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Abstract: The development of standards and guidelines by professional societies offers clinicians guidance toward providing evidence-based care. The ultimate goals of standards and guidelines are to standardize care and improve patient safety and outcomes while also minimizing risk. The American Society of ExtraCorporeal Technology (AmSECT) currently offers perfusionists several clinical resources, primarily the Standards and Guidelines for Perfusion Practice; however, no document exists specific to pediatric perfusion. Historically, the development of a pediatric-specific document has been limited by available scientific evidence because of smaller patient populations, sample sizes, and variable techniques among congenital perfusionists. In the current setting of evolving clinical practices and increasingly complex cardiac operations, a subcommittee of pediatric perfusionists developed the Standards and Guidelines for Pediatric and Congenital Perfusion Practice. The development process included a comprehensive literature review for supporting evidence to justify new recommendations or updates to the existing AmSECT Adult Standards and Guidelines document. Multiple revisions incorporating feedback from the community led to a finalized document accepted by the AmSECT member and made available electronically in May 2019. The Standards and Guidelines for Pediatric and Congenital Perfusion Practice is an essential tool for pediatric perfusionists, serves as the backbone for institutionally based protocols, promotes improved decision-making, and identifies opportunities for future research and collaboration with other disciplines. The purpose of this article is to summarize the process of development, the content, and recommended utilization of AmSECT’s Standards and Guidelines for Pediatric and Congenital Perfusion Practice. AmSECT recommends adoption of the Standards and Guidelines for Pediatric and Congenital Perfusion Practice to reduce practice variation and enhance clinical safety. Keywords: congenital heart disease, cardiopulmonary bypass, pediatric perfusion, education.
Standards and guidelines also seek to improve the quality of care provided, minimize risk, and validate practices that impact patient care and outcomes. These documents offer a source of transparency among colleagues and contribute to an increasing demand for safety and standardization in cardiac surgery.

AmSECT initially offered practice guidelines to perfusionists in 1993, when the “Essentials for Perfusion Practice” was developed by the Perfusion Quality Committee (8). Since then, those guidelines have been updated in 2013 and 2017 by the International Consortium for Evidence-Based Perfusion Committee, resulting in the current document, the Standards and Guidelines for Perfusion Practice (1). Internationally, documents outlining standards and guidelines for perfusion practice exist as well. The following two documents have been recently published in Europe and Brazil, respectively: the European Association for Cardio-Thoracic Surgery/the European Association of Cardiothoracic Anesthesiology/the European Board of Cardiovascular Perfusion guidelines on cardiopulmonary bypass (CPB) in adult cardiac surgery (9) and the Brazilian Society for Cardiovascular Surgery/the Brazilian Society for Extracorporeal Circulation standards and guidelines for perfusion practice (10).

In 2017, AmSECT leadership requested the development of a separate document specific to pediatric and congenital CPB, one that had not previously existed. The need for a separate document has been identified in the past by the AmSECT Pediatric and Congenital Perfusion Committee (PCPC), as well as other international perfusion organizations (10,11). A subcommittee of AmSECT’s PCPC was assigned the task of developing the document entitled Standards and Guidelines for Pediatric and Congenital Perfusion Practice (12). The title purposefully includes the terms pediatric and congenital to reflect the broad range in size and age of patients cared for by pediatric and congenital perfusionists. Although similarities exist between adult and pediatric perfusion practices, pediatric patients often require unique considerations because of a higher acuity and precision of care. The purpose of this article is to summarize the process of development, the content, and the recommended utilization of AmSECT’s Standards and Guidelines for Pediatric and Congenital Perfusion Practice (12).

MATERIALS AND METHODS

To maintain consistency throughout AmSECT-approved documents, the AmSECT Standards and Guidelines for (Adult) Perfusion Practice serve as the template for developing the Standards and Guidelines for Pediatric and Congenital Perfusion Practice (1). The existing document was reviewed for areas of significant differences or unique considerations and/or circumstances between adult and pediatric perfusion practice. The subcommittee also reviewed adult-specific practices that did not apply to pediatrics. It was ultimately determined there were specific topics that lacked sufficient detail, level of recommendation (guideline vs. standard), or overall content that should be included in the pediatric document. The Standards and Guidelines for Pediatric and Congenital Perfusion Practice cover a total of 21 categories for standards. Table 1 displays the current content within the document, along with a summary of significant changes. Standards denoted with an “*” are entirely new standards or modified standards, amplifying the requirements for recommendations for pediatric perfusion.

Bullet points were also added to indicate pediatric-specific additions for that standard. The remaining standards are unchanged from the previously existing document for adult perfusion practice (1).

The PCPC subcommittee reviewed more than 275 articles from the medical literature to support the new recommendations and justify revisions, additions, or deletions from the existing adult document. Types of evidence reviewed included randomized controlled trials, prospective or retrospective cohort studies, and case series. For content areas that lacked supporting evidence, surveys of current practice trends served as a measure of consensus, established standard of care, or expert opinion within the pediatric community.

The review and approval processes are described in Figure 1. The PCPC reviewed the initial draft, followed by increasingly larger groups of pediatric and congenital perfusionists and subject-matter experts. Subject-matter experts included a group of over 100 pediatric and congenital perfusionists who have been recognized by AmSECT with the Fellow of Pediatric Perfusion (FPP), a designation awarded by AmSECT for recognition of significant contributions to the advancement of the field of pediatric perfusion. Subsequent versions of the document incorporated all pertinent feedback received. A final draft was then presented at two international pediatric and congenital perfusion meetings for discussion and explanation of the updates, as well as to provide a forum for feedback. After incorporating the feedback received from the FPP group and attendees from the international meeting presentations, a final version of the Standards and Guidelines was submitted to the AmSECT Board of Directors, along with the legal team at AmSECT headquarters. Once approved by both the aforementioned groups, and in accordance with society bylaws, the final document was distributed to the members for a final vote. With 74% of the AmSECT membership votes in favor, final acceptance of the Standards and Guidelines for
Table 1. Summary of current standards and guidelines for Pediatric and congenital perfusion document and highlighted modifications.

<table>
<thead>
<tr>
<th>Standard 1: Development of Institutionally-Based Protocols</th>
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<tr>
<td>Standard 2: Qualification, Competency and Support Staff*</td>
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<td>Standard 3: Communication</td>
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<td>Standard 6: Safety Devices*</td>
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<td>• Bubble detector on cardioplegia pump</td>
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<td>Standard 7: Monitoring*</td>
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<td>• Continuous blood gas monitoring</td>
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<td>• Cerebral/somatic oximetry monitoring</td>
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<td>• Distal arterial blood flow measurement</td>
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<td>Standard 8: Anticoagulation*</td>
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<td>• Heparin resistance management</td>
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<td>Standard 9: Gas Exchange*</td>
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<td>• Circuit component selection</td>
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<td>• Prime volume minimization</td>
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<td>• Circuit prime gas and electrolyte levels</td>
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<td>• preBUF</td>
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<td>Standard 14: Protamine and Cardiomyte Suction</td>
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<td>Standard 15: Blood Management*</td>
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<td>• Minimum hematocrit</td>
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<td>• Donor exposures/age of transfused blood</td>
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<td>Standard 16: Fluid Management*</td>
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<td>• Continuous fluid balance monitoring</td>
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<td>• Modified/dilution/zero balance ultrafiltration</td>
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<td>Standard 17: Level of Readiness</td>
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<td>Standard 18: Staffing*</td>
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<td>• n + 1 staffing</td>
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<td>Standard 19: Duty Hours</td>
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<td>Standard 20: Quality Assurance and Improvement</td>
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<td>Standard 21: Maintenance</td>
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*New or modified standards. • Pediatric-specific addition to standard.

Pediatric and Congenital Perfusion Practice occurred on May 31st, 2019.

RESULTS

Review of New Standards

To facilitate the understanding of the Standards and Guidelines verbiage, the following terms and their definitions are listed in Table 2: Standard, Guideline, and Protocol, as well as the use of the words: “shall” and “should” (8). Standards, defined as minimum requirements, are supported by extensive evidence and standard of care consensus. Standards promote safety and limit the potential to cause harm. Guidelines are also supported through evidence and promote safety through best practices; however, they provide flexibility when not applicable to programs.

The most impactful update to pediatric and congenital perfusion practice recommendations is the addition of three entirely new sections: circuitry, priming, and fluid management. Ten new standards and guidelines were also added to the existing sections. Five guidelines were elevated to standards, meaning they should be considered a mandatory requirement in the pediatric and congenital patients, as opposed to a recommendation in the adult patient population. Although not inclusive, a sample of the main pediatric updates is listed along with justifications and evidence.

Standard 12. Circuitry

Standard 12.1: The perfusionist shall select circuit components taking into consideration prime volume, surface area, safety, and the expected metabolic requirements of the patient.

Standard 12.2: Both the number and size of shunts within the circuit shall be minimized to prevent steal from arterial blood flow (13–15).

Guideline 12.1: The perfusionist should consider assisted venous return taking into consideration any patient-specific contraindications (16–20).

The deleterious effects of excessive hemodilution due to prime volume and the inflammatory response resulting from surface area contact during CPB are well-defined in the pediatric and congenital cardiac literature; therefore, a separate circuitry standard is warranted, independent of its inclusion in Standard 9 Blood Management. The pediatric and congenital patient does not conform to a “one-size-fits-all” circuit. It is, therefore, essential to customize and minimize the extracorporeal circuit size, taking into consideration safety, especially with regard to equipment limitations, as well as anatomic and physiologic factors, other than patient weight, that may impact equipment selection.

The importance of limiting the size and number of shunts within the extracorporeal circuit is recommended because of the potential for arterial blood flow “steal,” resulting in inadvertent hypoperfusion. Studies have shown that at lower flows, up to 40% of total pump flow may be diverted away from the patient’s systemic blood flow through open shunts (14,15). Standard 7.13 Patient Monitoring requires measurement of arterial flow distal to all intra-circuit shunts as well, which makes shunts potentially less significant. However, for centers unable to immediately fulfill this requirement because of equipment or budget limitations, the Standards and Guidelines maintain that the shunt number and size should still be limited whenever possible. Another concern with unnecessary shunts is the increased arterial pump revolutions per minute required to maintain systemic blood flow, which may result in red blood cell hemolysis.

Also related to reducing circuit size, a new guideline recommends using assisted venous return to limit the length or size of venous tubing. For safety purposes and at the discretion of the perfusionist, the guideline recommends that any contraindications to assisted venous return should be taken into consideration when in use. Studies have shown the benefits of assisted venous return outweigh the risks in pediatric and congenital perfusion when used correctly and safely (17).

**Standard 13. Priming**

**Standard 13.1:** The perfusionist shall consider the impact the prime has on the smaller circulating blood volume of the pediatric patient and its effect on
- electrolyte levels,
- colloid osmotic pressure, and
- coagulation.

**Guideline 13.1:** When priming with exogenous blood, the use of prebypass ultrafiltration (preBUF) or washed red blood cells should be used during priming procedure (23–28).

**Guideline 13.2:** The perfusionist should consider matching prime composition to the individual patient values.

The circuit prime composition is comparatively more significant in smaller patients because of prime volumes that may be equal to, or multiples of, a pediatric patient’s total circulating blood volume. For that reason, the authors require a circuit prime blood gas and electrolyte level be measured prebypass to identify and correct any potential physiologic abnormalities. In addition, it is understood the definition of “physiologic” may vary between patients of various size and/or institution. This standard offers a way to protect against human error that may exist even in the presence of written protocols. To assist with optimization of prime composition, preBUF or red cell washing are guidelines used during priming procedures to obtain more physiologic levels of glucose, potassium, and sodium than banked blood (26–28).

**Standard 16. Fluid Management**

**Standard 16.1:** Fluid balance shall be monitored continually and documented during CPB (29–32).

**Guideline 16.1:** The use of modified ultrafiltration (MUF) should be utilized (unless contraindicated) to optimize hemodynamics and hematocrit (33–36).

**Guideline 16.2:** The use of dilutional or zero balance ultrafiltration (ZBUF) should be considered during CPB (37–43).
As previously mentioned in Standard 12 Circuitry, the availability of a distal arterial flow probe offers a higher precision of care to neonatal and pediatric patients.

**Standard 18.1:** At minimum, the “n + 1” staffing model shall be utilized at all times, where “n” equals the number of operating/procedure rooms in use at any given time at a single site (11,54,55).

Last, one of the new, more controversial standards that was previously a guideline is the recommendation for an n + 1 staffing model. One study found that “incident rates occur almost 1.4 and 2.7 times higher in pediatric centers than in adult and combined centers, respectively” (55). Since the time of the study, operations and technology have become even more complex; therefore, the need for a second perfusionist becomes essential to minimize the rate of incidents and/or manage them when they occur.

**DISCUSSION**

The development and publication of AmSECT’s Standards and Guidelines for Pediatric and Congenital Perfusion Practice provide a timely and important step in advancing the pediatric and congenital perfusion subspecialty (12). They follow the practice of other professions such as cardiac surgery and cardiology, whose professional societies have published multiple evidence-based documents, including systematic reviews, clinical guideline documents, and consensus standards. The standards and guidelines are not meant to dictate specific patient care across all institutions, understanding that strong clinical judgment and institution-specific protocols should always take precedence.

A recurring theme throughout the process of generating the Pediatric and Congenital Standards and Guidelines is improved patient safety. The authors intend that teams use this document to review their existing clinical protocols to seek opportunities for improved patient care and/or confirm best practices in their programs. Errors in cardiac surgery remain a risk factor estimated by up to 12% for cardiac surgical patients (56). Tools such as these may reduce that percentage, knowing that “human error is both ubiquitous and inevitable” (57); therefore, it is our professional responsibility to do everything possible to prevent error.

Overall mortality for pediatric and congenital heart surgery is reported to be less than 4%, and decreasing each year for even the most complex patient populations (58,59). With lower mortality rates and increasingly complex surgeries, coupled with the constant introduction of new technology, the margin for error becomes increasingly narrow. Now more than ever, these Standards and Guidelines become appropriate ways to reduce variation and risk in practices, which is safer for our patients, and will...
also help strengthen the quality of research and outcomes-related data.

Some of the challenging aspects of developing the Standards and Guidelines for Pediatric and Congenital Perfusion Practice document include the limitations of what can be recommended or required of perfusionists, and lack of robust scientific evidence. Although it would be ideal to have entirely evidence-based practice, the published literature does not currently allow for that in pediatric and congenital perfusion. In addition to the advantages previously mentioned, one benefit of the process of generating this document is the identification of gaps in the current published literature, which will hopefully inform and stimulate future initiatives. In the absence of peer-reviewed publications, lower levels of evidence such as surveys of practice trends and local and regional standards of care are valued as the best available evidence. Collaborations between the professional societies of perfusionists and of multiple related professions (e.g., cardiac surgery, cardiology, anesthesia, and intensivist care) will establish the foundation for the development of additional evidence-based publications to inform future Standards and Guidelines documents (60,61).

CONCLUSION

The immediate implementation of all aspects of the newly adopted AmSECT Pediatric and Congenital Standards and Guidelines may be limited at some institutions by available resources; however, over time, the document may offer support to advocate for essential equipment or staffing needs. Finally, there is the struggle for mutually agreeable consensus locally, regionally, and/or nationally between the wide variety of pediatric and congenital practices and institutions that comprise our profession. The subcommittee was very purposeful in presenting the draft documents throughout the process to increasingly larger groups to ensure thorough vetting by multiple subject-matter experts.

Future plans for AmSECT’s Pediatric Standards and Guidelines taskforce include updating the document periodically based on newer evidence as it becomes available. In addition, we recognize that standards and guidelines documents encourage opportunities for collaboration and thoughtful communication between perfusionists and our colleagues in other disciplines, specifically surgeons and anesthesiologists. For that reason, we sought and successfully achieved endorsement from both the Congenital Heart Surgeons’ Society and the Congenital Cardiac Anesthesia Society.

Important Note on Scope

AmSECT recognizes that individual medical centers may have local policies that may supersede AmSECT’s Standards and Guidelines. Likewise, AmSECT recognizes that some districts or states may have laws that supersede AmSECT’s Standards and Guidelines. As a result, perfusionists practicing within those jurisdictions should comply in all respects with those policies and laws. These Standards and Guidelines may also be superseded by the judgment of the healthcare professional, taking into account the facts and circumstances of the individual patient and case.

ACKNOWLEDGMENTS

We acknowledge the feedback from the following groups and committees: the AmSECT Pediatric and Congenital Perfusion Committee, the International Consortium for Evidence-Based Perfusion (ICEBP) Committee, and the AmSECT Fellows of Pediatric Perfusion. We also acknowledge feedback from attending delegates at AmSECT’s Pediatric Perfusion Meeting in 2018 and AmSECT’s 57th International Conference in 2019.

REFERENCES


