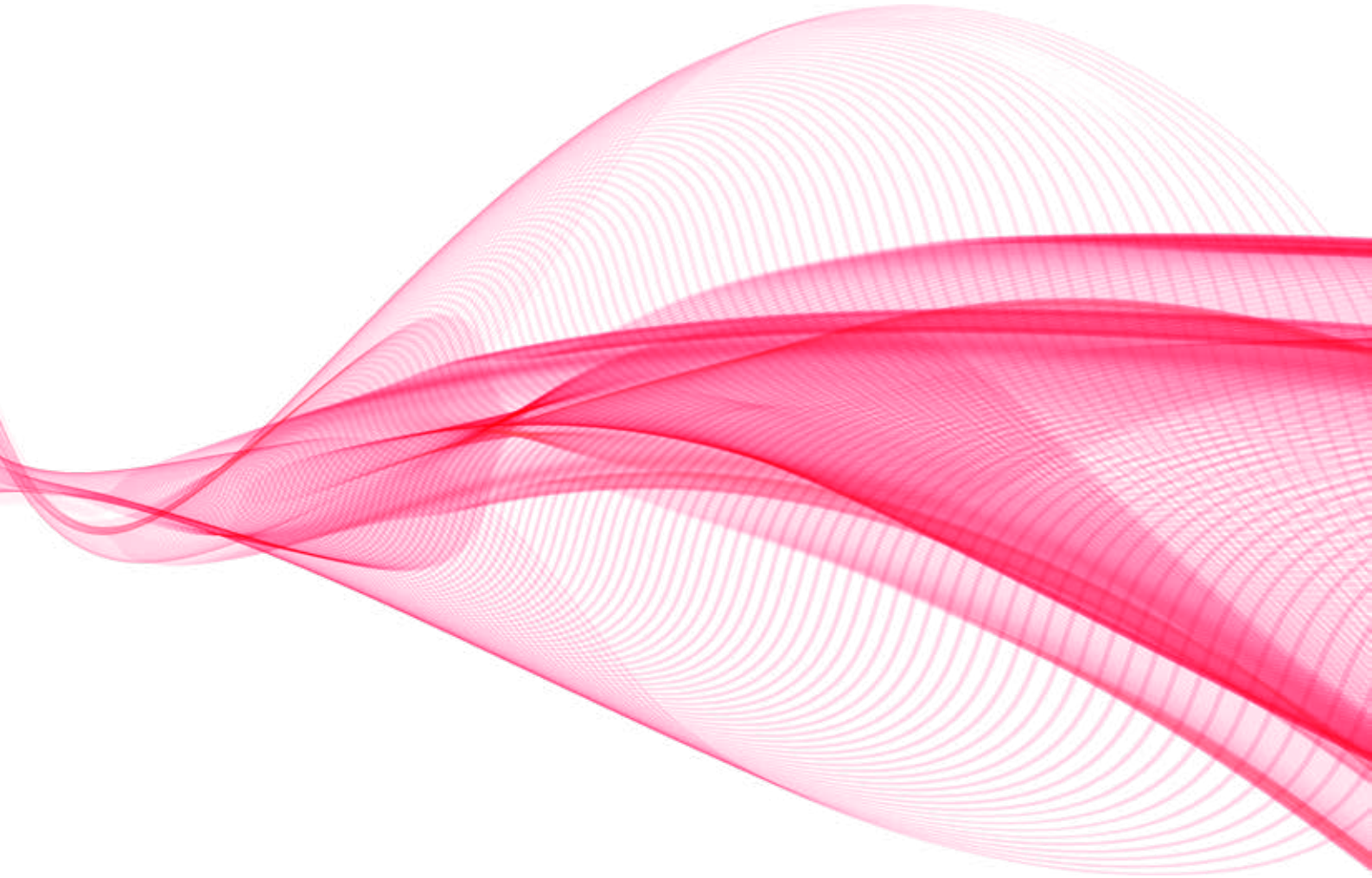
# STANDARDS OF PRACTICE

## SOCIETY DOCUMENTS



The Society of Clinical Perfusion Scientists of Great Britain and Ireland

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The Society of Clinical Perfusion Scientists of Great Britain and Ireland

The College of Clinical Perfusion Scientists of Great Britain and Ireland

# STANDARDS OF PRACTICE DOCUMENT

(agreed October 1999 updated April 2019)

## 1.0 Preamble

**1.1** When a society of individuals involved in clinical work prefers to call itself a 'profession', it must set for itself standards of conduct, behaviour and competence for all aspects of its work, that are worthy of the term 'professional'. Such standards should encompass such diverse aspects of the work as:

1.1.1 Clinical competence.
1.1.2 The safety and well-being of patients and colleagues.
1.1.3 The utmost honesty and integrity as far as clinical and research responsibilities are concerned.
1.1.4 The utmost honesty and integrity as far as financial and business dealings are concerned.
1.1.5 The maintenance of the strictest confidentiality as far as patients, colleagues and other health-care professionals are concerned (within the confines of legal requirements to disclose information).

**1.2** A society of professionals should be prepared to set and to regulate such standards with a Code of Conduct that is of sufficient precision and clarity that ambiguity is avoided, whilst setting the general tenor of behaviour for situations and conditions not specifically envisaged.

**1.3** Such a code of conduct should be binding on all members and be enforceable by the appropriate professional body.

**1.4** This is a working document, to be discussed and refined in the light of experience.

**1.5** The Standards of Practice must be read in conjunction with the document: A Guide to Good Practice in Clinical Perfusion, July 2009. (Produced by the Department of Health, Gateway Reference 10286).

## 2.0 The General Obligations of Members of the Society

**2.1** The interests of the patient are at all times paramount. It is imperative therefore that members maintain their personal integrity so that they may conscientiously perform their duties and honour their obligations to the patient.

**2.2** Members shall deliver a service to the utmost of their abilities to all patients irrespective of race, religion, gender, sexual orientation, national origin, age, physical or mental condition.

**2.3** All members must uphold the dignity and honour of the profession of perfusion by accepting its disciplines and exposing illegal, unethical and incompetent conduct.

**2.4** All members have both a personal and a professional obligation to protect all patients from illegal, unethical and incompetent conduct by any person.

**2.5** All members should recognise a responsibility to seek changes in techniques and practices which they do not believe to be in the best interest of patients. They should be encouraged and supported by all members in pursuit of this principle.

**2.6** Members shall abide by the law, and are governed by the rules and regulations of their employing authority.

**2.7** Members are responsible for reporting breaches of this code to the appropriate professional body.

## 3.0 Clinical Competence

**3.1** Responsibility for clinical perfusion procedures can only be taken by an accredited Clinical Perfusion Scientist.

**3.2** Trainee members who have yet to achieve the full accreditation of the Society should not undertake, nor be asked to undertake, responsibilities without the direct supervision of an accredited Clinical Perfusion Scientist, who shall be responsible for the procedure.

**3.3** Direct describes the supervision as being by a named Clinical Perfusion Scientist dedicated to a particular trainee at a particular time, not distracted by other clinical duties/responsibilities, and in close proximity to that trainee.

**3.4** Members shall accept responsibility for the exercise of sound judgment in the delivery of services to the patient and shall be accountable for the quality of the service provided.

**3.5** Members shall ensure, through continuing education and training that they are fully acquainted with developments in perfusion.

**3.6** No senior or experienced member will delegate responsibilities to a less senior or experienced member unless they are certain that the junior member has been adequately trained for the task.

**3.7** Members shall not undertake responsibilities for which they have not been fully trained, or when they are not fully acquainted with the issues pertaining to a particular technique.

**3.8** Should members be placed in a situation in which they are expected to undertake a clinical responsibility for which they are inexperienced, inadequately trained, or when they otherwise feel that their performance may be inadequate, they shall inform the most senior member available and the responsible clinician.

**3.9** Members shall not misrepresent in any manner, either directly or indirectly, their skills, training, professional credentials, identity or services.

## 4.0 Education and Training

**4.1** Members shall ensure that they maintain an up-to-date knowledge of all aspects of the theory and practice of perfusion that are applicable to them.

**4.2** Members shall make available to colleagues all available information. Members have a duty to educate and inform colleagues.

**4.3** Members involved in education and training, shall ensure that their teaching is of a high standard and that they have adequate funding and facilities.

**4.4** Members who have responsibilities concerning the examination of colleagues for proficiency, shall ensure that all such responsibilities are carried out with the utmost impartiality, fairness and confidentiality.

## 5.0 Research and Publication

**5.1** Whilst undertaking research into perfusion topics, presenting data to meetings and conferences, or publishing results, members shall maintain the highest standards.

**5.2** Members shall recognise the rights of patients involved in research and conduct research in accordance with accepted ethical and reporting standards.

**5.3** Members shall recognise the rights of animals involved in research and conduct research in accordance with accepted ethical and reporting standards.

**5.4** All members who participate or contribute as an author or investigator will receive proper recognition and responsibility for the data being presented and/or published. Implicit in this is that there should be:

5.4.1 Full acknowledgement and disclosure for all sources, references and support received during the research or writing of the publication.

5.4.2 The avoidance of all plagiarism.

## 6.0 Confidentiality; Rights of Patients and Colleagues

**6.1** The Clinical Perfusion Scientist shall safeguard the rights of patients and colleagues.

**6.2** The Clinical Perfusion Scientist must safeguard the confidentiality of the patient and colleagues within the constraints of the law and this Code of Practice.

**6.3** The Clinical Perfusion Scientist should not make public information of a "commercial in confidence" nature particularly if its disclosure would prejudice fair competition.

## 7.0 Conflicts of Interest

**7.1** A member's professional practice and principles shall always take preference over business practices.

**7.2** Members shall always place their standards of practice above financial gain.

**7.3** Members shall fully disclose to all appropriate authorities any business practice that may appear as a conflict of interest. These include any material relationship with any company supplying (or receiving) goods or services from the member, such as :

7.3.1 Any consultancy fees
7.3.2 Fees for technical advice
7.3.3 Any fees related to education and training
7.3.4 The acceptance of any fees, gratuities or sponsorship from industry

**7.4** Members shall ensure that where they are responsible for choosing equipment for use in the delivery of their service, that such choices are influenced solely by the quality of the equipment and/or its cost and are not influenced by any material gain.

## 8.0 Selection of Equipment

**8.1** The Society maintains that by virtue of the standard of their clinical and technical knowledge and experience, ultimately, the choice of equipment used during perfusion procedures should be made by the most senior Clinical Perfusion Scientist, following appropriate consultation and assessment with other colleagues. In arriving at this decision the member shall take the following factors into account:

8.1.1 The safety of patients and staff
8.1.2 Clinical suitability and patient outcomes
8.1.3 The clinical advantages and disadvantages of all relevant competing systems
8.1.4 Relevant documented research and clinical data should be reviewed
8.1.5 The quality of service provided by the competing companies
8.1.6 The transparent costs of all goods and services charged by all competing companies

**8.2** Decisions should be taken in the light of all the above considerations and the decision should not be influenced or compromised by gratuities, gifts, hospitality, consulting engagements, employment status, or any other material or personal gain.

## 9.0 General Conduct of Members

**9.1** Members are required at all times when on duty to conduct themselves in a professional and seemly manner.

**9.2** The following are examples of professional misbehaviour:

9.2.1 Temperamental outbursts

9.2.2 Physical aggression

9.2.3 Inappropriate conversations within earshot of patients

9.2.4 Sexual harassment of any kind

## 10.0 Tiredness and European Working Time Directive (EWTD)

10.1 The Clinical Perfusion Scientist will regularly work an extended day and is often called upon to work into and through the night. In these circumstances the Perfusion Scientist must follow the recommendations of the EWTD, when rostered to work the following day, by taking the minimum 11 hour break between shifts. Perfusion managers are obliged to run EWTD compliant rosters and must follow local adopted EWTD policies for their organisation.

10.2 Perfusion Scientists must be aware of the local policies for their organisation with respect to fitness to work. Perfusion managers must ensure that the perfusion staff are fit and able to carry out their required duties and follow the policies for their organisation when this is not the case for any reason.

## 11.0 Health and Safety

**11.1** All Clinical Perfusion Scientists should be aware of Health and Safety regulations for vaccinations and for the disposal of clinical waste, such as sharps, and for the removal of blood splashes. Perfusion Scientists should be aware of hospital policies with regard to these issues.

**11.2** All members have a responsibility to patients, colleagues and themselves as far as their health is concerned.

**11.3** Should the Clinical Perfusion Scientist, for whatever reason, feel too unwell to undertake their responsibilities safely and effectively, the Clinical Perfusion Scientist must report this.

**11.4** If the Clinical Perfusion Scientist is undergoing treatment with drugs that are liable to impair their concentration, judgement or effectiveness (such as: some analgesics; tranquillisers; anti-depressants; cold and sinus remedies; antihistamines etc.), the Clinical Perfusion Scientist must report this. Most such drugs carry a warning concerning the operation of equipment, but if the Clinical Perfusion Scientist is in any doubt, the Clinical Perfusion Scientist should take advice. It is advisable that the Clinical Perfusion Scientist seek advice from their prescribing doctor of the possible side effects of the medicine the Clinical Perfusion Scientist is receiving.

**11.5** Members shall take medical advice if they suspect they are suffering from any communicable condition, or condition that puts patient safety at risk. Such conditions shall be reported to the relevant hospital authorities.

**11.6** Members shall take all reasonable steps to prevent infection of patients or themselves.

**11.7** Members shall ensure that they are fully inoculated against such conditions as Hepatitis.

## 12.0 Alcohol and Drugs

**12.1** Perfusion Scientists must be aware of the local policies for their organisation with respect to fitness to work. Perfusion managers must ensure that the perfusion staff are fit and able to carry out their required duties and follow the policies for their organisation when this is not the case for any reason.

## 13.0 Departmental Protocols

**13.1** The most senior member of any Perfusion department will be responsible for the provision of detailed, Trust approved, Standard Operating Procedures and Drug Protocols for the information and instruction of all members of the department. These Procedures and Protocols should be reviewed, at least annually, as suggested in: A Guide to Good Practice in Clinical Perfusion, page 17, (Produced by the Department of Health, Gateway Reference 10286, July 2009). The following essential issues to be dealt with in such a document, should be:

13.1.1 Those components of the circuitry that are deemed mandatory by individual units (specifying such items e.g. arterial line filters).

13.1.2 The procedures for priming perfusion systems.

13.1.3 The procedure by which heparin activity or anti-coagulation is evaluated and implemented.

13.1.4 The minimum ACT value required by the department.

13.1.5 Instructions for dealing with emergency procedures, including:

13.1.5.1 Electrical failure
13.1.5.2 Gas failure
13.1.5.3 Oxygenator failure
13.1.5.4 Circuit failure and rupture
13.1.5.5 Air embolism

13.1.6 A procedure for checking the availability of safety devices and back-up equipment.

13.1.7 The setting up and use of safety devices.

**13.2** A Guide to Good Practice in Clinical Perfusion, page 18, (Produced by the Department of Health, Gateway Reference 10286, July 2009), recommends the use of pre-bypass checklists. These checklists are to be developed and agreed by the Chief Perfusionist and must be fully used and signed by the relevant member.

## 14.0 Maintenance of Records

**14.1** The format for recording clinical records will include:

14.1.1 Patient names
14.1.2 Record number
14.1.3 Data upon which predicted flows are to be calculated
14.1.4 Bypass times
14.1.5 Ischaemic times
14.1.6 A.C.T. (or other anti-coagulation) readings
14.1.7 A record of acid-base/blood-gas and relevant clinical chemistry results
14.1.8 Description of Unusual events during perfusion and untoward incidents
14.1.9 Any Drug administrations

**14.2** The member shall maintain an accurate record of all clinical activities.

**14.3** The most senior member in each unit should ensure that a record of all maintenance is kept. This should record routine maintenance and all faults that have occurred with each device.

**14.4** As primary medical documents they will be readily available.

**14.5** The member is then obliged to follow local and national policies regarding information governance and data protection.

## 15.0 Reporting of Untoward Incidents

**15.1** All relevant untoward incidents that occur during a clinical perfusion should be reported to the most senior member of each unit. This member is responsible for reporting such incidents to their country specific medical devices agency (see appendix), the hospital Trust and the Society and College's Safety Committee.

# APPENDIX

## INCIDENT REPORTING

### 1. Republic of Ireland

Irish Medicines Board (IMB)
Medical Devices Department
Kevin O'Malley House
Earlsfort Centre
Earlsfort Terrace
Dublin 2,
Ireland

www.medicaldevices.ie
Tel: 353-1-676 4971
Tel: 353-1-676 4976
Fax: 353-1-676 7836
Email: www.imb@imb.ie

### 2. England

MHRA (Medicines & Healthcare Products Regulatory Agency)
Central Enquiry Point
151 Buckingham Palace Road
London SW1W 9SZ

020 3080 6000
Email: info@mhra.gsi.gov.uk
Web www.mhra.gov.uk

### 3. Scotland

Incident Reporting and Investigation Centre
(Equipping & Technical)
Health Facilities Scotland
NHS National Services Scotland
Gyle Square
1 South Gyle Crescent
EDINBURGH EH12 9EB

0131 275 6000(Tel)

0131 314 0700 (Fax)
0131 275 7575 (IRIC Helpline)
http://www.hfs.scot.nhs.uk/about/equipping-and-technical/

## 4. Northern Ireland

Northern Ireland Adverse Incidents Centre
Health Estates
Stoney Road
Dundonald
Belfast BT16 1US

Tel 02890 523 868
Email: NIAIC@dhsspsni.gsi.gov.uk
www.dhsspsni.gov.uk/niaic

## 5. Wales

Welsh Assembly Government
The Office of the Chief Medical Officer
4th Floor, East Wing
Cathays Park
Cardiff CF10 3NQ

02920 823 505

## 6. The Society and College of Clinical Perfusion Scientists Safety Committee

The Society of Clinical Perfusion Scientists of Great Britain & Ireland
Fifth Floor, The Royal College of Surgeons of England
35–43 Lincoln's Inn Fields
London
WC2A 3PE

Tel: (+44) 020 7869 6891
Email: safetycommittee@scps.org.uk