Provisional Standard One Decision

Society of Clinical Perfusion Scientists (SCPS)

July 2024

professional standards authority

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1. The Accreditation process

How we assess organisations against Standard One ('public interest test')

The Professional Standards Authority accredits registers of people working in health and social care occupations not regulated by law. To be accredited, organisations holding such registers must prove they meet our *Standards for Accredited Registers*[1] (the Standards). Once accredited, we check that Registers continue to meet our Standards.

There are nine Standards. Registers must meet Standard One before we can assess against how the register meets the remaining Standards. Standard One checks eligibility under our legislation, and if accreditation is in the public interest.

Organisations may apply for a preliminary assessment against Standard One before submitting a full application.

Preliminary Standard One decisions are made by an Accreditation Panel following an assessment of evidence by the Accreditation Team. The evidence usually includes the organisation's application, a desk-based review of relevant sources of evidence about the benefits and risks of the role(s) registered, and responses received through our 'Share your experience' public consultation.

If the Panel decides that the activities of registrants fall within the definition of healthcare, and that overall, the benefits of the services of practitioners outweigh the risks then it may determine that Standard One is provisionally met. If the Panel decides that either of these requirements is not met, then this will be communicated to the organisation with the reasons for the decision, and it may apply again later.

Decisions for preliminary assessments against Standard One are provisional. If an organisation later submits a full application, we will check whether there have been any changes which effect this outcome. An Accreditation Panel can also issue recommendations for the organisation to consider should they decide to complete a full application. More about how we assess against Standard One can be found in our *Supplementary Guidance for Standard One*[2].

2. About the Society of Clinical Perfusion Scientists (SCPS)

About the organisation

Name of Organisation	Society of Clinical Perfusion Scientists (SCPS)

[1] https://www.professionalstandards.org.uk/docs/default-source/publications/standards/standards-for-accredited-registers.pdf?sfvrsn=e2577e20_6

[2] https://www.professionalstandards.org.uk/docs/default-source/accredited-registers/standards-for-accredited-registers/accredited-registers-supplementary-guidance-for-standard-one.pdf?sfvrsn=3e5f4920_6

Website	http://www.scps.org.uk/college/college-register
Type of Organisation	Charity
Role(s) covered	Clinical Perfusion Scientists (also known as “clinical perfusionists”).
Number of registrants	486 as of 31 May 2024.
Overview of Governance	The SCPS is the professional body for clinical perfusionists practicing in the UK. It is overseen by an Executive Committee which is an elected committee made up of 11 members. Sub-Committees include the Safety Committee, Education Sub-Committee, and the Equality, Diversity and Inclusion (EDI) Sub-Committee. The College of Clinical Perfusion Scientists of Great Britain & Ireland (CCPS) is responsible for maintaining the register. The College is overseen by the College Council which is made up of 12 members.
Overview of the aims of the register	The CCPS states that ‘We are a charity, whose purpose is the protection, promotion and maintenance of the health and safety of patients undergoing a wide range of cardiac and related procedures.’[3] The CCPS’ Constitution[4] provides details of its primary objectives, which include the following: • ‘for the benefit and safety of the public to advance and maintain quality in the delivery of perfusion services, best clinical practice, knowledge and education, via peer review and the joint Codes of Practice. To liaise with and consult with other professional bodies and institutions deemed necessary in pursuing these objectives.’ • To liaise with and consult with the Society of Clinical Perfusion Scientists, forming joint committees and working parties as and when necessary, to discuss all matters of training, education, governance and professional status for Clinical Perfusion Scientists. • The maintenance of Perfusionist Registers. • The accreditation of all centres undertaking cardiothoracic surgery including the evaluation of training resources where provided. The SCPS’ By-laws[5] state that the objectives of the society are ‘to promote the advancement of Perfusion Technology for the benefit of the public.’

[3] https://www.scps.org.uk/college/the-college
[4] https://global-uploads.webflow.com/5da4ad68b9d5374c5a54c71d/6192474b71b0734c701f29df_Constitution%20of%20the%20College%20v2021.pdf
[5] THE SOCIETY OF PERFUSIONISTS (webflow.com)

Inherent risks of practice

Risk criteria	Clinical Perfusion Scientists
1. Scale of risk associated with Clinical Perfusion Scientists *a. What do Clinical Perfusion Scientists do?* *b. How many Clinical Perfusion Scientists are there?* *c. Where do Clinical Perfusion Scientists work?* *d. Size of actual/potential service user group*	• Clinical Perfusion Scientists are members of the open-heart surgery team. NHS Careers describes their main role as to 'use a number of highly technical, mechanical and electronic devices to ensure that oxygen reaches a patient's body through the blood, when the patient's lungs and heart are temporarily not functioning' and 'control the equipment (heart-lung machine) which temporarily takes over a patient's respiration (breathing) or circulation of blood (or both) during open-heart surgery.'[6] a. As of 1 September 2023, there were 488 registrants on the SCPS' register, practising across the UK. The SCPS believes this number includes all Clinical Perfusion Scientists currently practising in the UK. b. Clinical Perfusion Scientists work in clinical settings within the NHS and private hospital care in England, Scotland, Wales and Northern Ireland. The *Guide to Good Practice in Clinical Perfusion* (2009)[7] states that as well as working as part of the multi-disciplinary surgical team, Clinical Perfusion Scientists may 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.' c. Although there is no exact data for how many people receive the services of Clinical Perfusion Scientists, as set out above, Clinical Perfusion Scientists predominantly work in cardiac theatres delivering cardiopulmonary bypasses for heart and lung surgeries. In accordance with the National Adult Cardiac Surgery (NACSA) 2023 Summary Report[8], there were 24,807 adult cardiac cases conducted in the UK between 2021-2022. The SCPS anticipates an increase in the number of cardiac operations, due to the delayed operations following Covid-19 and an aging population. Perfusion services are also provided for children at some hospitals that perform open heart surgery. For example, around 500 patients ranging in age from newly born to 16 years of age receive perfusion services at Great Ormond Street Hospital each year.[9] In addition, Clinical Perfusion Scientists may be required for procedures such as liver perfusion, and to operate Extra Corporeal Membrane Oxygenation (ECMO) machines, which

[6] Clinical perfusion science | Health Careers
[7] https://www.scps.org.uk/resources/useful-downloads
[8] https://www.nicor.org.uk/wp-content/uploads/2023/06/10633_NICOR-Annual-Summary_NACSA_v4.pdf
[9] https://www.gosh.nhs.uk/wards-and-departments/departments/clinical-specialties/perfusion-information-parents-and-visitors/about-perfusion-service/

	function as a temporary life support system for patients whose lungs (V-V ECMO) or heart (V-A) aren't working or combination of the following for mixed heart and lung dysfunction.
2. Means of assurance	*The Guide to Good Practice in Clinical Perfusion* (2009) states that '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.'[10] This is emphasised on the SCPS' website which states that 'Clinical Perfusion Scientists must be registered with the College of Clinical Perfusion Scientists to practise in Great Britain and Ireland.' All Clinical Perfusion Scientists will be employed by either NHS or independent hospitals and therefore subject to employer checks such as criminal records checks. Hospital settings are also required to have systems of clinical governance in place and are subject to inspection by the systems regulators. The Medicines Act 1968 and associated secondary legislation regulates the administration of medicines in the UK. This framework allows Clinical Perfusion Scientists to 'follow a prescriber's directions to administer POMs [prescription only medicines], including controlled drugs, which are for parenteral administration to a specific patient. 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 to the prescriber for further directions if required.'[11] The Medicines and Healthcare products Regulatory Agency (MHRA) regulates medicines, medical devices and blood components for transfusion in Great Britain[12]. This includes the use of devices and the drugs used within the procedures carried out by Clinical Perfusion Scientists. The MHRA has a 'yellow card reporting system' for reporting the side effects, and injuries and near misses caused by medical devices in England. There are similar schemes for reporting issues with medical devices in Wales, Northern Ireland and Scotland.
3. About the sector in which *Clinical*	Clinical Perfusion Scientists practise in hospital settings, either within the NHS or independent sector. They work mostly in the operating theatre

[10] https://global-uploads.webflow.com/5da4ad68b9d5374c5a54c71d/5da4ad68b9d537fd6654c82a_SCPS%20-%20Good%20Practice%20Guide.pdf

[11] https://global-uploads.webflow.com/5da4ad68b9d5374c5a54c71d/5da4ad68b9d537fd6654c82a_SCPS%20-%20Good%20Practice%20Guide.pdf

[12] For information about regulation of medical devices in Northern Ireland see: https://www.gov.uk/guidance/regulating-medical-devices-in-the-uk#regulation-of-medical-devices-in-northern-ireland

***Perfusion Scientists* operate**	alongside the surgical team. They may also work in intensive care, the emergency department and non-cardiac theatres.
4. Risk perception • *Need for public confidence in Clinical Perfusion Scientists?* • *Need for assurance for employers or other stakeholders?*	Clinical Perfusion Scientists are responsible for helping to keep the patient's vital organs alive during cardiac bypass and other surgical procedures. Misuse of the ECMO machine and other medical devices used by Clinical Perfusion Scientists can cause almost instant death. It is therefore important that the public, employers and other health professionals can have confidence in Clinical Perfusion Scientists, as a key part of the surgical team. The Gritten Report (2007) [13] recommended that a national review of the regulation of Clinical Perfusion Scientists should be carried out, following an investigation into the death of a child at Bristol Childrens Hospital two years earlier. The *Guide to Good Practice in Clinical Perfusion* (Department of Health, 2009) states that 'The government fully recognises the need for this key group of staff to be regulated by statute' and that '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.'[14] In March 2015, the Health and Care Professions Council (HCPC) highlighted in a briefing to the UK Parliament Health Committee that it had previously recommended the statutory regulation of Clinical Perfusion Scientists, and that it remained of the view that this should be considered 'on the basis of patient safety.'[15]

3. Share your experience

As part of our assessments, we seek feedback from service users, the public, professional and representative organisations, employers and others on their experience of a Register.

[13] ROOT CAUSE ANALYSIS REPORT (webflow.com)
[14] Guide to Good Practice in Clinical Perfusion (webflow.com)
[15] enclosure-on-statutory-regulation-of-further-professions.pdf (hcpc-uk.org)

We received ten responses to our invitation to share experience on the SCPS' application for preliminary assessment against Standard One. This included five from Clinical Perfusion Scientists currently practising in the UK.

Responses highlighted the inherent risks involved in cardiac bypass operations and noted the importance of having highly skilled and knowledgeable people carrying out these roles. Other key themes were the risk of low staffing levels affecting quality of care, problems with equipment, and a lack of appropriate skills such as communication skills, ability to problem solve and make decisions. The lack of protection of title, meaning anyone can claim to be a Clinical Perfusion Scientist, was also highlighted. We have considered these themes within our assessment.

4. Outcome

The Accreditation Panel met on 8 February 2024 to consider the SCPS' application for a preliminary assessment against Standard One ('public interest test'). Overall, the Accreditation Panel determined Standard One was provisionally met.

The Accreditation Panel also issued the following Recommendations for the SCPS to consider if it decides to complete a full application:

- **Recommendation One:** The SCPS should update its risk matrix to make clearer how it is mitigating the technical risks arising from use of ECMO and other equipment.

We also considered that the risks associated with the role of clinical perfusion scientist appear sufficiently high, and potential impacts on patients sufficiently great, to recommend that the UK Government should consider whether accredited voluntary registration is likely to be adequate. We noted that the following information could help establish this:

1. Understanding the extent to which the requirement for Clinical Perfusion Scientists to be registered with the SCPS is implemented within the NHS, and the independent sectors.
2. Understanding how reporting and learning from patient safety concerns relating to clinical perfusion science are co-ordinated across the systems regulators, national patient safety bodies and the SCPS.
3. Gathering data about the number of patient safety incidents relating to clinical perfusion that are due to errors by the Clinical Perfusion Scientist, to inform understanding of the inherent risks of the role.

Standard 1: Eligibility and 'public interest test'

This section of the report summarises the key considerations in reaching this conclusion for each part of Standard One.

Summary

The Panel found Standard 1 was provisionally met at its meeting on 8 February 2024. This is a provisional outcome and will be reviewed if the SCPS submits a full

application for accreditation to see if there are any changes that could affect this decision. As noted above, we also considered that the risks associated with the role of clinical perfusion scientist appear sufficiently high, and potential impacts on patients sufficiently great, to recommend that the UK Government should consider whether accredited voluntary registration is likely to be adequate.

The Accreditation Panel's findings

Standard 1a: Eligibility under our legislation

The Authority's powers of accreditation are set out in Section 25E of the National Health Service Reform and Health Care Professions Act 2002[16]. Standard 1a considers whether a Register is eligible for accreditation, based on whether the role(s) it registers can be considered to provide health and care services and are not required by law to be registered with a statutory body to practise in the UK.

Clinical Perfusion Scientists have a key, recognised role within surgical teams and can therefore be considered as delivering healthcare services. *The Guide to Good Practice in Clinical Perfusion* (2009)[17] states that Clinical Perfusion Scientists '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 [cardiopulmonary bypass] during cardiac surgery.'

Clinical Perfusion Scientists are not required to be registered by law in the UK. We noted that the register also includes those working in the Republic of Ireland. This assessment covers the UK countries only.

The Accreditation Panel found that the role of Clinical Perfusion Scientist falls within the scope of the Accredited Registers programme and that Standard 1a is met.

Standard 1b: Public interest considerations

Under Standard 1b, we consider whether it is likely to be in the best interests of patients, service users and the public to accredit a register, with consideration of the types of activities practised by its registrants. This involves consideration of the overall balance of the benefits and risks of the activities.

Factors considered by the Accreditation Panel are discussed below.

i. Evidence that the activities carried out by registrants are likely to be beneficial

There is strong evidence for the benefits to patients of the services provided by Clinical Perfusion Scientists.

Use of heart-lung machine during cardiopulmonary bypass for heart failure

[16] Roles that are required to be enrolled with a statutory register to practise in the UK are set out in Section 25E (2) of the National Health Service Reform and Health Care Professions Act 2002, available at: National Health Service Reform and Health Care Professions Act 2002 (legislation.gov.uk)

[17] https://global-uploads.webflow.com/5da4ad68b9d5374c5a54c71d/5da4ad68b9d537fd6654c82a_SCPS%20-%20Good%20Practice%20Guide.pdf

As noted above the main role of a clinical perfusion scientist is as part of the surgical team responsible for the cardiopulmonary bypass (heart-lung) machine during cardiopulmonary bypass (CPB) procedures such as operations to treat heart failure.

Heart failure is when the heart is unable to pump blood around the body properly. It cannot usually be cured but it can be controlled through lifestyle changes, medicines, implantation of devices or surgery. If the heart valves are damaged, a cure may be possible by replacing or repairing them.[18] A heart transplant can be carried out when heart failure is severe and medical treatments are not helping. Cardiopulmonary bypass will be used during this type of surgery. NHS England states that 'most people can eventually return to their normal activities after a heart transplant and experience a significant improvement in their symptoms for many years.'[19] CPB procedures therefore have high benefits to patients.

Typically, CPB operations involve replacing or repairing heart valves, heart and lung transplants and/or coronary artery bypass graft surgery. During CPB, the functioning of the heart and lungs are temporarily stopped by the perfusionist. The bypass machine provides an artificial heart and lungs by oxygenating the blood and removing excess carbon dioxide using an artificial gas exchange. The newly oxygenated blood is then pumped around the patient's body. This allows a surgeon to perform the operation in a controlled environment.

Once the patient is connected to the bypass machine, the surgeon isolates the heart using a clamp and the Clinical Perfusion Scientist administers medication called 'cardioplegia' to temporarily stop the heart. During the operation the clinical perfusion scientist will be responsible for monitoring the bypass machine, checking blood chemistry, and monitoring heart activity. Depending on the type of operation, they may also monitor brain activity and kidney output. This helps increase the patients' chances of survival, and of minimising the bodily damage from the bypass.

Another type of treatment used for heart failure that involves the use of the heart-lung machine by a Clinical Perfusion Scientist is the fitting of a left ventricular assist device (LVAD). The British Heart Foundation states that LVAD 'is used to treat people with severe heart failure and is sometimes given to people on the waiting list for a heart transplant…Some patients being considered for a heart transplant may need to have an LVAD implanted if they are unlikely to survive until a suitable donor heart becomes available. The device helps the failing heart and aims to restore normal blood flow.'[20] The SCPS highlighted that there are two types of LVAD, both used by Clinical Perfusion Scientists: one being short-term, commonly used in post-operative recovery and the other for long-term use as an implantable device.

Use of ECMO during open-heart surgery

The ECMO machine works in a similar way to the heart-lung machine used in CPB but is provided on wards for patients who are suffering cardiac and respiratory failure. It involves diverting blood from a major vessel through an external gas exchange membrane, and back into the blood vessel.

[18] Heart failure - NHS (www.nhs.uk)
[19] Heart transplant - NHS (www.nhs.uk)
[20] Left ventricular assist device (LVAD) - Heart Matters magazine - BHF

NICE Guidance IPG482 *Extracorporeal membrane oxygenation (ECMO) for acute heart failure in adults* (2014)[21] notes that ECMO can be used after heart surgery to 'assist in the transition from the cardiopulmonary bypass to ventilation or as a bridge to myocardial recovery, cardiac transplant or the implant of a left ventricular assist device'. The guidance notes that 'The evidence on the efficacy of extracorporeal membrane oxygenation (ECMO) for acute heart failure in adults is adequate but there is uncertainty about which patients are likely to benefit from this procedure, and the evidence on safety shows a high incidence of serious complications. Therefore, this procedure should only be used with special arrangements for clinical governance, consent and audit or research.'[22]

NICE Guidance IPG391 *Extracorporeal membrane oxygenation for severe acute respiratory failure in adults* (2011)[23] describes ECMO as 'temporary life support technique, used to treat respiratory failure (where the lungs do not work effectively) in critically ill patients. The aim is to increase oxygen levels in the blood. During the procedure, a tube carries blood from the right side of the heart then pumps it through an artificial lung where it picks up oxygen. This oxygen-rich blood is then passed back into the person's blood system.'[24] The guidance notes that 'this procedure should only be used with special arrangements for clinical governance, consent and research' and that 'Extracorporeal membrane oxygenation for severe acute respiratory failure in adults should only be carried out by clinical teams with specific training and expertise in the procedure.'

Additional benefits: cell salvage, point of care testing and organ preservation

The Accreditation Panel considered the additional benefits of Clinical Perfusion Scientists in addition to their core role within CPB and open-heart surgery.

Clinical Perfusion Scientists also have a role in cell salvage, through collecting blood lost throughout a surgery, which can then be processed and transfused back to the patient later in the surgery. This reduces the need for blood transfusions, reduces infection and helps to improve the body's immune response.[25] A guideline written by the Association of Anaesthetists stated that 'The use of cell salvage is recommended when it can be expected to reduce the likelihood of allogeneic (donor) red cell transfusion and/or severe postoperative anaemia. We support and encourage a continued increase in the appropriate use of peri-operative cell salvage and we recommend that it should be available for immediate use 24 hours a day in any hospital undertaking surgery where blood loss is a recognised potential complication'[26].

The SCPS also highlighted 'point of care testing' as a benefit. This includes activities such as viscoelastic blood testing, undertaking whole blood counts, and platelet

[21] https://www.nice.org.uk/guidance/ipg482/resources/extracorporeal-membrane-oxygenation-ecmo-for-acuteheart-failure-in-adults-1899869988516037
[22] https://www.nice.org.uk/guidance/ipg482/chapter/1-Recommendations
[23] https://www.nice.org.uk/guidance/ipg391/chapter/1-Guidance
[24] Overview | Extracorporeal membrane oxygenation for severe acute respiratory failure in adults | Guidance | NICE
[25] Cell salvage: Returning a patient's own blood during surgery :: Royal Papworth Hospital
[26] Association of Anaesthetists guidelines: cell salvage for peri-operative blood conservation 2018 - Klein - 2018 - Anaesthesia - Wiley Online Library

function tests. These tests are used to assess the level of anticoagulation (the process of stopping the formation of a blood clot) within the blood, the presence of coagulation deficiencies, and are used as part of transfusion algorithms to accurately target blood product transfusion. Monitoring the main components and clotting factors of the blood allows Clinical Perfusion Scientists to support clinicians in identifying areas of deficiency and to treat accordingly. This type of targeted strategy limits unnecessary transfusions and can reduce risk of further bleeding post operatively.

Organ preservation is the process of protecting organs and ensuring that they remain viable for transplantation. Kaliyev et al (2020)[27] highlight the benefits of using a portable perfusion and monitoring system to maintain the liver outside the body, in comparison with traditional cold storage methods. NICE interventional procedures guidance [IPG549] (2016) notes that 'Current evidence on the efficacy of normothermic extracorporeal preservation of hearts for transplantation following donation after brainstem death shows that the procedure extends preservation times compared with conventional cold storage. The evidence on safety is adequate in the short term. Therefore, this procedure may be used with standard arrangements for clinical governance and audit.[28]' This guidance did however encourage further research into the normothermic extracorporeal preservation in the UK.

The treatment of melanomas in limbs using isolated limb perfusion (ILP) is a further benefit. Cancer Research UK described this as 'a way of having chemotherapy into one arm or leg, without the drugs circulating through the rest of your body'[29]. This can reduce the adverse effects often experienced with chemotherapy. A systematic review published in 2010 concluded that 'ILP is effective in achieving clinical responses in patients with unresectable locally advanced melanoma of the limbs. The disease-free and overall survival rates provided by ILP are acceptable. ILP is safe, with a low incidence of severe regional and systemic toxicity.'[30]

The Accreditation Panel concluded that there is strong evidence for the benefits of the activities undertaken by Clinical Science Perfusionists.

ii. Evidence that any harms or risks likely to arise from the activities are justifiable and appropriately mitigated by the register's requirements for registration.

The Accreditation Panel considered the risks associated with the practice of Clinical Perfusion Scientists. These have been identified from our desk-based research, and those identified by the SCPS in its risk matrix. We found that the SCPS' risk matrix appeared to capture the key risks associated with the role.

Risks arising from lack of technical competence

[27] https://cardiothoracicsurgery.biomedcentral.com/articles/10.1186/s13019-020-01367-w
[28] https://www.nice.org.uk/guidance/ipg549/chapter/1-Recommendations
[29] https://www.cancerresearchuk.org/about-cancer/melanoma/treatment/advanced-treatment/chemotherapy-advanced-melanoma/chemotherapy-arm-or-leg
[30] Isolated Limb Perfusion for Malignant Melanoma: Systematic Review on Effectiveness and Safety | The Oncologist | Oxford Academic (oup.com)

The SCPS has identified risks relating to lack of professional competence. These include registrants failing to follow best clinical practice in terms of CPB contributing to the injury or death of the patient, and other key activities such as ECMO. They have also identified the risk of administering the wrong medicine, or a wrong dose; and of operating medical devices such as ECMO incorrectly. It appears from the evidence we reviewed, and the operation we observed, that Clinical Perfusion Scientists have a relatively high degree of autonomy and clinical judgment within their area of practise, within the surgical team.

Risks from CPB

The risks to patients arising from CPB are significant, and include severe physical, neurological, psychological disability or death. There is a risk of multiple organ failure arising directly from perfusion. This can occur through low blood oxygen levels caused by insufficient oxygen delivery, irreversible heart cell death from lack of adequate myocardial protection and swelling of the brain from mismanagement of electrolyte balance. Errors in perfusion can contribute to other negative outcomes of CPB, highlighted by Passaroni et al (2015) as including 'haemorrhage, low cardiac output, arrhythmias, respiratory failure, renal failure, neurological or neuropsychiatric changes, fluid and electrolyte imbalances, abdominal changes, haemolysis, and inflammation.'[31] For example, accidently introducing air into the circulatory system through incorrect use of the heart-lung and/or ECMO machine can result in a gross air embolism to the brain, which can have major adverse consequences even when the volume of air is small (Kjaer, 2017)[32].

Risks associated with the administration of medicines

Clinical Perfusion Scientists are frequently responsible for administering medicines, under the supervision of a clinician. This includes medicines that can be toxic in high doses. An example of this is cardioplegia, which is used to temporarily to stop the heart during a procedure. However, in high doses it can cause irreversible damage to the heart.[33] The SCPS told us that Cardioplegia is prepared by the Clinical Perfusion Scientist before the start of surgery, cross checked with an Operating Department Practitioner (the anaesthetic assistant) and then signed off by a perfusionist for administration and any waste doses. This will be prescribed by a doctor.

However, these types of mitigations can fail. The Gritten Report (2007) provided an independent root cause analysis report into the adverse perfusion-related incident that led to the death of a paediatric cardiac surgery patient at United Bristol Healthcare NHS Trust on 27 May 2005. The report found that the cause of death was likely to have been the result of excessive administration of ionised calcium by the Clinical Perfusion Scientist. Although several influencing factors were identified, such as the pressures of the workplace environment, the case highlights the fact that errors made by the Clinical Perfusion Scientist can cause serious injury and death.

[31] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4462970/pdf/rbccv-30-02-0235.pdf
[32] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5373014/

A Patient Safety Alert issued by NHS England in 2018[34] warned of risk of death or severe harm from inadvertent intravenous administration of solid organ perfusion fluids. The alert highlights instances of harm arising from the administration of perfusion fluids, based on incidents reported to the National Reporting and Learning System. For example, in one case, the intravenous administration of perfusion fluid to a patient caused severe bradycardia that needed emergency intervention. The alert set out actions for NHS funded care where organ transplantation is undertaken, such as checking which organ perfusion fluids have been approved for use. Although the alert does not mention the role of Clinical Perfusion Scientists specifically, relevance to all medical and theatre staff is highlighted.

Risks relating to blood transfusion

Errors can also arise in relation to the blood transfusion often carried out by Clinical Perfusion Scientists during a procedure. Errors in transfusion include incorrect blood component transfusion, avoidable or delayed transfusion, and errors in handling or storing the blood product. This can increase the risk of adverse reactions by patients such as acute lung injury, circulatory overload, and infection. The Serious Hazards of Transfusion (SHOT) 2022 Annual Report[35] noted its concern that most incidents reported that year were preventable. It identified inaccurate documentation and labelling as a theme. It also highlighted that the 'appropriate management of patients receiving cell salvaged blood is vital as unexpected clinical reactions can and do happen'. Although the report does not mention specific roles within the transfusion team, as seen earlier in this report, Clinical Perfusion Scientists often have a key role in cell salvage and transfusion activities more broadly.

Risk of infection

A further risk is that of potential infection from contact with contaminated equipment/disposables used by the Clinical Perfusion Scientist. The SCPS highlighted that aerosolisation of warm water tanks in the heater cooler units in the operating theatre can cause harmful microbes like mycobacteria to be transmitted to patients in surgery. Other sources of infection include residual infected blood on equipment from previous surgeries, general dust and dirt on equipment, and contamination of sterile disposables within the sterile operating field from skin or human contaminants. The risk of infection is mitigated following pre-operative protocols for the safe use of equipment, which Clinical Perfusion Scientists must follow.

Personal and professional behaviours

The SCPS has identified the risk of registrants acting in inappropriate ways towards colleagues or patients. This could include acting in a way that violates sexual or emotional boundaries, discrimination, or operating in a way that causes harm, abuse, or neglect of a patient. Mitigations include adhering to the *SCPS Code of Ethical*

[34] https://www.england.nhs.uk/wp-content/uploads/2019/12/Patient_Safety_Alert_-_solid_organ_perfusion_fluids.pdf
[35] https://www.shotuk.org/wp-content/uploads/myimages/SHOT-REPORT-2022-FINAL-Bookmarked-1.pdf

Conduct and *Code of Practice*[36], institutional training including safeguarding and the introduction of the SCPS Equality, Diversity and Inclusion Sub-committee to raise awareness of protected characteristics *and is pending release of EDI policy for membership*.

Aggravating risk factors: vulnerability of patients, and working in unfamiliar environments

Those receiving the services of Clinical Perfusion Scientists are likely to be very ill. The SCPS highlighted that adults receiving ECMO and Extracorporeal Life Support (ECLS) are likely to have more than one disease or condition at the same time, which can increase the risk of poor outcomes. In general, delivering perfusion services to children carries additional risks. Great Ormond Street Hospital[37] highlights risks of complications arising through procedures involving an ECMO machine, highlighting that it is only used for very ill children who would die without ECMO support.

The SCPS includes a specific risk about performing perfusion on children, known as 'paediatric perfusion', within its risk matrix. The SCPS describes CPB as being higher risk for children than for adults. This is due to the margins for error being smaller in terms of aspects such as medicine dose, and blood gas value ranges.

The SCPS also identified the risk of Clinical Perfusion Scientists not being aware of contraindications ahead of surgery that could result in negative patient outcomes. A contraindication is a specific situation in which a medicine, procedure, or surgery should not be used because it may be harmful to the patient. The SCPS also highlighted that the development and use of perfusion techniques and machines in new and innovative ways could pose further contradictions and risks.

The SCPS has identified risks arising from Clinical Perfusion Scientists working in different environments. It highlights that independent healthcare organisations may rely on locum Clinical Perfusion Scientists to maintain appropriate staffing levels. Working in an unfamiliar environment whilst working as a locum, or otherwise could increase the likelihood of errors in the maintenance and management of medical devices such as the heart-lung machine or ECMO.

The role of the SCPS in mitigating risks

Professional competence

A key mitigation for these risks is appropriate education and training. The SCPS has worked in partnership with the University of Bristol to develop a MSc in Clinical Perfusion, which addresses the SCPS' academic and professional requirements for trainee Clinical Perfusion Scientists. Successful completion of this course is a requirement for new applicants to register with the SCPS. The programme is only available to students who have secured a Clinical Perfusion Scientist trainee position with an accredited hospital training centre in Great Britain or Ireland. The curriculum

[36] Available at: https://www.scps.org.uk/society/society-documents
[37] Extracorporeal membrane oxygenation (ECMO) | Great Ormond Street Hospital (gosh.nhs.uk)

for the MSc includes advanced physiology and disease states of blood and organs that are affected by CPB, and principles and practical aspects of currently used techniques in adult and paediatric perfusion science[38].

Although the MSc provides assurance of the training for current applicants, registrants who applied before its introduction in 2017 include those whose knowledge is experience-based. These registrants may be working in NHS or independent hospitals. We would look at education, training and continued professional development (CPD) requirements in greater detail if the SCPS submits a full application for accreditation. In the meantime, we note the NHS Careers website notes that to secure a post as a trainee clinical perfusion scientist with an NHS Trust, 'the minimum entry requirement for entry into a trainee position is a 2:1 BSc degree in a science or medicine-related subject' and provides a link to the Bristol MSc[39]. NHS Scotland sets out the requirement to complete the Bristol MSc[40].

A further key mitigation for these competency-related risks is the requirement for registrants to adhere to *The Guide to Good Practice in Clinical Perfusion,* which details the role of the perfusionist. This sets out the governance frameworks in which Clinical Perfusion Scientists are expected to operate. Further detail on governance and audit as a specific mitigation is set out below.

Audit and clinical governance

The Guide to Good Practice in Clinical Perfusion also highlights the importance of hospitals' audit and governance functions in managing risks relating to clinical perfusion. For example, this allows for appropriate quality management frameworks including management of medicines to be developed.

The SCPS has developed further guidance to support effective clinical governance, such as *The recommendations for standards of monitoring and safety during cardiopulmonary bypass* (2023)[41].

The SCPS has a Safety Committee, which plays a key role in promoting good practice within clinical perfusion practice. The Safety Committee collates information about patient safety concerns, including through an online form on its website. It liaises with relevant regulatory agencies, such as the Medicines and Healthcare Products Regulatory Agency (MHRA), to share information about risk. The Safety Committee publishes reports to share learning arising from its review of concerns. For example, in January 2023 it published a report about an incident involving an

[38] https://www.bristol.ac.uk/study/postgraduate/taught/msc-clinical-perfusion-science/
[39] https://www.healthcareers.nhs.uk/explore-roles/healthcare-science/roles-healthcare-science/physiological-sciences/clinical-perfusion-science/entry-requirements-skills-and-interests (accessed 8 January 2024)
[40] https://www.careers.nhs.scot/explore-careers/healthcare-science/clinical-perfusionist/ (accessed 8 January 2024)
[41] https://assets-global.website-files.com/5da4ad68b9d5374c5a54c71d/655e2412229ae770b9acba94_Recommendations%20for%20Standards%20of%20Monitoring%20and%20Safety%20during%20Cardiopulmonary%20Bypass%202023.pdf

oxygenator leak, and details of action taken to raise awareness with the manufacturer[42].

The CCPS accredits perfusion departmental units[43]. If an incident reported to the SCPS Safety Committee suggests concerns about safety practices within hospital perfusion departments, this will be escalated to the CCPS. Depending on severity, this may trigger a visit by the CCPS to the department.

If the SCPS applies for full accreditation, we will assess how concerns reported to the Safety Committee that raise concerns about an individual Clinical Perfusion Scientist are investigated.

Risks that are beyond the SCPS' control

The regulation of individual healthcare practitioners is known as "professional registration." The main two other aspects of healthcare regulation are that of the environment in which care is delivered, carried out by the "systems regulators" for each UK country; and of medicines and medical devices, carried out by the MHRA. The regulation of these aspects of 'people, place and product' often interrelate.

The purpose of the Accredited Registers programme is to give assurance about the practice of individual healthcare practitioners who are not required by law to be registered by law to practise (which is known as "statutory regulation"). Registration with an Accredited Register is voluntary. Standard One checks whether it is in the public interest to accredit a Register. Accordingly, the Accreditation Panel may highlight issues that may relate to public protection, but which may not be directly addressed by voluntary registration alone.

During this assessment, we noted that key mitigations developed by the SCPS include the development of a dedicated education and training route, and guidance on good practice. If the SCPS submits a full application for accreditation, we will assess the strength of other mitigations relating to professional registration, such as complaints handling processes. In the meantime, the Accreditation Panel considered that the severity of the risks associated with Clinical Perfusion Scientists increases the importance of a cohesive regulatory framework.

Although registration with the SCPS is not a legal requirement to practise as a Clinical Perfusion Scientist, the UK Government has issued requirements for NHS bodies to only employ those registered with the SCPS. The systems regulators and the MHRA also have an important role in mitigating these through ensuring effective clinical and medicines management. The SCPS appears to work with other relevant bodies such as the MHRA to identify and share learning about patient safety concerns arising from clinical perfusion.

However, the Accreditation Panel noted areas of potential weaknesses in the overarching regulatory framework. Since the UK Government has only addressed

[42] https://www.scps.org.uk/archived-perfusion-reports/108
[43] https://assets-global.website-files.com/5da4ad68b9d5374c5a54c71d/64e89c31689629d826665948_Accredited%20and%20non%20accredited%20units%20August%202023.pdf

NHS bodies employing Clinical Perfusion Scientists, the extent to which independent hospitals require SCPS registration for Clinical Perfusion Scientists is unclear. This gives the potential for someone who has not met the necessary requirements for NHS practise, and/or does not otherwise meet the SCPS' registration requirements, to work in the independent sector.

It is not clear whether the systems regulators would check the registration status of Clinical Perfusion Scientists working in independent hospitals. For example, the Care Quality Commission's inspection framework for acute surgery in Independent Hospitals does not make specific reference to the SCPS' good practice guidance or include any prompts for inspectors to consider the registration status of Clinical Perfusion Scientists[44].

Although the Safety Committee appears to play a key role in raising awareness of clinical perfusion incidents, and of sharing learning from these, it is not clear how this is embedded within national patient safety reporting approaches. For example, we did not see any evidence of information sharing protocols or frameworks guiding how concerns reported to the SCPS' Safety Committee are shared with national bodies, such as the Health Services Safety Investigation Body for England. It is consequently difficult to assess the extent to which there is shared understanding of the risks arising from clinical perfusion.

In addition, the Accreditation Panel noted that the SCPS has highlighted risks of professionals without experience equivalent to the two-year MSc course it requires for registration operating equipment such as ECMO machines safely. We have not reviewed any evidence in relation to this, and it is outside the scope of our assessment. However, we note that since not all SCPS registrants have completed the MSc course, there may be considerable variation in the formal training that Clinical Perfusion Scientists and other professionals have completed in relation to ECMO and other medical devices commonly used in perfusion.

The Accreditation Panel noted that the HCPC reiterated its recommendation to the Government for Clinical Perfusion Scientists to be considered by the Government for statutory regulation in 2015. We have not applied our methodology for assessing the inherent risk of roles in detail, *Right Touch Assurance (RTA)* (2015), to the role of Clinical Perfusion Scientists. However, the Accreditation Panel determined that the risks appear sufficiently high, and potential impacts on patients sufficiently great, to recommend that the UK Government should consider whether accredited voluntary registration is likely to be adequate. It noted that the following information could help establish this:

1. Understanding the extent to which the requirement for Clinical Perfusion Scientists to be registered with the SCPS is implemented within the NHS, and the independent sectors.
2. Understanding how reporting and learning from patient safety concerns relating to clinical perfusion science are co-ordinated across the systems regulators, national patient safety bodies and the SCPS.

[44] https://www.cqc.org.uk/sites/default/files/inspection-framework-independent-hospitals-surgery.pdf

3. Gathering data about the number of patient safety incidents relating to clinical perfusion that are due to errors by the Clinical Perfusion Scientist, to inform understanding of the inherent risks of the role.

In the meantime, we also recommend that the SCPS updates its risk matrix to make clearer how it is mitigating the technical risks arising from use of ECMO and other equipment.

- **Recommendation One:** The SCPS should update its risk matrix to make clearer how it is mitigating the technical risks arising from use of ECMO and other equipment.

iii. Commitment to ensuring that the treatments and services are offered in a way that does not make unproven claims or in any other way mislead the public

The majority of SCPS registrants are employed, and do not advertise their services directly to the public. Websites of individuals are not included on the SCPS' register and therefore the team have not conducted registrant website checks.

We did not identify any concerns in relation to this part of the assessment. However, as set out in the section above, the SCPS has advised there may be risks associated with people using perfusion in their job titles who had not completed the training required for registration. This was also highlighted in some Share Your experience responses. Although this is not directly within the SCPS' remit, the SCPS' work to promote use and recognition of its register could help to mitigate this risk.

5. Impact assessment (including equalities)

The Authority is required to carry out an assessment of the impact of accreditation on service users before accreditation is granted. This impact assessment included an equalities impact assessment as part of the consideration of our duty under the Equality Act 2010. Once accredited, the impact assessment is reviewed as part of a Register's annual renewal, and at any point if there are concerns or significant changes in the external environment in the meantime.

We have not published a full impact assessment since a decision on whether to accredit has not yet been made. However, we have considered which are the main groups likely to be affected by accreditation of the SCPS and what the main impacts are likely to be in terms of equalities, cost/markets, social and environmental impacts. This has included consideration of our duty as a public sector body under the Equality Act 2010.

The evidence we reviewed during the assessment indicated that people receiving the services of Clinical Perfusion Scientists are more likely to have multiple conditions and may be very ill. This includes children and adults receiving care for serious conditions such as heart failure. The risks associated with clinical perfusion, and the level of autonomy of the role, mean that the inherent risk of the role of Clinical Perfusion Scientists is high in comparison with other unregulated healthcare roles. We noted that the Government's requirement for Clinical Perfusion Scientists

employed by the NHS to be registered with the SCPS may not have been adopted within independent hospitals. For this reason, although we think it would strengthen public protection and therefore be in the public interest to accredit the SCPS, as set out in this report we recommend that the UK Government considers whether accredited voluntary registration of Clinical Perfusion Scientists is likely to be sufficient.