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Qualification, knowledge, tasks and responsibilities of the clinical perfusionist in Germany

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Abstract

Consensus paper of the German Society of Cardiovascular Engineering, the German Society for Thoracic and Cardiovascular Surgery, the German Society of Cardiology, the German Society of Pediatric Cardiology, the German Society of Anesthesiology and Intensive Care Medicine, the German Interdisciplinary Association of Intensive Care Medicine and Emergency Medicine and the German Society of Medical Intensive Care and Emergency Medicine.

Keywords: Clinical perfusionists • Professional recognition • Qualified occupation • Certification • Medical professions • Qualification of cardiovascular perfusionists • European Certificate in Cardiovascular Perfusion • German Qualifications Framework • State-recognized occupation

INTRODUCTION

The long-standing interprofessional and trustful interdisciplinary cooperation between clinical perfusionists or perfusionists (in Germany to be equated with ‘Kardiotechniker’), and cardiac surgeons, anaesthesiologists, internists/cardiologists and paediatric cardiologists, is an integral part of treating patients of all ages with congenital and acquired cardiac, thoracic and vascular diseases. To date, German federal law does not recognize clinical perfusion as a qualified occupation with a specific certification. Nationwide no educational standard exists as an entry requirement to professionally perform clinical perfusion, nor are there any duties and tasks described. For the federal state of Berlin, however, there is a state law according to which the professional title and the activity are protected as a ‘Kardiotechniker’ [medical professions act of 15 June 1983 (MedFberGBe)]; there is also a training and examination regulation for perfusionists (KardTechAPrO) [1]. Therefore, the

nationwide gap should be closed by joint recommendations regarding the required knowledge, special duties and responsibilities of the clinical perfusionist.

BACKGROUND

The use of extracorporeal circulation (ECC) in cardiac surgical patients has been established for over 60 years. In the context of the complex treatment processes for these patients, the preoperative, intraoperative and postoperative subprocesses require interdisciplinary cooperation between the clinical perfusion department and the medical departments of cardiac surgery, anaesthesiology, internal medicine/cardiology and paediatric cardiology. The cardiac surgeon, anaesthesiologist, cardiologist, paediatric cardiologist and the perfusionist, with their respective areas of expertise, act in an extended heart team with the common goal to treat cardiac patients successfully.

The interaction and competence of all personnel involved in cardiac surgery, structured processes and a suitable infrastructure are essential for maintaining for the quality of treatment and results. The definition of binding responsibilities and necessary

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Male and female forms are neglected to improve the readability. All person-related statements nevertheless apply to both genders.

quality standards and the definition of required knowledge and tasks of the professional groups involved are important steps in this context in order to be able to implement a legally resilient division of responsibilities (also in terms of liability) on the basis of a clear division of tasks and the principle of trust.

To achieve the stated goals, the relevant technical and medical topics are outlined in the following chapters, and the competence and field of activity of the clinical perfusionist are placed in the context of the medical specialties.

Since the beginning of ECC, the range of applications for such systems has expanded considerably as a result of constant technical development, innovation and research. Accordingly, the demands placed on the clinical perfusionist have also increased significantly. The core and by far the predominant field of activity of the clinical perfusionist is the operation of cardiopulmonary bypass in cardiac surgery. In 2018, a total of 72 331 of the 98 707 cardiopulmonary operations in Germany were performed using ECC [2]. Other responsibilities provided by the clinical perfusionist are not presently a part of these recommendations.

HISTORY

The first successful heart operation using a heart–lung machine (HLM) was performed by John Heysham Gibbon Jr on 6 May 1953. Mary Gibbon, his wife, was his perfusionist. She operated the HLM, which had been developed during >20 years of joint work; she controlled the patient's ECC while her husband successfully closed an atrial septal defect [3].

In Germany, ECC was first successfully used by Rudolf Zenker on 19 February 1958 in a similar procedure at the University Hospital of Marburg. At that time, the HLM was operated by the assistant physician Hans Georg Borst [4].

In the following years, the new and independent field of clinical perfusion, open to members of different occupations, gradually established itself in Germany, initially without further structured qualifications. The respective tasks were taken over partly by physicians, but predominantly by non-physician personnel. At the beginning, the newly created positions in the hospital organization, called 'clinical perfusion departments', were often filled by state-certified nurses as well as by technically trained specialists, e.g. medical technicians and graduate engineers from various fields (e.g. medical technology, electrical engineering or precision engineering with specialization in medical technology). All occupational groups were trained and qualified in their respective hospitals. The personnel structure of these departments at an early stage reflected the close and intensive connection between technology and medicine. As expected, with technical and medical progress, the medical products and technical systems used, as well as the therapeutic procedures, became increasingly complex, so that today the safe operation of ECC with the differentiated use of the HLM must be carried out exclusively by specially qualified personnel.

TRAINING AND CERTIFICATES

The USA

In the USA, a state licence is usually required for a professional activity such as that of a perfusionist [5]. A prerequisite for this licence is a successfully completed degree (bachelor's or master's

degree) at an accredited university [6]. In many states [7], this licensing is subject to proof of the Certified Clinical Perfusionist certificate issued by the American Board of Cardiovascular Perfusion [8, 9]. In 2018, 4122 perfusionists held an American Board of Cardiovascular Perfusion certificate [10].

Europe

Due to the lack of legal regulations at the European level, the European Board of Cardiovascular Perfusion (EBCP) has set itself the goals of defining the competence level of clinical perfusionists with regard to structured training and of establishing the corresponding requirements uniformly throughout Europe [11]. The EBCP was founded in 1991 as an independent institution with the goal of creating and implementing minimum requirements for vocational training and further education throughout Europe [9, 11–14]. The EBCP is listed under the European Economic and Social Committee as a Registry with the Fich-ID 43 (<https://www.eesc.europa.eu>). From the beginning, it was supported in its work by the European Association for Cardio-Thoracic Surgery and the European Association of Cardiothoracic Anaesthesiology.

This goal is also reflected in the joint statement on the Qualification of Cardiovascular Perfusionists of the European Association for Cardio-Thoracic Surgery and European Association of Cardiothoracic Anaesthesiology, which clearly establishes the need for the qualification of clinical perfusionists [15]. Furthermore, it has been intended for some time to establish the clinical perfusionist as a health care professional within the meaning of the European Union's Professional Recognition Directive [16] [Directive 2005/36/EC and Regulation (EU) No. 1024/2012] as a regulated profession.

The EBCP regulates the certification process and accredits training centres (universities, colleges and academies) that offer structured and qualified training for clinical perfusionists according to defined criteria. Upon successful completion of the training at a facility accredited by the EBCP, the European Certificate in Cardiovascular Perfusion is awarded.

A special exception in Europe is Austria. Only in this European Union member state is training as a clinical perfusionist regulated by law and the 'Diplom-Kardiotechniker' a state-recognized and thus protected profession [17]. The Austrian Federal Act on Cardiotechnical Services ['Kardiotechnikergesetz' (KTG)] regulates a professional monopoly in § 1 [1] KTG and the competences of the clinical perfusionist in § 2 KTG.

Because there are no federal regulations on training or working as a clinical perfusionist in the Federal Republic of Germany, the German Society of Cardiovascular Engineering, as the responsible specialist society, recommended the contents of the European Certificate in Cardiovascular Perfusion as proof of qualification for a clinical perfusionist as a minimum standard for Germany as early as 2010 [18–20]. However, there is still no nationwide mandatory training and qualification for clinical perfusionist employees.

KNOWLEDGE, TASKS AND RESPONSIBILITIES OF THE CLINICAL PERFUSIONIST

The clinical perfusionist's scope of activity: tasks with and without medical delegation

The clinical perfusionist represents a medical profession that is not limited to the practice of medicine. In addition to the

medical activities, there are also engineering areas of responsibility that do not fall under the practice of medicine [21, 22].

Anyone wishing to engage in the independent practice of medicine in Germany requires a licence as provided by law. For physicians, this licence is defined in the 'Bundesärzteordnung' (federal medical code). In addition, apart from the provisions of the 'Heilpraktikergesetz' (HeilprG, Non-Medical Practitioners Act), other professional groups are authorized by law to engage in the practice of medicine in specific areas, e.g. licenced psychological psychotherapists, § 1 PsychThG.

In the absence of a licence as provided by law, clinical perfusionists are currently only allowed to engage in the practice of medicine by delegation.

The clinical activity of the clinical perfusionists involving patients constitutes the practice of medicine, even if it requires specific technical knowledge and skills in addition to medical knowledge. In addition to operating/controlling the HLM directly, this clinical activity includes, for example, all preparatory measures for its concrete use. On the other hand, activities that are only indirectly related to patient care are not subject to the practice of medicine. These include, for example, the maintenance of medical equipment and accessories or research and teaching activities.

The profession of clinical perfusionist is characterized by the close interweaving of basic technical and engineering knowledge and skills with special medical knowledge. In the close, trusting cooperation between the physician and the clinical perfusionist, the latter acts on a medical (physician's) order (responsibility for orders). The clinical perfusionist is then responsible for the practical implementation of the medical order (responsibility for implementation). In this activity, the clinical perfusionist is guided by internal hospital guidelines or (if available) binding standard operating procedures (SOPs). These guidelines or SOPs are developed and agreed upon by practitioners of all specialist areas involved in the treatment process in the form of an action corridor (in particular, cardiac surgery, anaesthesiology and clinical perfusion). If the clinical perfusionist moves within this action corridor in an individual case, he carries out the ordered activity independently (general delegation). In case of deviation from the guidelines, a medical consultation/coordination is necessary (specific delegation).

Thus, his activity does not involve the independent practice of medicine within the definition of § 1 HeilprG, because the clinical perfusionist is only responsible for the implementation within the previous consensus on the basis of the medical order (general/specific delegation).

The activity of the clinical perfusionist is indispensable for the practice of medicine and surgical care by the involved physicians, because it requires skills and knowledge beyond the medical field of competence. In such cases, according to the jurisprudence, the personal action of the physician is excluded: 'the duty of care of the physician in charge (in these cases) is limited to (...) supervising the professional and individual reliability of the (...) assistant and ensuring that the assistant remains aware of the high responsibility associated with his activity' (Federal Court of Justice, judgement of 24 June 1975—VI ZR 72/74). In connection with the medical authority to issue orders, the physician cannot take over the activities of the clinical perfusionist himself. His duty of supervision, and consequently his right of supervision, thus remains limited to the examination of the professional and individual reliability of the perfusionist.

Definition: clinical perfusionist

The clinical perfusionist has medical and technical knowledge that allows him to plan, prepare and perform the ECC based on scientific evidence. For medical treatment procedures requiring ECC, the clinical perfusionist acts on a medical order (responsibility for orders) and independently operates the ECC, taking into account the patient-specific circumstances after mono-/multidisciplinary coordination (cardiac medical specialties, health professions) and in accordance with the relevant legal requirements (responsibility for implementation). A clinical perfusionist's scope of activity can include taking part in mechanical cardiovascular and organ replacement therapies (heart, lungs and kidneys) and thoracic organ transplantation procedures. Furthermore, the clinical perfusionist's tasks include medical documentation and differentiated measures for quality assurance. Providing technical or surgical assistance (for example, in cardiac implantable electronic device implantations) as well as participating in clinical or experimental research projects can be part of the clinical perfusionist's range of activities. Moreover, the clinical perfusionist is responsible for the technical support, maintenance and operational safety of the employed medical devices, taking into account and adhering to the specifications of the Medizinproduktegesetz (Medical Devices Act) and potential other statutory regulations.

Qualification of the clinical perfusionist

Only persons who can prove their personal qualifications by means of a valid certificate, recognized by the relevant professional associations, should be considered for the practice of the clinical perfusionist in Germany. At the European level, this currently means the European Certificate in Cardiovascular Perfusion, which is issued by the EBCP.

The exact details of the structural conditions and the content requirements of the training as well as the requirements to be fulfilled in order to obtain the certificate can be found on the organisations' websites (www.dgftk.de, www.ebcp.eu).

In principle, 2 training pathways are available in Germany today: first, there is a consecutive postgraduate path following initial vocational training (e.g. state-recognized nursing programme) at the Academy for Cardiovascular Perfusion; the second path is the direct study of an (e.g. biomedical) engineering subject with a specialization in the field of clinical perfusion. The contents of a training programme for a clinical perfusionist are summarized in Table 1 and correspond to the syllabus of the EBCP (<https://www.ebcp.eu/examination.html>). The professional societies involved in this consensus paper recommend aiming for a uniform academic degree at level 6 according to the German Qualifications Framework (bachelor's degree).

DIVISION OF ACTIVITIES AND RESPONSIBILITIES IN DAILY CLINICAL ROUTINE

The perfusionist is a member of an interdisciplinary cardiac team comprising all occupational groups. With the different expertise of cardiac surgeons, cardiologists, paediatric cardiologists,

Table 1: Syllabus of the education programme for clinical perfusion (<https://www.ebcp.eu/examination.html>)

1. Anatomy and Pathophysiology
1.1. General Anatomy
1.2. Embryology and Anatomy of the Newborn
1.3. Anatomy of the Heart and Lungs
1.4. Anatomy of the Neural System and Neuropathology
1.5. Congenital Heart Disease and Treatment Options
1.6. Acquired Heart Disease and Treatment Options
1.7. Pulmonary Disease
1.8. Visceral Organs
1.9. The Immune System
1.10. The Inflammatory Response
1.11. Dying Process and Death
2. Physiology
2.1. Cellular
2.2. Systemic Circulation
2.3. Respiration
2.4. Kidney
2.5. Heart
2.6. Haematology
3. Pharmacology
3.1. Pharmacological Principles
3.2. Clinical Pharmacology
3.3. Infusion Solutions: Composition and Application
4. Perfusion Technology
4.1. Historical Development
4.2. Extracorporeal Circulation
4.3. Myocardial Protection
4.4. Pathophysiological Effects of ECC
4.5. Basic Physics
4.6. Applied Microbiology
4.7. Mechanical Circulatory Support
4.8. Blood-saving Measures and Blood Cell Salvage
4.9. Research Methods
4.10. Clinical Research

anaesthesiologists, nurses and clinical perfusionists, this team enables the complex treatment of patients with heart disease.

With regard to the tasks of the clinical perfusionist, a distinction must be made between general and specific medical delegations. These tasks are performed in a binding structured agreement between the physician and the clinical perfusionist. A distinction must be made between standard procedures (general delegation) and patient-specific, i.e. individual case-related measures (specific delegation).

General delegation

Within the scope of the general delegation, the core task of the clinical perfusionist is the operation and monitoring of the equipment necessary for ECC (HLM) including its accessories. This definition also implies the immediate preparation and follow-up as well as standardized testing of the devices in connection with their use. The main application is cardiopulmonary bypass by means of HLM, which takes over the pumping function of the heart and the gas exchange function of the lungs during heart surgery.

Further standard procedures within the scope of the medical general delegation to the clinical perfusionist are, for example, perfusate composition and blood gas analysis. Such standard procedures are operated on the basis of applicable legal

regulations and internal hospital guidelines (e.g. SOPs) under the responsibility of the clinical perfusionist.

Specific delegation

Complementary patient-specific activities of the clinical perfusionist, which are not defined in the hospital's internal guidelines or SOPs, require a separate (specialist) medical order in the sense of a specific delegation (e.g. haemofiltration, special pharmacological therapy, administration of blood and blood products and mechanical autotransfusion).

Selection of the extracorporeal circulation system

There are a number of possible modifications for ECC systems that result, among other things, from various product specifications. The clinical perfusionist makes the necessary adjustments within the framework of the general delegation in the context of the type and scope of the planned operation. For example, there are different arterial pump types (centrifugal versus roller pump), different suction and venting systems and different open and closed venous reservoirs.

In addition to the conventional ECC systems (conventional extracorporeal circuit) most frequently used worldwide, minimally invasive ECC systems are increasingly being used. Furthermore, special perfusion systems in various sizes are used for neonates up to adolescents. The respective system is selected by the clinical perfusionist as part of the general delegation in the context of the type and scope of the planned operation.

Interdisciplinary cooperation

The interprofessional and interdisciplinary cooperation (e.g. heart surgeon, anaesthesiologist, paediatric-/cardiologist and clinical perfusionist) in the context of the use of the ECC must be established on a standardized and binding basis.

Standard operating procedures. To supplement and concretize legal requirements and legal provisions, internal SOPs are therefore to be implemented for the use of the various ECC systems in question.

CONCLUSION

This consensus paper describes the qualifications, tasks and responsibilities of the clinical perfusionist and the interdisciplinary cooperation with physicians in the fields of cardiac surgery, anaesthesiology, paediatric cardiology and cardiology as an integral part of the cardiac surgical treatment of patients with cardiac, thoracic and vascular diseases. The participating professional associations recommend that the designation 'clinical perfusionist' should only be used by persons who meet the requirements set out above and that the outlined activities should only be performed by specialists whose qualifications correspond to the criteria described in this paper and who demonstrably maintain these qualifications through continuous further medical training in accordance with the Continuing Medical Education of medical specialists. In addition, it is recommended that the training and

the job description of the clinical perfusionist be converted into a state-recognized occupation, following the example of Austria.

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