rated with mitigating action identified. Such risks need to be placed on the risk register of the provider organisation and reported through the Clinical Governance, Risk and/or Audit Committees, depending on local arrangements. A risk workshop involving as many members of the team as possible, to ensure that all risks are understood and agreed across the team may be useful.

4 Systematic checking and recording

There should be a clear requirement to check each component of CPB before its operation. A standard checklist should be designed and checks of the individual components recorded on the sheet, and signed by the clinical perfusionist. At the 'Sign Out' stage of surgery, any equipment problems should be recorded. Equipment should be maintained on a regular basis, any action required clearly documented and always used in accordance with the instructions and recommendations of the manufacturer.

5 Medicines management: clinical perfusion protocols, PSDs

As outlined earlier in this document, until clinical perfusionists are regulated by statute, they cannot be considered for exemptions under medicines legislation. Even when regulated by statute, further public consultation and further amendments to legislation are required before a profession can be considered for exemption, and appropriate education and training needs to be developed and commissioned. It is clear in law that clinical perfusionists cannot administer POMs for parenteral administration unless they are following directions from a prescriber for the patient concerned. Where possible, those directions should be written and signed prior to administration.

To aid best practice and compliance with the law, a provider of clinical perfusion services must therefore have a set of agreed clinical perfusion medicine management protocols which are common to a group of patients. There should be separate protocols for adult and paediatric practice.

Protocols should be developed for the following three areas:

- the CBP priming fluid (including doses, volumes and strengths, of medicines and fluids to be added by the clinical perfusionist);
- drugs which are routinely added to the CPB circuit by the clinical perfusionist during or at termination of CPB. The medicine management protocols may include a dose range. The clinical perfusionist may only work outside the dose range under direct instruction from an appropriate prescriber; and

- additional drugs which may be initiated by the anaesthetist and/or the surgeon as part of a response to changes in the clinical condition of the patient and added to the CPB circuit by the clinical perfusionist.

Annex B provides a Framework for the Administration of Named Medicines, which can be used as a guide to the development of local protocols involving all relevant members of the cardiac surgical team, clinical perfusionists and pharmacy for approval by both the Trust's Medicines Management Group or equivalent (in any other provider organisation of NHS commissioned care) and the Clinical Governance Committee. The agreed medicine management protocols should then be signed by all practicing cardiac anaesthetists, cardiac surgeons and clinical perfusionists. If individual clinicians have different preferences, these should be clearly set out in additional clinician-specific protocols and approved by the Medicines Management Group or equivalent. The internal protocols should be regularly reviewed and updated and be guided by any changes to the overarching Framework for the Administration of Named Medicines following ongoing review by the Society for Cardiothoracic Surgery in Great Britain and Ireland (SCTS) and the Association of Cardiothoracic Anaesthetists (ACTA) led by CCPS. Where relevant, clinical perfusion medicines management protocols should also take account of legal requirements in respect of the administration of Controlled Drugs, including approval by the organisation's Accountable Officer for Controlled Drugs.

Individual PSDs for each patient, to be followed by the clinical perfusionist, can be based on the agreed "common" medicine management protocols. At the team discussion before the cardiac procedure is commenced, the decision should be made as to which protocol will be followed for that specific patient, and this will then become the PSD. This decision should be ultimately made, recorded and signed by both surgeon and anaesthetist in the patient's records prior to commencement of the procedure.

The PSD should be clear and explicit in respect of agents, doses and dose ranges to be used during CPB. Annex B sets out a framework to inform local PSD discussions about agents and medicines. Any medicine or fluid used that is not detailed in the PSD must be individually prescribed by the anaesthetist or surgeon. In the course of an operation, if the written directions need to be departed from or supplemented by a verbal direction, this should be signed and recorded in the patient's records by the prescriber as well as being documented on the clinical perfusion record.

The clinical perfusionist should follow the PSD under the direction of the cardiac anaesthetist and/or surgeon. However, the anaesthetist remains responsible for ensuring that patients are adequately anaesthetised before, during and after surgery. The PSDs can be standardised and printed where appropriate, with space to include the patient's identifying details (name, date of birth, hospital registration number, NHS Number) and precise drug dosages administered during CPB. It is best practice that this record is signed by the clinical perfusionist and anaesthetist and surgeon, and a record of the PSD must be available in the patient's notes.

Following the development of local medicine management protocols, written PSDs should be in place before administration of the medicine or fluid, even though by law such directions can be verbal. In the context of clinical perfusion, it is expected that verbal directions for administration will be confined normally to emergency situations or situations in which, in the course of surgery, a different approach to treatment needs to be taken. However, it is best practice for the medicine or fluid to be checked before administration if at all possible, and the direction must be clearly recorded and signed by the prescriber in the patient's notes, as soon as possible thereafter.

It is recognised that activities other than CPB undertaken by clinical perfusionists may involve the use of medicines and in such circumstances the principles outlined above should apply and local PSDs and arrangements should be put in place.

For all types of mechanical circulatory support that may be practiced within a unit including extra corporeal membrane oxygenation (ECMO), extra corporeal life support (ECLS) and ventricular assist device (VAD), there should be a Quality Management System in place including relevant SOPs, Medicine Management protocols and identification of clinical roles and responsibilities.

To ensure that clinical perfusionists are supported and developed to undertake the responsibilities outlined above, appropriate education and training in the safe use of medicines and their side effects should be provided.

6 Teamwork and human factors training

All those involved in cardiac surgery should undergo compulsory training in teamwork, human factors 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.

7 Peer review

A review of all incidents should be conducted and an annual review and audit undertaken to ensure compliance with the Quality Management Framework which could form part of annual report of the clinical perfusion to the Trust Board (or equivalent). This may also facilitate and support the annual submission of outcome data to the Society for Cardiothoracic Surgery National Database for acquired heart disease and the Central Cardiac Audit Database for congenital heart disease.

Periodically it may be good practice for such a review to be undertaken by peers external to the Trust (or equivalent) based on guidelines published by CCPS. This will help to ensure that this Good Practice Guide is being followed and implemented. Consideration should also be given on how best to draw on externally available specialist expertise with proportionality in mind. This could be facilitated by the cardiac service network within which the service is located. The outcome of such a review should be documented in the Annual Report.

Implementation Requirements

Implementation of the good practice outlined in this document and the establishment of a Quality Management Framework will require concerted action from individual bodies and organisations. It is vital that all parties are clear about their roles, responsibilities and accountabilities in respect of clinical perfusion services.

Service commissioners

Service commissioners should specify that all providers of clinical perfusion services, whether NHS organisation or from the independent sector, should have a Quality Management Framework and System and effective governance arrangements for clinical perfusion services and seek evidence that the Quality Management Framework and System and governance arrangements are adhered to.

Trust Boards

One role of the Board is to provide active leadership, within a framework of prudent and effective controls, which enable risk to be assessed and managed. Legally there is no distinction between the Board duties of executive and non-executive directors: they all share responsibility for the direction and control of the organisation. Each needs to be personally assured of safe clinical perfusion practice within the Trust, and specifically they should ensure that:

- all clinical perfusionists employed by and/or providing clinical perfusion services within the Trust have been appropriately educated and trained, are accredited by and professionally registered with the College of Clinical Perfusion Scientists (CCPS) and perform the requisite minimum number of clinical perfusions per annum to maintain competence;
- all staff understand the legal implications for their practice of the Medicines Act 1968 and associated secondary legislation and of the Misuse of Drugs Regulations 2001 concerning the possession, administration and destruction of controlled drugs;
- there is a Quality Management Framework and System in place for the delivery of clinical perfusion services, with a Manual which includes Standard Operating Procedures and a Risk Assessment Framework which have been approved by relevant Trust (or equivalent) Committees;
- audit and review of compliance with the Quality Management System is undertaken annually and included within an annual report and a periodic review of clinical perfusion practice is established, based on the guidelines published by the CCPS;²⁷ and
- cardiac surgical teams receive training in team work and human factors.

²⁷ CCPS Visitor Guidelines – forthcoming

Clinical Governance Committees

The Clinical Governance Committee should receive an annual report of the clinical perfusion service, routine audit reports of compliance with the Quality Management Framework and its SOPs, and reports of adverse incidents in clinical perfusion if and when they occur. Specifically it should ensure that:

- Quality Management Systems and procedures for clinical perfusion services, including a Manual which includes Standard Operating Procedures, a Risk Assessment Framework and a Framework for the Administration of Named Medicines with clinical perfusion protocols which have been approved by the Medicines Management Group (or equivalent), are established, approved, complied with and audited annually;
- a periodic review of clinical perfusion practice is undertaken, based on the guidelines published by the CCPS; and
- incident reporting, investigation and subsequent learning requirements are followed and adhered to and any change in practice required is both introduced and audited.

Medicines Management Group/Committee

The Medicines Management Group or equivalent should:

- use the suggested Framework for the Administration of Named Medicines in Annex B as a basis for the development of local clinical perfusion protocols in conjunction with clinical perfusionists and members of the cardiac surgical team;
- approve and regularly review all medicines and fluids protocols for clinical perfusion services, and Patient Specific Directions;
- seek external peer review of those protocols, where appropriate; and
- receive regular audit reports on the use and recording of medicines during clinical perfusion, and specifically during unplanned procedures in emergency situations.

Individual professional practitioners

Individual professionals within the multi-disciplinary cardiac surgical team should:

- ensure that they adhere to best practice and deliver a legal and safe service;
- ensure that they understand the legal implications for their practice of the Medicines Act 1968 and associated secondary legislation and of the Misuse of Drugs Regulations 2001, concerning the possession, administration and destruction of controlled drugs;
- ensure that they adhere to the Code and Standards of Practice of their professional body and/or regulatory council;
- raise concerns if they feel that the systems and processes within which they work, or individual colleagues, are compromising patient safety;
- undertake CPD to ensure that they keep up to date with clinical, technological and service developments and the requirements of revalidation; and

- record and regularly review clinical perfusion practice together across the whole cardiac surgical team.

Cardiac service networks

Cardiac service networks could play a positive role in enabling the sharing of best practice, protocols and SOPs, and arranging and supporting external peer review of clinical perfusion services.

Professional bodies

The relevant professional bodies should:

- define and regularly review professional Standards of Practice working in collaboration with each other;
- facilitate discussion and sharing of best practice; and
- ensure that all practitioners on relevant professional registers (statutory and non-statutory) have reached the required levels of knowledge, skills and competences for registration and revalidation as appropriate, and have performed the minimum number of procedures required (where relevant).

In addition, the CCPS should:

- ensure that requirements for continuing professional development are explicit, and that those on the CCPS register have provided evidence of compliance with those requirements; and
- in respect of accreditation of service and/or training, have a robust inspection and approval system involving peer review.

If all stakeholders implement the recommended actions set out above, any risks associated with the administration of medicines by clinical perfusionists will be minimised. It will also ensure that these services continue to deliver high quality care for cardiac patients within the multidisciplinary surgical team.

Conclusion

This document sets out in detail, guidance on good practice in the provision of clinical perfusion services and the administration of drugs by clinical perfusionists. It clarifies the roles and responsibilities of all parties and stakeholders. Clinical perfusion is a key aspect of cardiac surgery, which is now common place. To ensure the best standards of care, and to minimise risk to patients, this Good Practice Guide is commended to NHS commissioners and providers of clinical services, and to the professionals and their professional bodies.

The Department of Health is very grateful to the members of the Clinical Perfusion Working Group for their sustained commitment and significant contribution to the development of this Good Practice Guide and to their professional societies for their endorsement. Details of the Working Group membership are below. Further details of the relevant professional societies' policies are available at:

The Society of Clinical Perfusion Scientists of Great Britain and Ireland (SCPS)
The College of Clinical Perfusion Scientists of Great Britain and Ireland (CCPS)
www.scps.org.uk

The Association of Cardiothoracic Anaesthetists (ACTA)
www.acta.org.uk

The Society for Cardiothoracic Surgery in Great Britain and Ireland (SCTS)
www.scts.org.uk

Clinical Perfusion Working Group Membership

Professor Sue Hill PhD DSc CBIol FIBiol Hon MRCP OBE
Chief Scientific Officer
Department of Health

Professor Roger Boyle CBE
National Director for Heart Disease and Stroke
Department of Health

Dr Donna L Greenhalgh MB.ChB., FRCA
Consultant Anaesthetist
University of South Manchester Hospital
Association of Cardiothoracic Anaesthetists committee member

Dr David Smith, BMedSci, DM, FRCA
Consultant Anaesthetist
Southampton General Hospital and Senior Lecturer in Anaesthesia
Representing the Association of Cardiothoracic Anaesthetists

Mr Timothy J Jones MD FRCS(CTh)
Consultant Paediatric Surgeon

Birmingham Children's Hospital
Representing the Society for Cardiothoracic Surgeons in Great Britain and Ireland

Mr Malcolm Dalrymple-Hay
Representing the Society for Cardiothoracic Surgeons in Great Britain and Ireland

Stephen Robins PgDip AACPSCPS
Registrar and Chairman of Education Training
Clinical Perfusion Department
Heart and Lung Centre
New Cross Hospital
Wolverhampton WV10 0QP

Robin Jones
Guys and St Thomas's Hospitals NHS Foundation Trust
Chair, Society of Clinical Perfusion Scientists

Professor Maggie Pearson MA PhD Hon MFPH
Director
MAGGIE PEARSON Solutions

Dr Jonathan Sheffield OBE MBChB FRCPath
Medical Director
University Hospitals Bristol NHS Foundation Trust

Sian Thomas
Director
NHS Employers

Sue Dodd
Department of Health

Patricia Saunders
Department of Health

Annex A

Corporate Manslaughter

Under the Corporate Manslaughter and Homicide Act 2007 (the CMA 2007), which came substantially into force on 6 April 2008, organisations, including those in the NHS and other public service providers, are explicitly more accountable for deaths caused by their failings, including systems failures. The CMA 2007 puts the law on corporate manslaughter onto a new footing, setting out a new statutory offence. It does not create new duties. These duties are already owed in the civil law of negligence: the new offence is based on these.

In summary, an organisation is guilty of the new offence if the way in which its activities are managed or organised causes a death and amounts to a gross breach of a relevant duty of care to the deceased, as manifest in the organisation's systems and processes, and/or their implementation.

A breach is defined as "gross" if it can be shown to fall far short of the standard which could be reasonably expected. A duty of care exists, for example, in respect of the systems of work and equipment used and in relation to products or services supplied to patients.

The offence is concerned with the corporate liability of the itself and does not apply to individual directors, senior managers or other individuals. Nor is it possible to convict an individual of assisting or encouraging the offence. However, it is important to note that individuals can already be prosecuted for gross negligence manslaughter and for health and safety offences. The CMA 2007 does not change this and prosecutions against individuals will continue to be taken where there is sufficient evidence and it is in the public interest to do so.

The CMA 2007 relates to how the fatal activity was managed or organised throughout the organisation, including any systems and processes for managing safety and how these were operated in practice, including the organisation's compliance with its legal health and safety responsibilities. Its health and safety culture will therefore come under scrutiny, in terms of the extent to which non-compliance is tolerated.

Of particular importance to NHS Boards is the specific requirement in CMA 2007 that the way in which the activities of the organisation are organised or managed by senior management²⁸ must be a major factor in the breach. Senior management is therefore potentially culpable for deficient systems, processes and practice. There is no need to demonstrate individual criminal liability.

Similarly, the degree to which organisational culture, systems and accepted practices encourage or tolerate failure or non-compliance with the policies and procedures of an organisation will be scrutinised. Whilst fines for NHS bodies, which will be paid from public money, may be relatively low, the Publicity Order following a successful conviction requires the organisation concerned to acknowledge publicly their shortcomings and to apologise for them. This would incur significant reputational risk for the Board and senior officers.

²⁸ Defined in section 1(4)(c) CMA 2007 as those persons who have a significant role in making or implementing decisions about how activities in all or a substantial part of the organisation are managed. This could therefore be a Chief Executive, Board member, or Divisional Manager/Clinical Director

Whilst complex systems and processes such as health care will always carry some risk, organisations can minimise their potential exposure to corporate manslaughter convictions by having clear policies and procedures in place, and ensuring that they are adhered to. Organisations must already comply with health and safety legislation: the CMA 2007 does not affect those requirements. However, the introduction of the new offence is an opportunity for organisations to satisfy themselves that systems and processes for managing health and safety are adequate. Compliance, therefore, needs to be clearly recorded, reported and audited. Risks need to be regularly assessed, managed and monitored by the provider's Audit Committee or equivalent.

Annex B

A Framework for the Administration of Named Medicines by Clinical Perfusion Scientists during Cardiopulmonary Bypass

Framework version: (where applicable)

Valid from

Expires

Background

This document provides a framework for the development of locally agreed drug protocols for the administration of named medicines during cardiopulmonary bypass (CPB). Within each cardiothoracic surgical unit a number of medicines management protocols will need to be developed for specific groups of patients and for variations in individual clinicians' practices. Prior to each operation it will be decided which protocol will be followed for each specific patient. Separate protocols must be in place for adult and paediatric practice.

The development of the medicines management protocols should be the responsibility of a designated group consisting of an anaesthetist, cardiac surgeon, chief clinical perfusionist and hospital pharmacist. The agreed medicines management Protocols should then be approved by the Medicines Management Group or equivalent of the Trust and the Clinical Governance Department and Committee. Once approved the protocols must be read, signed and dated by all the Trust's anaesthetists, clinical perfusionists and surgeons practicing within the unit and be an integral part of Standard Operating Procedures and the Quality Management Framework. Adherence to the guidelines in this Framework, and their utility in clinical practice should be regularly audited and reviewed.

The medicines management protocols should be reviewed and updated on an annual basis.

It must be emphasised that this document is a framework to act as a guide for the development of local protocols. The framework outlines the range and depth of information that should be detailed in all local drug administration protocols. The drugs, form, strength and dose range will need to represent and cover local practices.

Team Working

Team working and communication have been highlighted as essential for patient safety during surgery.²⁹ As part of a major drive to improve the safety of surgery around the world, in June 2008 the World Health Organisation launched its Safe Surgery Save Lives initiative,³⁰ which has introduced a new safety checklist for surgical teams, to reduce surgical errors and improve patient safety. The checklist, which is being piloted in England at St Mary's Hospital London, identifies three stages to an operation, and a checklist coordinator confirms that specified tasks have been completed, before the team proceeds to the next stage. The three stages are:

- **'Sign In'**, before anaesthesia, in which patient identity and the site of surgery are confirmed and any known risks in terms of allergy, airway or bleeding are confirmed;
- **'Time Out'**, before skin incision, in which all team members introduce themselves by name and role, the patient and site of surgery are again confirmed and any anticipated critical events are identified and discussed; and
- **'Sign Out'**, before the patient leaves the operating room, in which the name of the procedure is recorded, all instruments are accounted for and the team reviews any concerns for recovery and management of the patient.

This approach to safer surgery provides a context in which the safe conduct of CPB can be set.

²⁹ Commission for Health Improvement (2000) *The Commission for Health Improvement Investigation into Carmarthen NHS Trust*. Report to the Assistant Minister for Health and Social Services for the National Assembly for Wales; Committee on Orthopaedic Practice and Economics. The Canadian Orthopaedics Association. *Position Paper on Wrong Sided Surgery in Orthopaedics*

³⁰ <http://www.npsa.nhs.uk/corporate/news/safe-surgery-saves-lives/>

Suggested approval list:

CLINICAL PERFUSION MANAGER

Name _____

Signature _____

Date

LEAD CARDIAC ANAESTHETIST

Name _____

Signature _____

Date

LEAD CARDIAC SURGEON

Name _____

Signature _____

Date

PHARMACY MANAGER

Name _____

Signature _____

Date

CLINICAL GOVERNANCE LEAD

Name _____

Signature _____

Date

CLINICAL DIRECTOR

Name _____

Signature _____

Date

This framework applies to the following clinical perfusion scientists who must be registered with the College of Clinical Perfusion Scientists of Great Britain and Ireland.

I have read and understand this framework and agree to use it.

Name _____

Date

Signature

CCPS Registration No: _____

Name _____

Date

Signature

CCPS Registration No: _____

Name _____

Date

Signature

CCPS Registration No: _____

Name _____

Date

Signature

CCPS Registration No: _____

Name _____

Date

Signature

CCPS Registration No: _____

Name _____

Date

Signature

CCPS Registration No: _____

Name
Date
Signature
CCPS Registration No:

Name
Date
Signature
CCPS Registration No:

This Framework has been agreed by the following cardiac surgeons and cardiac anaesthetists

Name
Date
Signature
GMC Registration No:

Name
Date
Signature
GMC Registration No:

Name
Date
Signature
GMC Registration No:

Name
Date
Signature
GMC Registration No:

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GMC Registration No:

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GMC Registration No:

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GMC Registration No:

Name
Date
Signature
GMC Registration No:

This framework applies to the following list of prescription-only medicines (POM), routinely used during CPB at the direction of an appropriate prescriber. The list includes:

- medicines added to the CPB circuit prime;
- medicines administered during CPB according to protocol; and
- medicines administered on the direction of the surgeon or anaesthetist in specific or emergency situations.

There are separate lists for adults and children, with the relevant dose ranges.

The medicines on this list are subject to annual update . Other medicines may be given on the direction of the anaesthetist or surgeon. When these directions need to be given orally, they should be written subsequently in the patient's notes and in the clinical perfusion record. Where this occurs regularly, the medicine will be added to this list and therefore be included in the annual update.

Medicines for adults

Group A: Medicines added to the CPB circuit prime

Gelatin Solution (eg. Gelofusine)	Plasmalyte A Solution
Hartmann's Solution	Ringer's Solution
Heparin Sodium	Sodium Bicarbonate
Mannitol	Starch Solution (eg. Voluven)

Group B: Medicines administered during CPB according to protocol

Calcium Chloride	Phenylephrine
Gelatin Solution (eg. Gelofusine)	Plasmalyte A Solution
Hartmann's Solution	Potassium Chloride
Heparin	Ringer's Solution
Mannitol	Sodium Bicarbonate
Metaraminol	Sodium Chloride 0.9%
Phentolamine	

Group C: Medicines administered on the direction of Surgeon or Anaesthetist

Amiodarone	Magnesium Sulphate
Aprotinin	Methyl Prednisolone
Cardioplegia	Milrinone
Dexamethasone	Noradrenaline
Furosemide	Sevoflurane
Insulin	Thiopental
Isoflurane	Tranexamic Acid

Any medicine administered under this framework must be recorded on the clinical perfusion record and/or the anaesthetic record in accordance with unit protocols. Blood or blood products should only be administered in accordance with local transfusion policies and in accordance with standard operating procedures/unit protocols.

In the following descriptions, the dose range and maximum dose information pertain only to use of the medicine during CPB.

Adults Group A: Medicines added to the CPB circuit prime

In the following descriptions, the dose range and maximum dose information pertain only to use of the medicine during priming of the circuit. Refer to SOP for priming of CPB circuit.

Medicine	GELATIN SOLUTION (eg. GELOFUSINE)
Legal Status	POM
Form And Strength	Intravenous infusion 4% in 500 ml and 1000 ml bags. Also contains Na ⁺ 154 mmol and Cl ⁻ 120 mmol per litre.
Indications	CPB prime.
Contra-Indications	Susceptibility to circulatory overload.
Dose Range	500-1000 ml of a 4% solution.
Maximum Dose	Hypersensitivity reactions may occur including, rarely, severe anaphylactoid reactions.
Acute Side-Effects	Hypersensitivity reactions may occur including, rarely, severe anaphylactoid reactions.

Medicine	HARTMANN'S SOLUTION
Legal Status	POM
Form And Strength	Compound Sodium Lactate intravenous infusion 1000 ml. Each litre contains: Na ⁺ 131 mmol, K ⁺ 5 mmol, Ca ⁺⁺ 2 mmol, Cl ⁻ 111 mmol, lactate 29 mmol.
Indications	CPB prime.
Contra-Indications	Severe hepatic damage, respiratory alkalosis, or any condition where plasma lactate is elevated.
Dose Range	Up to 2 L of Hartmann's solution is used in the priming solution of the bypass circuit.
Acute Side-Effects	Rare. Anaphylactic/anaphylactoid reactions, urticaria, skin rashes and pruritus. Chest tightness, chest pain with tachycardia or bradycardia. Nasal congestion, coughing, sneezing, bronchospasm and difficulty in breathing have been reported.

Medicine	HEPARIN SODIUM
Legal Status	POM
Form And Strength	Injection 1000 units/ml in 5 ml, 10 ml or 20 ml ampoules.
Indications	Anticoagulation.
Contra-Indications	Haemophilia and other haemorrhagic disorders, thrombocytopenia, recent cerebral haemorrhage.
Dose Range	5000 units.
Acute Side-Effects	Haemorrhage, thrombocytopenia.

Adults Group A

Medicine	MANNITOL
Legal Status	POM
Form And Strength	Intravenous infusion 10% and 20% in 500 ml bags.
Indications	Osmotic diuretic.
Contra-Indications	Pulmonary oedema. Check bags of 20% for mannitol crystals before use.
Dose Range	0.5-1.0 g/kg.
Maximum Dose	200g.
Acute Side-Effects	Chills, fever.

Medicine	PLASMALYTE A SOLUTION
Legal Status	POM
Form And Strength	500 or 1000 ml plastic container. 1000 ml contains 140 mmol Na ⁺ , 5 mmol K ⁺ , 3 mmol Mg ²⁺ , 98 mmol Cl ⁻ , 27 mmol acetate, and 23 mmol gluconate.
Indications	CPB prime.
Contra-Indications	None; caution in renal failure, hyperkalaemia.
Dose Range	500-2000 ml in circuit prime.
Maximum Dose	Fever, phlebitis, thrombosis.
Acute Side-Effects	Hypersensitivity reactions, thromboembolism, electrolyte disturbance.

Medicine	RINGER'S SOLUTION
Legal Status	POM
Form And Strength	Ringer's Solution intravenous injection 500 ml or 1 L bags. Each litre contains: Na ⁺ 147 mmol, K ⁺ 4mmol, Ca ²⁺ 2.2 mmol, Cl ⁻ 156 mmol.
Indications	CPB prime.
Contra-Indications	None.
Dose Range	Up to 2 L of Ringer's solution may be used in the CPB prime.
Maximum Dose	Rare. Anaphylactic/anaphylactoid reactions, urticaria, skin rash and pruritus. Chest tightness, chest pain with tachycardia or bradycardia. Nasal congestion, coughing, sneezing, bronchospasm and difficulty in breathing have been reported.
Acute Side-Effects	Haemorrhage, thrombocytopenia.

Adults Group A

Medicine	SODIUM BICARBONATE
Legal Status	POM
Form And Strength	Injection BP 8.4% (1 mmol/ml in 50 ml glass syringe).
Indications	May be added to the CPB prime to adjust pH
Contra-Indications	Metabolic or respiratory alkalosis, hypocalcaemia, or hypochlorhydria.
Dose Range	Up to 50 mmol according to base deficit
Maximum Dose	None in this context
Acute Side-Effects	Rare. Anaphylactic/anaphylactoid reactions, urticaria, skin rash and pruritus. Chest tightness, chest pain with tachycardia or bradycardia. Nasal congestion, coughing, sneezing, bronchospasm and difficulty in breathing have been reported.

Medicine	STARCH SOLUTION (e.g. VOLUVEN)
Legal Status	POM
Form And Strength	Hydroxyethyl starch 6% solution in 500 ml bags. Each 1 L also contains Na ⁺ 154 mmol, Cl ⁻ 154 mmol. Solution has a pH of 4-5.5.
Indications	CPB prime.
Contra-Indications	Fluid overload including pulmonary oedema. Renal failure with oliguria or anuria. Patients receiving dialysis. Intracranial bleeding. Severe hypernatraemia or severe hyperchloraemia. Known hypersensitivity to hydroxyethyl starches.
Dose Range	500-800 ml are used in the prime.
Acute Side-Effects	Rarely, anaphylactoid reactions. Bradycardia, tachycardia, bronchospasm, non-cardiac pulmonary oedema. Pruritus. Haemodilution and coagulation disturbances. Acidosis.

Adults Group B: Medicines administered during CPB according to protocol

Medicine	CALCIUM CHLORIDE
Legal Status	POM
Form And Strength	Injection 10% 100 mg/ml (Ca ²⁺ 0.68 mmol/ml). Injection 13.4% 134 mg/ml (Ca ²⁺ 0.9 mmol/ml).
Indications	Acute hypocalcaemia.
Contra-Indications	Conditions associated with hypercalcaemia and hypercalciuria (e.g. some forms of malignant disease).
Dose Range	5-10 ml of either strength solution.
Target Range	Serum Ca ²⁺ 1.1-1.4 mmol/L.
Acute Side-Effects	Peripheral vasodilatation, hypotension.

Adults Group B

Medicine	GELATIN SOLUTION (eg. GELOFUSINE)
Legal Status	POM
Form And Strength	Intravenous infusion 4% in 500 ml and 1000 ml bags. Also contains Na ⁺ 154 mmol and Cl ⁻ 120 mmol per litre.
Indications	Low circulating volume.
Contra-Indications	Susceptibility to circulatory overload.
Dose Range	Initially 200 ml of a 4% solution.
Maximum Dose	Administered according to clinical need. The usual maximum volume added during adult bypass is 2 L, although much larger volumes may be required in some procedures (e.g. dissecting aneurysm).
Acute Side-Effects	Hypersensitivity reactions may occur including, rarely, severe anaphylactoid reactions.

Medicine	HARTMANN'S SOLUTION
Legal Status	POM
Form And Strength	Compound Sodium Lactate intravenous infusion 1000 ml. Each litre contains: Na ⁺ 131 mmol, K ⁺ 5mmol, Ca ⁺⁺ 2 mmol, Cl ⁻ 111 mmol, lactate 29 mmol.
Indications	Low circulating volume.
Contra-Indications	Severe hepatic damage, respiratory alkalosis, or any condition where lactate level is elevated.
Dose Range	Repeated bolus doses of 200 ml.
Maximum Dose	Administered repeatedly according to clinical need, with a usual maximum of 3 L.
Acute Side-Effects	Rare. Anaphylactic/anaphylactoid reactions, urticaria, skin rashes and pruritus. Chest tightness, chest pain with tachycardia or bradycardia. Nasal congestion, coughing, sneezing, bronchospasm and difficulty in breathing have been reported.

Medicine	HEPARIN SODIUM
Legal Status	POM
Form And Strength	Injection 1000 units/ml in 5 ml, 10 ml or 20 ml ampoules.
Indications	Anticoagulation.
Contra-Indications	Haemophilia and other haemorrhagic disorders, thrombocytopenia, recent cerebral haemorrhage.
Dose Range	5000 unit bolus if ACT < 400 s.
Maximum Dose	Seek medical advice.
Acute Side-Effects	Haemorrhage, thrombocytopenia.

Adults Group B

Medicine	MANNITOL
Legal Status	POM
Form And Strength	Intravenous infusion 10% and 20% in 500 ml bags.
Indications	Osmotic diuretic.
Contra-Indications	Pulmonary oedema. Check bags of 20% for mannitol crystals before use.
Dose Range	0.5-1.0 g/kg.
Maximum Dose	200 g.
Acute Side-Effects	Chills, fever.

Medicine	METARAMINOL
Legal Status	POM
Form And Strength	Injection 10 mg/ml in 1ml ampoule.
Indications	Acute hypotension.
Contra-Indications	Hypertension, pregnancy.
Dose Range	Dilute 10 mg to 10 ml with normal saline. Give 0.5–1 mg as required.
Maximum Dose	20 mg then seek medical advice.
Acute Side-Effects	Tachycardia.

Medicine	PHEHTOLAMINE
Legal Status	POM
Form And Strength	Injection 10 mg/ml in 1 ml ampoule.
Indications	Acute hypertension.
Contra-Indications	Hypotension.
Dose Range	Dilute 10 mg to 10 ml in normal saline (1 mg/ml). Give 0.5–1.0 ml bolus, repeated as required.
Maximum Dose	20 mg then seek medical advice.
Acute Side-Effects	Tachycardia, dizziness, nausea vomiting.

Medicine	PLASMALYTE A
Legal Status	POM
Form And Strength	500 or 1000 ml plastic container. 1000 ml contains 140 mmol Na ⁺ , 5 mmol K ⁺ , 3 mmol Mg ²⁺ , 98 mmol Cl ⁻ , 27 mmol acetate, and 23 mmol gluconate.
Indications	Volume replacement; CPB circuit prime fluid.
Contra-Indications	None; caution in renal failure, hyperkalaemia.
Dose Range	200 ml bolus as required, usual maximum 2 L.
Acute Side-Effects	Fever, phlebitis, thrombosis.

Adults Group B

Medicine	POTASSIUM CHLORIDE
Legal Status	POM
Form And Strength	Injection 1.5 g (20 mmol K ⁺) in 10 ml ampoule. Injection 1 g (13.4 mmol K ⁺) in 10 ml ampoule.
Indications	To maintain serum potassium concentration during cardiopulmonary bypass.
Contra-Indications	Caution in patients with renal or adrenal insufficiency, cardiac disease, or extensive tissue destruction as in severe burns.
Dose Range	10-20 mmol potassium chloride.
Target Range	K ⁺ 4.5–5.5 mmol/L.
Maximum Dose	Total dose administered during cardiopulmonary bypass should not exceed 80 mmol.
Acute Side-Effects	Hyperkalaemia, with paraesthesia, muscle weakness, hypotension, cardiac arrhythmias and cardiac arrest.

Medicine	RINGER'S SOLUTION
Legal Status	POM
Form And Strength	Ringer's Solution intravenous injection 500 ml or 1 L bags. Each litre contains: Na ⁺ 147 mmol, K ⁺ 4 mmol, Ca ⁺⁺ 2.2 mmol, Cl ⁻ 156 mmol.
Indications	Ringer's Solution is a component of the cardioplegia solution, and may be used for volume replacement in the CPB circuit.
Contra-Indications	None.
Dose Range	200 ml bolus doses to maintain circulating volume. Up to 2 L of Ringer's Solution may be used in the delivery of cardioplegia.
Maximum Dose	Administered according to clinical need, with a usual maximum of 3 L to maintain circulating volume.
Acute Side-Effects	Rare. Anaphylactic/anaphylactoid reactions, urticaria, skin rash and pruritus. Chest tightness, chest pain with tachycardia or bradycardia. Nasal congestion, coughing, sneezing, bronchospasm and difficulty in breathing have been reported.

Medicine	SODIUM BICARBONATE
Legal Status	POM
Form And Strength	Injection BP 8.4% (1 mmol/ml) in 50 ml glass syringe.
Indications	Control of metabolic acidosis.
Contra-Indications	Metabolic or respiratory alkalosis, hypocalcaemia, or hypochlorhydria.
Dose Range	30-100 mmol.
Maximum Dose	100 mmol then seek medical advice.
Acute Side-Effects	Sodium bicarbonate injection 8.4% is hypertonic. Tissue necrosis may follow extravasation at the site of injection. Excessive administration of bicarbonate may lead to metabolic alkalosis, especially in patients with impaired renal function, and sodium overload.

Adults Group B

Medicine	SODIUM CHLORIDE 0.9%
Legal Status	POM
Form And Strength	Intravenous Infusion 0.9% in 500 ml or 1 L bags.
Indications	Used as a flush and washer in the cell saver and as the crystalloid component of cardioplegia.
Contra-Indications	None.
Dose Range	Not applicable.
Maximum Dose	Not applicable.
Acute Side-Effects	Not applicable.

Adults Group C: Medicines administered on the direction of surgeon or anaesthetist

Medicine	AMIODARONE
Legal Status	POM
Form And Strength	50 mg/ml in 3 ml ampoules.
Indications	Control of atrial and ventricular dysrhythmias.
Contra-Indications	Sinus bradycardia, sino-atrial heart block, thyroid dysfunction, iodine sensitivity, severe respiratory failure, circulatory collapse, severe arterial hypotension, pregnancy and breast-feeding.
Dose Range	300–450 mg.
Maximum Dose	See above.
Acute Side-Effects	Raised serum transaminases, bradycardia, cardiac depression, tremors, sleep disorders, photosensitivity.

Medicine	APROTININ
Legal Status	POM
Form And Strength	Injection 10,000 kiu/ml in 50 ml glass bottles.
Indications	Reduction of blood loss and blood transfusion in high risk surgery.
Contra-Indications	Known sensitivity to aprotinin. Specific consent required.
Dose Range	2 x 10 ⁶ kiu (200 ml) – usually into CPB prime. Given following 1 ml test dose to detect allergy.
Maximum Dose	As above.
Acute Side-Effects	Renal impairment, renal tubular necrosis, hypersensitivity reactions including anaphylaxis, very rarely disseminated intravascular coagulation.

Adults Group C

Medicine	CARDIOPLEGIA SOLUTION
Legal Status	POM
Form And Strength	300, 500 or 1000 ml bags containing Mg ²⁺ 20 mmol/L, K ⁺ 20 mmol/L and procaine.
Indications	Myocardial protection on CPB during aortic clamping.
Contra-Indications	None in this context.
Dose Range	See protocol.
Maximum Dose	Hyperkalaemia.
Acute Side-Effects	Not applicable.

Medicine	DEXAMETHASONE
Legal Status	POM
Form And Strength	Dexamethasone sodium phosphate 4 mg/ml in 2 ml glass vial.
Indications	Cerebral protection on CPB and during DHCA.
Contra-Indications	None in this context.
Dose Range	0.5-1.0 mg/kg.
Maximum Dose	Hyperglycaemia.
Acute Side-Effects	Not applicable.

Medicine	FUROSEMIDE (FRUSEMIDE)
Legal Status	POM
Form And Strength	Injection 10mg/ml in 2 ml ampoule.
Indications	Oedema, chronic heart failure.
Contra-Indications	Precomatose states associated with liver cirrhosis, renal failure with anuria.
Dose Range	20-50 mg.
Maximum Dose	100 mg.
Acute Side-Effects	Hyponatraemia, hypokalaemia, hypomagnesaemia, hypochloraemic alkalosis.

Medicine	INSULIN
Legal Status	POM
Form And Strength	Human insulin 100 units/ml in 10 ml glass vial.
Indications	Control of hyperglycaemia, emergency management of hyperkalaemia.
Contra-Indications	Hypoglycaemia.
Dose Range	5–10 unit bolus, repeated if required
Maximum Dose	20 units.
Acute Side-Effects	Hypoglycaemia, hypokalaemia.

Adults Group C

Medicine	ISOFLURANE
Legal Status	POM
Form And Strength	Glass bottles containing 100 or 250 ml liquid isoflurane.
Indications	Control of hypertension, myocardial protection.
Contra-Indications	Malignant hyperpyrexia.
Dose Range	0.5–3%, administered via dedicated vaporizer into sweep gas flow.
Maximum Dose	Isoflurane can dissolve the plastic components of the CPB circuit if spilled onto them. Scavenge exhaust gas and measure isoflurane concentration.
Acute Side-Effects	Hypotension due to vasodilation.

Medicine	MAGNESIUM SULPHATE
Legal Status	POM
Form And Strength	Injection 20% 0.2 g/ml in 20 ml ampoule.
Indications	Injection 50% 0.5 g/ml in 2, 5 or 10 ml ampoule.
Contra-Indications	Treatment of arrhythmias, especially in the presence of hypokalaemia.
Dose Range	Hepatic impairment, renal impairment.
Maximum Dose	1–5 g.
Acute Side-Effects	Nausea, vomiting, thirst, flushing of skin, hypotension.

Medicine	METHYL PREDNISOLONE
Legal Status	POM
Form And Strength	Methyl prednisolone sodium succinate dry powder in glass vials of 40 mg, 125 mg, 500 mg, 1 g or 2 g for reconstitution with water.
Indications	Raised intracranial pressure, cerebral oedema, cerebral protection during CPB or DHCA.
Contra-Indications	Hypertension.
Dose Range	0.5–1.5 g.
Maximum Dose	1.5 g.
Acute Side-Effects	Hypersensitivity reactions, thromboembolism, electrolyte disturbance, hyperglycaemia.

Medicine	MILRINONE
Legal Status	POM
Form And Strength	Injection 1 mg/ml in 10 ml ampoule.
Indications	Acute heart failure including low output states following heart surgery.
Contra-Indications	Hypertrophic cardiomyopathy, obstructive cardiac valvular disease.
Dose Range	50 µg/kg.
Maximum Dose	As above.
Acute Side-Effects	Chest pain, tremor, bronchospasm, anaphylaxis, rash.

Adults Group C

Medicine	NORADRENALINE
Legal Status	POM
Form And Strength	Injection 1 mg/ml in 4 ml ampoule.
Indications	Acute hypotension, cardiac arrest.
Contra-Indications	Hypertension.
Dose Range	Dilute 1 mg to 20 ml in normal saline (50 µg/ml). Give 1–2 ml, repeated as required.
Maximum Dose	1mg (20 ml solution) then seek medical advice.
Acute Side-Effects	Hypertension, headache, bradycardia, arrhythmias, peripheral ischaemia.

Medicine	SEVOFLURANE
Legal Status	POM
Form And Strength	Bottles containing 250 ml liquid sevoflurane.
Indications	Control of hypertension, myocardial protection.
Contra-Indications	Renal impairment, susceptibility to malignant hyperthermia.
Dose Range	0.5–3%, administered via dedicated vaporizer into sweep gas flow.
Maximum Dose	Sevoflurane can dissolve the plastic components of the CPB circuit if spilled onto them. Scavenge exhaust gas and measure sevoflurane concentration.
Acute Side-Effects	Hypotension due to vasodilation.

Medicine	THIOPENTAL (THIOPENTONE)
Legal Status	POM
Form And Strength	Glass vial containing 500 mg thiopentone powder for reconstitution.
Indications	Induction of general anaesthesia, reduction of raised intracranial pressure, cerebral protection during circulatory arrest.
Contra-Indications	Hepatic impairment, porphyria, pregnancy, breast feeding.
Dose Range	Up to 30 mg/kg.
Maximum Dose	As above.
Acute Side-Effects	Cardiorespiratory depression, prolonged sedation.

Medicine	TRANEXAMIC ACID
Legal Status	POM
Form And Strength	Injection 100 mg/ml in 5 ml glass ampoules.
Indications	Reduction of blood loss and blood transfusion in high risk surgery.
Contra-Indications	Renal impairment. Specific consent required.
Dose Range	2 g (usually into CPB prime).
Maximum Dose	As above.
Acute Side-Effects	Nausea, vomiting, diarrhoea. Rarely, allergic reactions.

Children

Group A: Medicines added To the CPB circuit prime

Albumin	Methyl Prednisolone
Calcium Chloride	Plasmalyte A Solution
Gelatin Solution (eg. Gelofusine)	Ringer's Solution
Hartmann's Solution	Sodium Bicarbonate
Heparin	Starch Solution (eg. Voluven)
Mannitol	

Group B: Medicines administered during CPB according to protocol

Calcium Chloride	Phenylephrine
Gelatin Solution (eg. Gelofusine)	Plasmalyte A Solution
Hartmann's Solution	Potassium Chloride
Heparin	Ringer's Solution
Metaraminol	Sodium Bicarbonate
Phentolamine	Sodium Chloride 0.9%

Group C: Medicines administered on the direction of surgeon or anaesthetist

Dexamethasone	Methyl Prednisolone
Cardioplegia	Milrinone
Furosemide	Sevoflurane
Isoflurane	Thiopentone
Magnesium Sulphate	Tranexamic Acid

Any medicine administered under this framework must be recorded on the perfusion record and/or the anaesthetic record in accordance with unit protocols. Blood or blood products should only be administered in accordance with local transfusion policies and in accordance with standard operating procedures/unit protocols.

In the following descriptions, the dose range and maximum dose information pertain only to use of the medicine during CPB.

Children Group A: Medicines added to the CPB circuit prime

In the following descriptions, the dose range and maximum dose information pertain only to use of the medicine during priming of the circuit. Refer to SOP for priming of CPB circuit.

Medicine	ALBUMIN SOLUTION
Legal Status	POM
Form And Strength	4.5% solution in 100 or 250 ml glass bottles.
Indications	CPB prime.
Contra-Indications	None.
Dose Range	See protocol.
Maximum Dose	None in this context.
Acute Side-Effects	Hypersensitivity reactions may occur including, rarely, severe anaphylactoid reactions.

Children Group A

Medicine	CALCIUM CHLORIDE
Legal Status	POM
Form And Strength	Injection 10% 100 mg/ml (Ca ²⁺ 0.68 mmol/ml). Injection 13.4% 134 mg/ml (Ca ²⁺ 0.9 mmol/ml).
Indications	Acute hypocalcaemia; blood based CPB circuit prime.
Contra-Indications	Conditions associated with hypercalcaemia and hypercalciuria (e.g. some forms of malignant disease).
Dose Range	Blood prime: 2.5 mmol per unit of blood.
Maximum Dose	Blood Ca ²⁺ level 1.1–1.4 mmol/L.
Acute Side-Effects	Peripheral vasodilatation, hypotension.

Medicine	GELATIN SOLUTION (eg. GELOFUSINE)
Legal Status	POM
Form And Strength	Intravenous infusion 4% in 500 ml and 1000ml bags. Also contains Na ⁺ 154 mmol and Cl ⁻ 120 mmol per L.
Indications	CPB prime.
Contra-Indications	Susceptibility to circulatory overload.
Dose Range	10–30 ml/kg.
Maximum Dose	Administered according to clinical need and size of patient.
Acute Side-Effects	Hypersensitivity reactions may occur including, rarely, severe anaphylactoid reactions.

Medicine	HARTMANN'S SOLUTION
Legal Status	POM
Form And Strength	Compound Sodium Lactate intravenous infusion 1000 ml. Each litre contains: Na ⁺ 131 mmol, K ⁺ 5 mmol, Ca ⁺⁺ 2 mmol, Cl ⁻ 111 mmol, lactate 29 mmol.
Indications	Component CPB circuit prime; Circulatory volume replacement.
Contra-Indications	Severe hepatic damage, respiratory alkalosis, or any condition where lactate level is elevated.
Dose Range	10-50 ml/kg. Up to 2 L of Hartmann's solution may be used in the CPB circuit prime depending on body weight.
Maximum Dose	Administered repeatedly according to clinical need, with a usual maximum of 3 L.
Acute Side-Effects	Rare. Anaphylactic/anaphylactoid reactions, urticaria, skin rashes and pruritus. Chest tightness, chest pain with tachycardia or bradycardia. Nasal congestion, coughing, sneezing, bronchospasm and difficulty in breathing have been reported.

Children Group A

Medicine	HEPARIN SODIUM
Legal Status	POM
Form And Strength	Injection 1000 units/ml in 5ml, 10ml or 20ml ampoules.
Indications	Anticoagulation.
Contra-Indications	Haemophilia and other haemorrhagic disorders, thrombocytopenia, recent cerebral haemorrhage.
Dose Range	3000 units in CPB circuit prime - see unit protocol.
Maximum Dose	Seek medical advice.
Acute Side-Effects	Haemorrhage, thrombocytopenia.

Medicine	MANNITOL
Legal Status	POM
Form And Strength	Intravenous infusion 10% and 20% in 500 ml bags.
Indications	Osmotic diuretic.
Contra-Indications	Pulmonary oedema. Check bags of 20% for mannitol crystals before use.
Dose Range	0.5 g/kg (single dose to CPB prime)
Acute Side-Effects	Chills, fever.

Medicine	METHYL PREDNISOLONE
Legal Status	POM
Form And Strength	Methyl prednisolone sodium succinate dry powder in glass vials of 40 mg, 125 mg, 500 mg, 1 g or 2 g for reconstitution with water.
Indications	Raised intracranial pressure, cerebral oedema.
Contra-Indications	Hypertension.
Dose Range	CPB Prime: 20 mg/kg.
Maximum Dose	30 mg/kg.
Acute Side-Effects	Hypersensitivity reactions, thromboembolism, electrolyte disturbance.

Medicine	PLASMALYTE A
Legal Status	POM
Form And Strength	500 or 1000 ml plastic container. 1000 ml contains 140 mmol Na ⁺ , 5 mmol K ⁺ , 3 mmol Mg ²⁺ , 98 mmol Cl ⁻ , 27 mmol acetate, and 23 mmol gluconate.
Indications	CPB prime.
Contra-Indications	None; caution in renal failure, hyperkalaemia.
Dose Range	500-1000 ml depending on weight and volume status (10–50 ml/kg)
Maximum Dose	Fever, phlebitis, thrombosis.
Acute Side-Effects	Haemorrhage, thrombocytopenia.

Children Group A

Medicine	RINGER'S SOLUTION
Legal Status	POM
Form And Strength	Ringer's Solution intravenous injection 500 ml or 1 L bags. Each litre contains: Na ⁺ 147 mmol, K ⁺ 4 mmol, Ca ⁺⁺ 2.2 mmol, Cl ⁻ 156 mmol.
Indications	Prime, Crystalloid component of the cardioplegia solution.
Contra-Indications	None.
Dose Range	10–50 ml/kg. Up to 2 L of Ringer's Solution may be used depending on patient size.
Maximum Dose	Administered according to clinical need, with a usual maximum of 3 L.
Acute Side-Effects	Rare. Anaphylactic/anaphylactoid reactions, urticaria, skin rash and pruritus. Chest tightness, chest pain with tachycardia or bradycardia. Nasal congestion, coughing, sneezing, bronchospasm and difficulty in breathing have been reported.

Medicine	SODIUM BICARBONATE
Legal Status	POM
Form And Strength	Injection BP 8.4% (1 mmol/ml) in 50 ml glass syringe.
Indications	Control of metabolic acidosis. May be added to the bypass circuit prime to adjust pH. Blood based CPB prime.
Contra-Indications	Metabolic or respiratory alkalosis, hypocalcaemia, or hypochlorhydria.
Dose Range	Blood Prime: 10 ml 8.4% for every unit of blood.
Acute Side-Effects	Sodium bicarbonate injection 8.4% is hypertonic. Tissue necrosis may follow extravasation at the site of injection. Excessive administration of bicarbonate may lead to metabolic alkalosis, especially in patients with impaired renal function, and sodium overload.

Medicine	STARCH SOLUTION (e.g. VOLUVEN)
Legal Status	POM
Form And Strength	Hydroxyethyl starch 6% solution in 500 ml bags. Each 1L also contains Na ⁺ 154 mmol, Cl ⁻ 154 mmol. Solution has a pH of 4–5.5.
Indications	Component of CPB circuit prime.
Contra-Indications	Fluid overload including pulmonary oedema. Renal failure with oliguria or anuria. Patients receiving dialysis. Intracranial bleeding. Severe hypernatraemia or severe hyperchloraemia. Known hypersensitivity to hydroxyethyl starches.
Dose Range	500–800 ml used in the prime.
Maximum Dose	Administered according to clinical need depending on serum pH. The usual maximum volume is 2 L depending on patient size.
Acute Side-Effects	Rarely, anaphylactoid reactions. Bradycardia, tachycardia, bronchospasm, non-cardiac pulmonary oedema. Pruritus. Haemodilution and coagulation disturbances. Acidosis.

Children Group B: Medicines administered during CPB according to protocol

Medicine	CALCIUM CHLORIDE
Legal Status	POM
Form And Strength	Injection 10% 100 mg/ml (Ca ²⁺ 0.68 mmol/ml). Injection 13.4% 134 mg/ml (Ca ²⁺ 0.9 mmol/ml).
Indications	Acute hypocalcaemia.
Contra-Indications	Conditions associated with hypercalcaemia and hypercalciuria (e.g. some forms of malignant disease).
Dose Range	0.1–0.14 mmol/kg.
Maximum Dose	Blood Ca ²⁺ level 1.1-1.4 mmol/L.
Acute Side-Effects	Peripheral vasodilatation, hypotension.

Medicine	GELATIN SOLUTION (e.g. GELOFUSINE)
Legal Status	POM
Form And Strength	Intravenous infusion 4% in 500 ml and 1000 ml bags. Also contains Na ⁺ 154 mmol and Cl ⁻ 120 mmol per litre.
Indications	Low blood volume.
Contra-Indications	Susceptibility to circulatory overload.
Dose Range	Initially 10–30 ml/kg.
Maximum Dose	Administered according to clinical need and size of patient.
Acute Side-Effects	Hypersensitivity reactions may occur including, rarely, severe anaphylactoid reactions.

Medicine	HARTMANN'S SOLUTION
Legal Status	POM
Form And Strength	Compound Sodium Lactate intravenous infusion 1000 ml. Each litre contains: Na ⁺ 131 mmol, K ⁺ 5 mmol, Ca ⁺⁺ 2 mmol, Cl ⁻ 111 mmol, lactate 29 mmol.
Indications	Circulatory volume replacement.
Contra-Indications	Severe hepatic damage, respiratory alkalosis, or any condition where lactate level is elevated.
Dose Range	Up to 2 L of Hartmann's solution is used according to patient size.
Maximum Dose	Administered repeatedly according to clinical need, with a usual maximum of 3 L.
Acute Side-Effects	Rare. Anaphylactic/anaphylactoid reactions, urticaria, skin rashes and pruritus. Chest tightness, chest pain with tachycardia or bradycardia. Nasal congestion, coughing, sneezing, bronchospasm and difficulty in breathing have been reported.

Children Group B

Medicine	HEPARIN SODIUM
Legal Status	POM
Form And Strength	Injection 1000 units/ml in 5 ml or 20 ml ampoules.
Indications	Anticoagulation.
Contra-Indications	Haemophilia and other haemorrhagic disorders, thrombocytopenia, recent cerebral haemorrhage.
Dose Range	Additional bolus 150 units/kg if ACT < 400s.
Maximum Dose	Seek medical advice.
Acute Side-Effects	Haemorrhage, thrombocytopenia.

Medicine	METARAMINOL
Legal Status	POM
Form And Strength	Injection 10 mg/ml in 1 ml ampoule.
Indications	Acute hypotension.
Contra-Indications	Hypertension, pregnancy.
Dose Range	0.01 mg/kg, repeated as required, if not achieving response seek advice from anaesthetist / surgeon.
Acute Side-Effects	Tachycardia.

Medicine	PHEHTOLAMINE
Legal Status	POM
Form And Strength	Injection 10 mg/ml in 1 ml ampoule.
Indications	Acute hypertension.
Contra-Indications	Hypotension.
Dose Range	5–20 µg/kg repeated as required, if not achieving response seek advice from anaesthetist/surgeon.
Acute Side-Effects	Tachycardia, dizziness, nausea vomiting, prolonged hypotension

Medicine	PHENYLEPHRINE
Legal Status	POM
Form And Strength	Injection 10 mg/ml in 1 ml ampoule.
Indications	Acute hypotension.
Contra-Indications	Severe hyperthyroidism, pregnancy.
Dose Range	2–10 µg/kg (0.2–1.0 ml of 1 mg/ml solution) repeated as required, if not achieving response seek advice from anaesthetist / surgeon.
Acute Side-Effects	Tachycardia or reflex bradycardia.

Children Group B

Medicine	PLASMALYTE A
Legal Status	POM
Form And Strength	500 or 1000 ml plastic container. 1000 ml contains 140 mmol Na ⁺ , 5 mmol K ⁺ , 3 mmol Mg ²⁺ , 98 mmol Cl ⁻ , 27 mmol acetate, and 23 mmol gluconate.
Indications	Volume replacement.
Contra-Indications	None; caution in renal failure, hyperkalaemia.
Dose Range	10–50 ml/kg depending on volume status.
Acute Side-Effects	Fever, phlebitis, thrombosis.

Medicine	POTASSIUM CHLORIDE
Legal Status	POM
Form And Strength	Injection 1.5 g (20 mmol K ⁺) in 10 ml ampoule. Injection 1 g (13.4 mmol K ⁺) in 10 ml ampoule.
Indications	To maintain serum potassium concentration during CPB.
Contra-Indications	Caution in patients with renal or adrenal insufficiency, cardiac disease, or extensive tissue destruction as in severe burns.
Dose Range	0.2–0.5 mmol/kg Administered slowly into the CPB circuit, such that dilution occurs before reaching the patient.
Target Range	Blood K ⁺ level 4.5–5.5 mmol/L.
Maximum Dose	Single dose should not exceed 10 mmol This excludes the potassium delivered in the cardioplegia solutions.
Acute Side-Effects	Hyperkalaemia, with paraesthesia, muscle weakness, hypotension, cardiac arrhythmias and cardiac arrest.

Medicine	RINGER'S SOLUTION
Legal Status	POM
Form And Strength	Ringer's Solution intravenous injection 500 ml or 1 L bags. Each litre contains: Na ⁺ 147 mmol, K ⁺ 4mmol, Ca ⁺⁺ 2.2 mmol, Cl ⁻ 156 mmol.
Indications	Crystalloid component of the cardioplegia solution; circulatory volume replacement.
Contra-Indications	None
Dose Range	Up to 2 L of Ringer's Solution may be used depending on patient's size.
Maximum Dose	Administered according to clinical need, with a usual maximum of 3 L.
Acute Side-Effects	Rare. Anaphylactic/anaphylactoid reactions, urticaria, skin rash and pruritus. Chest tightness, chest pain with tachycardia or bradycardia. Nasal congestion, coughing, sneezing, bronchospasm and difficulty in breathing have been reported.

Children Group B

Medicine	SODIUM BICARBONATE
Legal Status	POM
Form And Strength	Injection 8.4% (1 mmol/ml) in 50 ml glass syringe.
Indications	Control of metabolic acidosis.
Contra-Indications	Metabolic or respiratory alkalosis, hypocalcaemia, or hypochlorhydria.
Dose Range	0.5–5 mmol/kg to correct acid base balance based on the following formula or equivalent: <5 kg weight: dose (mmol)=base excess x weight/4 Adolescent: dose (mmol)=base excess x weight/10 Child: dose (mmol)=base excess x weight/6
Acute Side-Effects	Sodium bicarbonate injection 8.4% is hypertonic. Tissue necrosis may follow extravasation at the site of injection. Excessive administration of bicarbonate may lead to metabolic alkalosis, especially in patients with impaired renal function, and sodium overload.

Medicine	SODIUM CHLORIDE 0.9%
Legal Status	POM
Form And Strength	Intravenous Infusion 0.9% in 500 ml or 1 L bags.
Indications	Used as a flush and washer in the cell saver and as the crystalloid component of cardioplegia.
Contra-Indications	None.
Dose Range	Not applicable.
Maximum Dose	Not applicable.
Acute Side-Effects	Not applicable.

Children Group C: Medicines administered on the direction of surgeon or anaesthetist

Medicine	CARDIOPLEGIA SOLUTION
Legal Status	POM
Form And Strength	300, 500 or 1000 ml bags containing Mg ²⁺ 20 mmol/L, K ⁺ 20 mmol/L and procaine.
Indications	Myocardial protection on CPB during aortic clamping.
Contra-Indications	None in this context.
Dose Range	See protocol.
Acute Side-Effects	Hyperkalaemia.

Children Group C

Medicine	DEXAMETHASONE
Legal Status	POM
Form And Strength	Dexamethasone sodium phosphate 4 mg/ml in 2 ml glass vial.
Indications	Cerebral protection on CPB and during DHCA.
Contra-Indications	None in this context.
Dose Range	0.5-1.0 mg/kg.
Acute Side-Effects	Hyperglycaemia.

Medicine	FUROSEMIDE (FRUSEMIDE)
Legal Status	POM
Form And Strength	Injection 10 mg/ml in 2 ml ampoule.
Indications	Oedema, chronic heart failure.
Contra-Indications	Precomatose states associated with liver cirrhosis, renal failure with anuria.
Dose Range	0.5–1 mg/kg.
Maximum Dose	2 mg/kg.
Acute Side-Effects	Hyponatraemia, hypokalaemia, hypomagnesaemia, hypochloraemic alkalosis.

Medicine	ISOFLURANE
Legal Status	POM
Form And Strength	Bottles containing 100 or 250 ml liquid isoflurane.
Indications	Control of hypertension, myocardial protection.
Contra-Indications	Hypersensitivity. Susceptibility to malignant hyperpyrexia.
Dose Range	0.5 – 2.5% administered via dedicated vaporizer into sweep gas flow.
Maximum Dose	5%.
Specific Caution	Waste gases must be scavenged and isoflurane concentration measured. Potential damage to CPB components if direct contact with liquid.
Acute Side-Effects	Hypotension, cardio respiratory depression.

Children Group C

Medicine	MAGNESIUM SULPHATE
Legal Status	POM
Form And Strength	Injection 20% (200 mg/ml,) in 20 ml ampoule. Injection 50% (500 mg/ml) in 2, 5 or 10 ml ampoule.
Indications	Treatment of arrhythmias, especially in the presence of hypokalaemia.
Contra-Indications	Hepatic impairment, renal impairment.
Dose Range	25–50 µg/kg.
Maximum Dose	100 µg/kg.
Acute Side-Effects	Nausea, vomiting, thirst, flushing of skin, hypotension.

Medicine	METHYL PREDNISOLONE
Legal Status	POM
Form And Strength	Methyl prednisolone sodium succinate dry powder in glass vials of 40 mg, 125 mg, 500 mg, 1 g or 2 g for reconstitution with water.
Indications	Raised intracranial pressure, cerebral oedema, steroid replacement therapy, antiinflammatory.
Contra-Indications	Hypertension; systemic infection.
Dose Range	20–30 mg/kg.
Maximum Dose	30 mg/kg.
Acute Side-Effects	Hypersensitivity reactions, thromboembolism, electrolyte disturbance.

Medicine	MILRINONE
Legal Status	POM
Form And Strength	Injection 1mg/ml in 10 ml ampoule.
Indications	Acute heart failure including low output states following heart surgery.
Contra-Indications	Hypertrophic cardiomyopathy, obstructive cardiac valvular disease.
Dose Range	50 µg/kg loading dose.
Maximum Dose	50 µg/kg loading dose in CPB circuit.
Acute Side-Effects	Chest pain, tremor, bronchospasm, anaphylaxis, rash.

Children Group C

Medicine	SEVOFLURANE
Legal Status	POM
Form And Strength	Bottles containing 250 ml liquid sevoflurane.
Indications	Control of hypertension, myocardial protection.
Contra-Indications	Susceptibility to malignant hyperpyrexia.
Dose Range	0.5-5% administered via dedicated vaporizer into sweep gas flow.
Maximum Dose	8%.
Caution	Waste gases must be scavenged and sevoflurane concentration measured. Potential damage to CPB components if direct contact with liquid.
Acute Side-Effects	Agitation, cardio respiratory depression, hypotension.

Medicine	THIOPENTAL (THIOPENTONE)
Legal Status	POM
Form And Strength	Glass vial containing 500 mg thiopentone powder for reconstitution.
Indications	Induction of general anaesthesia, reduction of raised intracranial pressure, cerebral protection during circulatory arrest.
Contra-Indications	Hepatic impairment, porphyria, pregnancy, breast feeding.
Dose Range	Up to 30 mg/kg.
Maximum Dose	30 mg/kg.
Acute Side-Effects	Cardiorespiratory depression, prolonged sedation.

Medicine	TRANEXAMIC ACID
Legal Status	POM
Form And Strength	100 mg/ml in 5 ml glass ampoules.
Indications	To prevent and treat bleeding post surgery.
Contra-Indications	Hypersensitivity reactions; Pro thrombotic conditions.
Dose Range	50 mg/kg loading dose in CPB prime solution Infusion: 10 mg/kg/hr during CPB.
Acute Side-Effects	Vomiting, diarrhoea, thromboembolism, allergic skin reactions, hypotension.



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