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Original Article

Complications relating to perfusion and extracorporeal circulation associated with the treatment of patients with congenital cardiac disease: Consensus Definitions from the Multi-Societal Database Committee for Pediatric and Congenital Heart Disease

Kenneth G. Shann,[1] Carmen R. Giacomuzzi,[2] Lynn Harness,[3] Gerard J. Myers,[4] Theron A. Paugh,[5] Nicholas Mellas,[1] Robert C. Groom,[6] Daniel Gomez,[7] Clarke A. Thuys,[8] Kevin Charette,[9] Jorge W. Ojito,[10] Julie Tinius-Juliani,[11] Christos Calaritis,[12] Craig M. McRobb,[13] Michael Parpard,[14] Tom Chancy,[14] Emile Bacha,[15] David S. Cooper,[14] Jeffrey Phillip Jacobs,[14] Donald S. Likosky,[16] on behalf of the International Consortium for Evidence-Based Perfusion

[1]Department of Cardiothoracic Surgery, Montefiore-Einstein Heart Center, Bronx, New York, United States of America; [2]Oregon Health and Sciences University – Doernbecher Children's Hospital, Portland, Oregon, United States of America; [3]Department of Cardiothoracic Surgery, Arkansas Children's Hospital, Little Rock, Arkansas, United States of America; [4]Queen Elizabeth II Health Sciences Center, IWK Health Center, Halifax, Nova Scotia, Canada; [5]University of Michigan Medical Center, Ann Arbor, Michigan, United States of America; [6]Maine Medical Center, Portland, Maine, United States of America; [7]Nationwide Children's Hospital, Columbus, Ohio, United States of America; [8]Department of Cardiac Surgery, Royal Children's Hospital, Melbourne, Victoria, Australia; [9]Children's Hospital of New York, New York, New York, United States of America; [10]The Congenital Heart Institute at Miami Children's Hospital, Miami, Florida, United States of America; [11]Department of Cardiothoracic Surgery, University of Southern California, Los Angeles, California, United States of America; [12]Montreal Children's Hospital, McGill University Health Centre, Montreal, Quebec, Canada; [13]Duke University Health Systems, Durham, North Carolina, United States of America; [14]The Congenital Heart Institute of Florida (CHIF), Divisions of Thoracic and Cardiovascular Surgery, Perfusion, and Critical Care, All Children's Hospital and Children's Hospital of Tampa, University of South Florida College of Medicine, Cardiac Surgical Associates (CSA), Florida Perfusion Services, and Florida Pediatric Associates, Saint Petersburg and Tampa, Florida, United States of America; [15]Department of Cardiac Surgery, Children's Hospital Boston, Boston, Massachusetts, United States of America; [16]Departments of Surgery and Community and Family Medicine, Dartmouth Medical School, and The Dartmouth Institute for Health Policy and Clinical Practice, Dartmouth College, Hanover, New Hampshire, United States of America

Abstract The International Consortium for Evidence-Based Perfusion (www.bestpracticeperfusion.org) is a collaborative partnership of societies of perfusionists, professional medical societies, and interested clinicians, whose aim is to promote the continuous improvement of the delivery of care and outcomes for patients undergoing extracorporeal circulation. Despite the many advances made throughout the history of cardiopulmonary bypass, significant variation in practice and potential for complication remains. To help address this issue, the International Consortium for Evidence-Based Perfusion has joined the Multi-Societal Database Committee for Pediatric and Congenital Heart Disease to develop a list of complications in congenital cardiac surgery related to extracorporeal circulation conducted via cardiopulmonary bypass, extracorporeal membrane oxygenation, or mechanical circulatory support devices, which include ventricular assist devices and intra-aortic balloon pumps. Understanding and defining the complications that may occur

Correspondence to: Kenneth G. Shann, CCP, Assistant Director, Perfusion Services, Senior Advisor, Cardiac Surgery Performance Improvement, Montefiore-Einstein Heart Center, Bronx, New York, United States of America. Tel: 718 920 8951; Fax: 718 652 1833; E-mail: kshann@montefiore.org

related to extracorporeal circulation in congenital patients is requisite for assessing and subsequently improving the care provided to the patients we serve. The aim of this manuscript is to identify and define the myriad of complications directly related to the extracorporeal circulation of congenital patients.

Keywords: Congenital heart disease; quality improvement; patient safety; outcomes; registry; operative morbidity; paediatric; surgery; congenital abnormalities; cardiac surgical procedures; heart; cardiopulmonary bypass

The International Consortium for Evidence-Based Perfusion (Fig. 1) is a collaborative partnership of societies of perfusionists, professional medical societies, and interested clinicians, whose aim is to promote the continuous improvement of the delivery of care and outcomes for patients undergoing extracorporeal circulation. The International Consortium for Evidence-Based Perfusion seeks to achieve these goals by developing an enhanced interdisciplinary strategy of care for patients and communication among the caregivers within the cardiac clinical microsystem. "Clinical microsystems are units at the front-line that provide most health care to most people", as described at the following website: [http://www.clinicalmicrosystem.org/]. The foundation of The International Consortium for Evidence-Based Perfusion is identified through its commitment to four guiding principles:

- Development of an international registry of perfusion to provide evaluation of current practice
- Development and publication of evidence-based guidelines, and integration of these guidelines into clinical practise
- Identification of gaps in the peer-reviewed literature with subsequent research in areas where the evidence is lacking
- Identification of gaps between current and evidence-based clinical practice in order to promote the improvement in the care of patients.

Additional information about this consortium may be found at http://www.bestpracticeperfusion.org/.

The International Consortium for Evidence-Based Perfusion recognizes that the practice of perfusion for congenital cardiac surgery is a unique discipline, and has therefore organized a standing committee to address the needs of this population of patients. To date, the committee consists of thirty-two individuals representing twenty-five congenital cardiac surgery centres in six countries. This committee convenes a conference call every month, is represented three times annually at the Multi-Societal Database Committee for Pediatric and Congenital Heart Disease Meeting, and corresponds routinely via e-mail.

The assessment and subsequent improvement of care for patients with congenital cardiac disease undergoing extracorporeal circulation requires a sufficient understanding of the complications that may occur. The Multi-Societal Database Committee for Pediatric and Congenital Heart Disease considers extracorporeal circulation to be a separate "organ-system". In this Supplement to Cardiology in the Young, the International Consortium for Evidence-Based Perfusion has made every effort to identify and define the myriad of complications related to extracorporeal circulation that may occur while congenital patients are supported by extracorporeal circulation. The terms in the final list of complications related to extracorporeal circulation, along with their precise descriptions and official definitions, as developed by The International Consortium for Evidence-Based Perfusion working in collaboration with The MultiSocietal Database Committee for Pediatric and Congenital Heart Disease, are listed in Part 4 of this Supplement.

Historical background

Since its introduction more than fifty years ago, the practice of extracorporeal circulation, also known as "perfusion", has undergone many changes. In its infancy, the technicians responsible for operating and maintaining extracorporeal equipment, also known as perfusionists, were mostly self-taught, as no formal training programs existed. Over time, perfusion has become a highly specialized discipline with formal education programs and official board certification established in many parts of the world. The first organized educational school of perfusion was created in 1963 at the Cleveland Clinic.[1] Perfusionists are recognized as the experts in areas of extracorporeal equipment and practice. Three types of extracorporeal circulation that fall within the scope of practice for perfusionists (Fig. 2):

- cardiopulmonary bypass
- extracorporeal membrane oxygenation, and
- mechanical circulatory support devices, otherwise known as ventricular assist devices.

Cardiopulmonary bypass

Cardiopulmonary bypass is defined as the process of diverting venous blood from a patient's heart and

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lungs to a gas exchange system for the addition of oxygen, removal of carbon dioxide, and subsequent re-infusion to the patient's arterial system. Cardiopulmonary bypass revolutionized the approach to cardiovascular surgery by affording surgeons the ability to work on a flaccid heart for extended periods of time for corrective procedures.[2] In May, 1953, Dr. John H. Gibbon, Jr. reported the first successful use of cardiopulmonary bypass using the Gibbon-IBM heart-lung machine at Jefferson Hospital in Philadelphia, Pennsylvania, United States of America, when he operated on an eighteen year old woman with an atrial septal defect.[3]

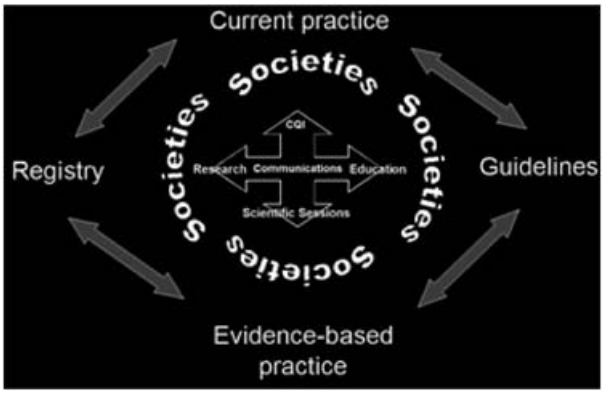

Figure 1.
The International Consortium for Evidence-Based Perfusion (www.bestpracticeperfusion.org) is a collaborative partnership of societies of perfusionists, professional medical societies, and interested clinicians, whose aim is to promote the continuous improvement of the delivery of care and outcomes for patients undergoing extracorporeal circulation. The International Consortium for Evidence-Based Perfusion seeks to achieve these goals by developing an enhanced interdisciplinary strategy of care for patients and communication among the caregivers within the cardiac clinical microsystem. CQI = Continuous Quality Improvement.

In the 1950s, the technological challenge was to create a practical and safe device that could oxygenate blood and remove carbon dioxide. In 1955, at the University of Minnesota, Dr. C. Walt Lillehei began the routine use of a disposable "bubble oxygenator".[4] In 1967, further advancements were made when DeWall and colleagues introduced the hard-shell bubble oxygenator with an integrated oxygenator and "heat exchanger" in a disposable and pre-sterilized unit.[5] In 1976, Bartlett and colleagues estimated that ninety percent of all cardiac operations worldwide were being performed with bubble oxygenators.[6]

Many innovators at the time did not believe the bubble oxygenator provided the safest and most efficient way to oxygenate blood and remove carbon dioxide. In 1967, Lande and colleagues introduced the first compact, disposable, commercially available "membrane oxygenator" for clinical use as a way of achieving separation between blood and gases.[7] The widespread use of membrane oxygenators, however, did not occur until the late 1980's and early 1990's. A body of evidence now exists that illustrates the benefits of membrane oxygenators to minimize gaseous embolization, and platelet and red blood cell destruction, relative to bubble oxygenators.[8–11] Although most studies confirming a benefit of membrane oxygenators were conducted in adults, Groom and colleagues, in a survey of programs of perfusion of pediatric cardiac surgery determined that membrane oxygenators are used exclusively for cardiopulmonary bypass in North

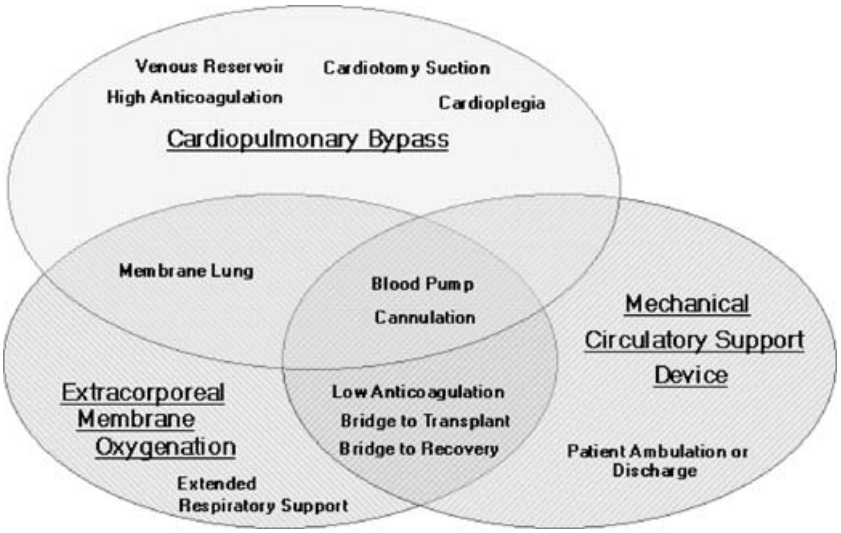

Figure 2.
This Venn diagram demonstrates the relationships of the three types of extracorporeal circulatory support that fall within the scope of practice for perfusionists: cardiopulmonary bypass, extracorporeal membrane oxygenation, and mechanical circulatory support devices, otherwise known as ventricular assist devices.

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America.[12] These oxygenators are now used among the estimated 19,000 cardiac procedures conducted in the United States of America, annually on paediatric patients.[13]

Extracorporeal membrane oxygenation

Extracorporeal membrane oxygenation is defined as the process of diverting venous blood from a patient to a gas exchange system for the addition of oxygen, removal of carbon dioxide, and subsequent re-infusion to the patient's arterial or venous system. Due to the time-dependent detrimental effects on the blood and end organs, bubble oxygenators were not feasible in the setting of prolonged extracorporeal support. In 1962, Cooley introduced the concept of temporary cardiorespiratory support outside of the operating room with a portable pump and bubble oxygenator.[14] A year later, Kolobow and colleagues introduced the silicone rubber membrane oxygenator, making long-term extracorporeal support practical.[15] The silicone membrane is often referred to as a "true membrane", due to the absence of direct gas and blood interface. To this day, the design by Kolobow is largely unchanged and still widely used in North American centres that provide therapy with extracorporeal membrane oxygenation.[12] Recently however, new membrane oxygenator materials, such as polymethylpentene, have been developed that are easier to use and preserve coagulation better than silicone membranes, while maintaining the same level of durability.[16]

In 1976, Bartlett and colleagues reported the first successful neonatal survivor of extracorporeal membrane oxygenation.[17] By 1989 two prospective randomized studies comparing extracorporeal membrane oxygenation to conventional medical therapy, showed a survivorship benefit among neonates cared for with extracorporeal membrane oxygenation.[18,19] The same year, the Extracorporeal Life Support Organization (www.elso.med.umich.edu) developed a voluntary registry of procedures involving extracorporeal life support in order to support research, regulatory agencies, and individual centres. By 2004, there were nearly 29,000 patients in this registry. According to the Extracorporeal Life Support Organization, extracorporeal life support for cardiac failure is increasing for all age groups from neonate to adult. From this registry, we have learned that the rates of survival to discharge for neonatal respiratory failure and cardiac failure are 77% and 38%, respectively.[20]

Mechanical circulatory support device

A mechanical circulatory support device is defined as a pump or apparatus that augments or replaces the function of the failing heart. Two types of mechanical circulatory support devices are ventricular assist devices and intra-aortic balloon pumps. The use of a mechanical circulatory support device was first reported in adult patients who could not be weaned from cardiopulmonary bypass due to cardiogenic shock.[21] Unfortunately, due to size limitations and technical barriers, mechanical circulatory support devices have had limited use in large infants and adolescent paediatric patients. Until recently, extracorporeal membrane oxygenation had been the only means of mechanical circulatory support for neonate and infant patients with cardiac failure.[22] Additional devices are being introduced into the marketplace to address growing demand for such devices in infants and neonates. The Berlin Heart Excor® Pediatric pulsatile pneumatic circulatory support device is an example of one device that has been approved for use recently in Europe.[23]

The International Consortium for Evidence-Based Perfusion prefers the term "mechanical circulatory support device". The list of complications developed by The MultiSocietal Database Committee for Pediatric and Congenital Heart Disease, working in collaboration with The International Consortium for Evidence-Based Perfusion, will retain the term ventricular assist device, but will acknowledge that the term "mechanical circulatory support device" is a preferred term by perfusionists. The rationale for retaining the term ventricular assist device is that this term is widely used at this time and is used in the Adult Cardiac Surgery Database of The Society of Thoracic Surgeons. In fact, the Adult Cardiac Surgery Database of The Society of Thoracic Surgeons is in the process of developing a specific module to track data about ventricular assist devices. The Dictionary of Complications provided in Part 4 of this Supplement will list and define the complications associated with ventricular assist devices and the complications associated with intra-aortic balloon pumps separately.

Consensus definitions

The International Consortium for Evidence-Based Perfusion developed consensus definitions for cardiopulmonary bypass, extracorporeal membrane oxygenation, and mechanical circulatory support devices using a combination of web-based communication software, conference calls, and email. These definitions highlight the similarities and differences between these three methods of extracorporeal circulatory support (Fig. 2).

Cardiopulmonary bypass is the process of diverting venous blood from a patient's heart and lungs to a gas exchange system for the addition of oxygen, removal of carbon dioxide, and subsequent re-infusion to the patient's arterial system. The two

primary functions of the system are to provide temporary support during cardiac procedures and to create an optimal environment for the completion of intracardiac repairs. Cardioplegia, usually a hyperkalemic solution, is commonly administered to the heart to induce diastolic cardiac arrest and create a flaccid myocardium amenable to intervention. Cardioplegia is a unique feature of this method of extracorporeal circulation.

Extracorporeal membrane oxygenation is the process of diverting venous blood from a patient to a gas exchange system for the addition of oxygen, removal of carbon dioxide, and subsequent re-infusion to the patient's arterial or venous system. The primary aim of extracorporeal membrane oxygenation is to provide extended support (days to weeks) for patients with reversible respiratory and/or cardiac failure to serve as a bridge to recovery or transplantation. Extracorporeal membrane oxygenation is associated with lower levels of anticoagulation than cardiopulmonary bypass and typically does not incorporate a reservoir. Of note, the term extracorporeal membrane oxygenation is commonly used interchangeably with extracorporeal life support.[24] Extracorporeal lung assist, extracorporeal carbon dioxide removal, and cardiopulmonary support are variants of extracorporeal membrane oxygenation.

Mechanical circulatory support device is the use of a blood pump or apparatus that augments or replaces the function of the failing heart. Mechanical circulatory support devices are designed to provide longer-term (weeks to months) support for patients with cardiac failure. These devices may serve as a bridge to recovery, to transplantation, or for permanent cardiac support. Unlike cardiopulmonary bypass and extracorporeal membrane oxygenation these devices do not incorporate a gas exchange system. Use of these devices, while routine among adults, is increasing in paediatric cardiac surgery.[25] Noteworthy features of these devices include the ability to function on battery power, and accommodate patient ambulation within and outside of the hospital setting.

Controversies

This manuscript and Part 4 of this Supplement identifies and defines events considered by the experts in extracorporeal circulation to be complications related to this "organ-system".

Controversy surrounded the fundamental definition of a complication. In the area of extracorporeal circulation, it is well recognized that microembolic events and haematologic abnormalities occur commonly. This quandary is termed "Normalization of Deviance".[26] By this concept, teams accept as normal, events or outcomes that in other venues might be considered a complication. This concept speaks to the core intention of this project, which is to create a framework by which we may evaluate our clinical practice, identify opportunities for improvement of process, and redesign our system to improve the care we provide to our patients.

The final complications list, as shown in Part 4 of this Supplement, includes many events that would be considered non-controversial for inclusion, and some events that would be challenged as complications. For example, the complication listed as "*Cannula complication, Dislodgement of arterial cannula*", is an event that is very clear in its definition, occurrence, and potential implication. On the other hand, "*Air complication with air in circuit, Gaseous emboli in arterial line – mechanically detected*" may be more controversial due to some of the following reasons:

- the conflicting evidence supporting the association between gaseous microemboli and adverse neurologic injury
- most centres do not utilize sensitive Doppler devices to monitor for embolic activity, and
- most centres do not measure the consequence of these emboli in their daily practice, such as neuropsychological injury.

While Rodriguez and colleagues reported differences in cerebral embolic signals among children undergoing cardiopulmonary bypass, some members of our committee argued that evidence linking the use of these devices to outcome in children is nonetheless lacking.[27] The spirit of our profession should balance fiscal mindfulness with providing exemplary care to our patients. To this end, we seek and encourage the identification of those processes of care within our practice associated with the generation of emboli in order to improve the care provided to our patients.

Further, we recognized that terms used routinely in practice lacked uniform and consistent definitions. For example, although "disseminated intravascular coagulation" remains a clinically accepted diagnosis, a universally accepted diagnostic algorithm does not exist.[28,29] Our efforts to define disseminated intravascular coagulation during extracorporeal membrane oxygenation were challenging due to the lack of uniformity in diagnosing disseminated intravascular coagulation without extracorporeal membrane oxygenation. Therefore, we chose the term "*Bleeding, Coagulopathy related*", defined as "Excessive bleeding greater than 10 millilitres per kilogram per hour despite attempts to maintain platelets, fibrinogen, thrombelastography, and international normalized ratio values within departmental protocols". In so doing, the definition of this complication allows for

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some specificity in its definition, while still accommodating protocol variations across institutions.

A further area of consternation reflected unwarranted variation in clinical practice. For example, the complication titled "*Hematologic complication, Extracorporeal membrane oxygenation circuit replacement for hematologic concerns*" reflects a complication, but may not always be adequately quantified. The practice at some institutions is to replace the circuit solely based on levels of plasma free haemoglobin exceeding 50 milligrams per decilitre. Members of our panel suggested that they would choose to replace the circuit if the levels of plasma free haemoglobin exceed 50–100 milligrams per deciliter in the setting of clinical symptoms of hemolysis, while others choose not to monitor levels of plasma free haemoglobin at all. With such varying practices across institutions, and limited evidence in the literature to support recommended guidelines for circuit replacement, the definition was derived, albeit regretfully, based on experiential practices.

Common to all discussions while developing the list of complications was the notion that we provide care in a very complex environment. We are all part of a larger cardiac microsystem (Table 1) made up of a large group of care providers. Improvement may be realized as each profession gains a greater understanding of their interdependences while appreciating the context in which care is provided. This project provides a common nomenclature to assist us in the dissemination of the current science, with the aim of facilitating the development of new knowledge.

Interactions with the cardiac system

Patients undergoing extracorporeal circulation are exposed to a unique relationship between the "extracorporeal organ-system" and their cardiac system. This point is exemplified in the setting of cardiopulmonary bypass and the processes of cardioplegia delivery and modified ultrafiltration. Cardioplegia is usually a hyperkalemic solution and is administered to the heart to induce diastolic cardiac arrest and protect the ischaemic myocardium from injury. Modified ultrafiltration is a technique designed to hemoconcentrate the patient and the cardiopulmonary bypass circuit after the cessation of cardiopulmonary bypass. Safe and effective practice of these techniques necessitates significant interdisciplinary interaction in order to maintain or enhance myocardial performance.

Cardioplegia

One of the initial descriptions of cardioplegia is credited to Hugh Bentall.[30] Cardioplegia raises unique issues for children, infants, and especially neonates. Many structural, functional, and metabolic differences between an adult and paediatric heart exist. The immature heart has a denser structure, and higher protein and water content per gram of tissue, than the adult counterpart. Prolonged periods of anaerobic metabolism are possible due to the decreased preload reserve and greater glucose metabolism of the paediatric heart.[31,32] Despite successful surgical procedures to repair congenital abnormalities, paediatric patients may experience morbidity and mortality related to reduced cardiac output and other complications of cardiopulmonary bypass.[33,34] Over half of these poorly functioning paediatric myocardiums, many of which may lead to the death of the patient, may result from inadequate cardioprotection during bypass.[31,33] Variability in cardioplegic solutions and strategies may partially account for these complications.[31–35] In 1997, Demmy and colleagues reported that in the United States of America alone, 167 different types of cardioplegia solutions are used for adult clinical cardiac transplantations, a finding that may not be too dissimilar for those having congenital procedures.[36]

Blood versus crystalloid

Many clinicians believe that blood cardioplegia provides optimal protection in the neonatal cyanotic heart. However, little difference between crystalloid and blood cardioplegia protection has been found when neonatal hearts are not stressed preoperatively and when ischaemic times are kept below 45 minutes.[37,38] Crystalloid cardioplegia is still widely used due to its ease of use and ability to improve surgical visibility. The myocardial cell's preference for glucose and the low activity of 5'nucleotidase contribute to the paediatric heart's ischaemic tolerance and make blood cardioplegia an ideal medium for cardioprotection.[39] In a prospective, controlled randomized trial, the use of blood cardioplegia in acyanotic infants maintained normal myocardial substrate metabolism due to reductions in lactate production and glutamate uptake.[37] Although the composition of cardioplegia solutions may vary, its cardioprotective effect may be attributed to hypothermia, potassium, alkalotic pH, membrane stabilizers, controlled pressures, and maintenance of diminished, while not absent, calcium concentrations. One object of myocardial protection is the delivery of oxygen to myocardial cells and the prevention of ischaemia. Oxygenated cardioplegic solutions will meet this need, unlike their non-oxygenated counterparts. Non-oxygenated solutions deliver 0.56 millilitres of oxygen per decilitre, while oxygenated crystalloid deliver 3.7 millilitres of oxygen per decilitre and blood cardioplegia deliver 4.2 millilitres of oxygen per decilitre.[40] Since the demands for oxygen of

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Table 1. Cardiac Microsystem Team Members.

Cardiopulmonary Bypass	Extracorporeal Membrane Oxygenation	Mechanical Circulatory Support Device
Patient	Patient	Patient
Patient's family	Patient's family	Patient's family
Physicians	**Physicians**	**Physicians**
Primary Care Physician	Primary Care Physician	Primary Care Physician
Cardiologist	Cardiologist	Cardiologist
Echocardiography Cardiologist	Echocardiography Cardiologist	Echocardiography Cardiologist
Interventional Cardiologist	Interventional Cardiologist	Interventional Cardiologist
Cardiology Fellow	Cardiology Fellow	Cardiology fellow
Cardiology Resident	Cardiology Resident	Cardiology resident
Surgeon	Surgeon	Surgeon
Surgical fellow	Surgical fellow	Surgical fellow
Surgical Resident	Surgical Resident	Surgical Resident
Anaesthesiologist	Anaesthesiologist	Anaesthesiologist
Anaesthesia Resident	Anaesthesia Resident	Anaesthesia Resident
Critical Care Physician	Critical Care Physician	Critical Care Physician
Internal Medicine Physician	Internal Medicine Physician	Internal Medicine Physician
Pulmonologist	Pulmonologist	Pulmonologist
Radiologist	Radiologist	Radiologist
Neurologist	Neurologist	Neurologist
Electrophysiologist	Electrophysiologist	Electrophysiologist
Pathologist	Pathologist	Pathologist
	Nephrologist	Nephrologist
	Hematologist	Hematologist
	Gastroenterologist	Gastroenterologist
Nurses	**Nurses**	**Nurses**
Nurse Practitioner	Nurse Practitioner	Nurse Practitioner
Office Nurse	Office Nurse	Office Nurse
Operating Room Nurse	Operating Room Nurse	Operating Room Nurse
Intensive Care Unit Nurse	Intensive Care Unit Nurse	Intensive Care Unit Nurse
Telemetry Nurse	Telemetry Nurse	Telemetry Nurse
	Transplant Coordinator	Transplant Coordinator
	Extracorporeal Membrane Oxygenation Coordinator	Mechanical Circulatory Support Device Coordinator
Allied Health Professionals	**Allied Health Professionals**	**Allied Health Professionals**
Perfusionist	Perfusionist	Perfusionist
Physician Assistant	Physician Assistant	Physician Assistant
Respiratory Therapist	Respiratory Therapist	Respiratory Therapist
Nutritionist	Nutritionist	Nutritionist
Physical Therapist	Physical Therapist	Physical Therapist
Occupational Therapist	Occupational Therapist	Occupational Therapist
Phlebotomist	Phlebotomist	Phlebotomist
Surgical Technologist	Surgical Technologist	Surgical Technologist
Echocardiography Technician	Echocardiography Technician	Echocardiography Technician
Radiological Technologist	Radiological Technologist	Radiological Technologist
Blood Bank Technologist	Blood Bank Technologist	Blood Bank Technologist
Pharmacist	Pharmacist	Pharmacist
Pharmacy Technician	Pharmacy Technician	Pharmacy Technician
	Social worker	Social worker
	Psychologist	Psychologist
	Extracorporeal Membrane Oxygenation Specialist	
Administration	**Administration**	**Administration**
Administrator	Administrator	Administrator

myocardial tissue at a temperature of 15 degrees Celsius may average 0.27 millilitres per minute per 100 grams for the left ventricle, a 30-minute ischaemic period may accumulate an oxygen debt of nearly 30 millilitres in the non-hypertrophied heart.[41] Thus, both oxygenated crystalloid and blood cardioplegia would be adequate for meeting this demand if the multi-dose technique is used.[40]

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Modified ultrafiltration

The use of ultrafiltration after separation from cardiopulmonary bypass was first reported by Naik, Elliott, and colleagues in 1991.[42,43] In a prospective, randomized trial of paediatric patients, this 10-minute application of modified ultrafiltration demonstrated significant reductions in the requirement for transfusion of donated blood and the total "body water" of the patient. Since that time, this practice has become a routine part of clinical practice in approximately seventy-five percent of programmes of paediatric cardiac surgery.[12]

In addition to the well reported improvements in removal of total body water, cytokines and increased hematocrits after cardiac surgery in the paediatric population,[42–46] the hemodynamic effects of modified ultrafiltration include increased blood pressure[42,47] and left ventricular systolic function[47,48] with a concomitant reduction in postoperative morbidity.[49] Aggarwal reported a significant decrease in posterior wall thickness with modified filtration secondary to reductions in myocardial water content.[50] Within a span of 17 years, modified ultrafiltration is now used routinely in paediatrics for reducing total body water, increasing hematocrit, and improving systemic vascular resistance.

Conclusion

This manuscript is the product of an interdisciplinary collaboration between perfusionists and other providers of care for patients with congenitally malformed hearts. The development of consensus-driven nomenclature for the complications of congenital cardiac surgery related to extracorporeal circulation will afford improved communication across the clinical team. Identifying and defining these complications will provide a foundation for future research and create opportunities for the shared goal of improving the care of patients.

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