PICS/AEPC/APPCS/CSANZ/SCAI/SOLACI: expert consensus statement on cardiac catheterization for pediatric patients and adults with congenital heart disease

Holzer, R.J.; Bergersen, L.; Thomson, J.; Aboulhosn, J.; Aggarwal, V.; Akagi, T.; ... ; Hijazi, Z.M.

JACC: CARDIOVASCULAR INTERVENTIONS VOL. 17, NO. 2, 2024

SCIENTIFIC SOCIETY CO-PUBLICATION

PICS/AEPC/APPCS/CSANZ/SCAI/SOLACI: Expert Consensus Statement on Cardiac Catheterization for Pediatric Patients and Adults With Congenital Heart Disease

Ralf J. Holzer, MD, MSc[a]†‡
Lisa Bergersen, MD, MPH[b]†‡
John Thomson, MBBS, PhD[c]†‡
Jamil Aboulhosn, MD[d]
Varun Aggarwal, MBBS[e]
Teiji Akagi, MD, PhD[f]
Mazeni Alwi, MBBS[g]§
Aimee K. Armstrong, MD[h]
Emile Bacha, MD[i]
Lee Benson, MD[j]
Regina Bökenkamp, MD, PhD[k]¶
Mario Carminati, MD[l]¶
Bharat Dalvi, MD[m]§
James DiNardo, MD[b]‖
Thomas Fagan, MD[n]**
Kenneth Fetterly, PhD[o]††
Frank F. Ing, MD[a]
Damien Kenny, MD[p]
Dennis Kim, MD, PhD[q]**
Emily Kish, RN, MSN[r]
Michael O'Byrne, MD, MSCE[s]
Clare O'Donnell, MD[t]‡‡
Xiangbin Pan, MD[u]
Joseph Paolillo, MD[v]
Carlos Pedra, MD, PhD[w]§§
Alejandro Peirone, MD[x]§§
Harsimran S. Singh, MD[i]
Lars Søndergaard, MD, DMSC[y]
Ziyad M. Hijazi, MD[z]¶¶

†Pediatric and Congenital Interventional Cardiovascular Society (PICS) representative. ‡Writing committee co-chair. §Asia-Pacific Pediatric Cardiac Society (APPCS) representative. ¶Association for European Paediatric and Congenital Cardiology (AEPC) representative. ‖Congenital Cardiac Anesthesia Society (CCAS) representative. **Society for Cardiovascular Angiography & Interventions (SCAI) representative. ††American Association of Physicists in Medicine (AAPM) representative. ‡‡Cardiac Society of Australia and New Zealand (CSANZ) representative. §§Latin American Society of Interventional Cardiology (SOLACI) representative. ¶¶Pediatric and Congenital Interventional Cardiovascular Society (PICS) president.

1. TABLE OF CONTENTS

This paper was jointly developed by *Journal of the Society for Cardiovascular Angiography and Interventions, JACC: Cardiovascular Interventions* and jointly published by Elsevier Inc. The articles are identical except for minor stylistic and spelling differences in keeping with each journal's style. Either citation can be used when citing this article.

From the [a]UC Davis Children's Hospital, Sacramento, California; [b]Boston Children's Hospital, Boston, Massachusetts; [c]Johns Hopkins Children's Center, Baltimore, Maryland; [d]UCLA Adult Congenital Heart Disease Center, Los Angeles, California; [e]University of Minnesota Masonic Children's Hospital, Minneapolis, Minnesota; [f]Okayama University Hospital, Okayama, Japan; [g]Institut Jantung Negara, Kuala Lumpur, Malaysia; [h]Nationwide Children's Hospital, Columbus, Ohio; [i]NewYork-Presbyterian Hospital, New York, New York; [j]Hospital for Sick Children, Toronto, Ontario, Canada; [k]Leiden University Medical Center, Leiden, the Netherlands; [l]Policlinico San Donato Hospital, Milan, Italy; [m]Glenmark Cardiac Center, Mumbai, India; [n]Children's Hospital of Michigan, Detroit, Michigan; [o]Mayo Clinic, Rochester, Minnesota; [p]Our Lady Children's Hospital, Dublin, Ireland; [q]Children's Healthcare of Atlanta, Atlanta, Georgia; [r]Rainbow Babies Children's Hospital, Cleveland, Ohio; [s]Children's Hospital of Philadelphia, Philadelphia, Pennsylvania; [t]Starship Children's Hospital, Auckland, New Zealand; [u]Cardiovascular Institute, Fu Wai, Beijing, China; [v]Atrium Health Levine Children's, Charlotte, North Carolina; [w]Instituto Dante Pazzanese, São Paulo, Brazil; [x]Children's Hospital of Cordoba, Cordoba, Argentina; [y]Rigshospitalet, Copenhagen, Denmark; and the zSidra Medicine, Doha, Qatar.
Address for correspondence: (R. Holzer). E-mail: rjholzer@ucdavis.edu.
Endorsement: American Association of Physicists in Medicine (Sections 7 and 11) and the Congenital Cardiac Anesthesia Society.
Abbreviations can be found in Appendix C.

ISSN 1936-8798/$36.00 https://doi.org/10.1016/j.jcin.2023.11.001

2. PREAMBLE

This document has been developed as an expert consensus document by the Pediatric and Congenital Interventional Cardiovascular Society (PICS), the Association for European Paediatric and Congenital Cardiology (AEPC), the Asia-Pacific Pediatric Cardiac Society (APPCS), the Cardiac Society of Australia and New Zealand (CSANZ), Society for Cardiovascular Angiography & Interventions (SCAI), and the Latin American Society of Interventional Cardiology (SOLACI), with additional endorsement from the Congenital Cardiac Anesthesia Society (CCAS) and the American Association of Physicists in Medicine (AAPM, Sections 7 and 11).

This expert consensus document is intended to inform practitioners, payors, hospital administrators, and other parties as to the opinion of the aforementioned societies about best practices for cardiac catheterization and transcatheter management of pediatric and adult patients with congenital heart disease (CHD), with added accommodations for resource-limited environments.

The practice of cardiac catheterization in this patient population has evolved considerably in recent decades, as have significant local, regional, national, and international variations in practice standards. Many areas of practice are evolving at a fast pace, and for the most part, rigorous evidence-based data are not available to guide clinical practice. In the context of current medicine-based evidence, an expert consensus document was considered the most appropriate document format to provide recommendations specific to cardiac catheterization in this patient population.

As part of this document's development process, it has been important to make a concerted effort to avoid any actual or potential conflicts of interest. All writing committee (WC) members provided disclosure statements as to relationships with industry or other entities (if any) that may be perceived as relevant to the content of this document. This was reviewed prior to finalizing the WC and updated at various stages throughout the writing, review, and revision processes. All relevant relationships with industry (RWI), including those without any financial interest, are listed for all WC members (Appendix A).[1]

3. EXECUTIVE SUMMARY

Requirements for cardiac catheterization procedures in pediatric patients and patients with CHD differ greatly from adult coronary or structural interventions, with limited existing practice standard recommendations. Those standards that do exist are often overly broad and do not account for variations in practices across the globe. Consequently, this document outlines comprehensive best practice recommendations including modifications and adaptations for resource-limited environments and adult CHD patients.

Catheterization laboratory management and administration

Physician leadership

The director of the congenital cardiac catheterization program is an essential requirement for laboratories practicing CHD catheterization and intervention. When the CHD program is embedded within a larger adult facility with shared cardiac catheterization laboratories (cath labs), it becomes important that the director of the congenital cardiac catheterization program maintains an associated leadership role.

The director of the congenital cardiac catheterization program should be a fully trained and certified congenital interventional cardiologist with significant clinical experience, ideally >5 years beyond completion of fellowship or similar training, with verifiable experience of at least 500 congenital cardiac catheterization cases performed as first operator following completion of training. The director is responsible for overall clinical performance and strategic direction of the congenital cardiac catheterization program. He/she will require protected time to fulfill those duties, at minimum the equivalent of 0.1 full-time equivalent (FTE), but ideally at least 0.2 FTE.

The director is expected to be a role model, must have demonstrable commitment to standard setting, and be responsible for maintaining a respectful teamwork environment. He/she should encourage best practices and quality of care through robust quality assurance (QA) and quality improvement (QI) processes, including data sharing and outcomes reporting. Other responsibilities include mentoring junior colleagues and all staff, overseeing privileging, training, maintaining current practice standards, safeguarding 24/7 coverage, and introducing new clinical procedures. The director also is responsible for introducing and implementing policies and protocols involving performance management, counseling, and grievance procedures.

Nonphysician leadership

A cath lab manager or equivalent is a desirable ideal standard for any cath lab. The cath lab manager (usually a senior staff member) functions as a team leader for the nursing and technical staff, working in close cooperation with the medical director and administrative leadership overseeing the program. The responsibilities of the cath lab manager overlap with the medical director but with a more specific focus on the cath lab's nursing and technical staff and inventory management.

Catheterization laboratory staffing

Staffing standards ideally should include sufficient personnel to safely assume the roles of scrub assistant, circulator, and recorder/monitor. Ideal staffing would require 2 circulators, as this allows for help during strategic points in a case and provides coverage for emergencies and complications. Additional assistance may be needed for complex interventions, hybrid procedures, and cases with operator-managed sedation (OMS). Cath lab staff should ideally be cross-trained for multiple roles within the laboratory.

For some complex congenital cases, having 2 qualified and fully trained operators may aid patient safety and good outcomes. The decision to arrange cases with a second fully qualified operator should be initiated by the main operating physician. When 2 qualified operators are performing the interventions together (if and when deemed necessary), the additional physician should be reimbursed for the time and/or (where applicable) recognized in terms of reported work "Relative Value Units" or similar policies of the country and facility involved.

Considerations for adult congenital heart disease patients

- Where local regulations dictate that adults must be treated by adult cardiologists, procedural staffing models that also include pediatric and/or adult congenital heart disease (ACHD) cardiologists should be adopted.
- In facilities where the adult congenital interventional cardiologist and pediatric cardiac interventional cardiologist report through separate (adult and pediatric) leadership structures, regular meetings of the entire congenital interventional team are important.

Considerations for resource-limited environments

- Cross-training is an essential requirement.
- Physician and nonphysician staff may have multiple roles to fill.
- Operators may have to perform a procedure with limited assistance during a case.

Procedural training and competency

One of the greatest challenges when it comes to training, experience, and competency is provision of minimum case number requirements. In this document, the WC agreed to an approach where (low) minimum case numbers are provided. On their own, this does not guarantee competence, but below those minimum numbers, it is extremely unlikely that an operator would have the necessary competence. This was combined with other assessment tools and requirements that further supplement the competency requirements.

Procedural training

Trainees pursuing an advanced interventional fellowship should have acquired core training in the basic principles of cardiac catheterization, including an introduction to basic technical skills. A thorough assessment and selection process should be put into place prior to offering an opportunity for an advanced fellowship.

The duration of advanced training may vary but should be a minimum of 1 year. While recommendations for total case numbers are somewhat subjective, any program under which a trainee wishes to pursue interventional training should guarantee a high variety of complex interventional procedures and ideally perform a minimum of 200 congenital cardiac catheterizations per year (per advanced fellow being trained) in that institution.

It is the responsibility of the training program director and catheterization program director to monitor core and dedicated interventional fellows in all aspects of their training. Curricular competencies include systems-based practice, practice-based learning and improvement, professionalism, and interpersonal and communication skills. Competency-based training or competence by design is an assessment format to determine training progress and competency. It requires the trainee to achieve an expected level of competency in predefined tasks rather than simply spending a defined amount of time in the subspecialty service or performing a certain number of procedures. Achievement of competency should be measured, monitored, and documented throughout the entire training curriculum.

Interventional training can be structured in several formats. The basic level of training is recommended for all pediatric cardiology trainees. The goal of such training is to provide basic knowledge of hemodynamics, angiography, radiation safety, indications, risks, and benefits of interventional procedures in pediatric patients and adults with CHD. The trainee's role during the basic level of training should be as an active participant. It is important that core training to required levels of competency can be provided without necessarily scrubbing into every case during the catheterization rotations.

The intermediate and advanced levels of training will be acquired through additional year(s) of dedicated interventional training following core training. The trainee undergoing advanced training should be afforded a greater experience and level of independence in the procedures than attained during the core competencies. At the conclusion of a trainee's program, it will be the (training) program director's responsibility to confirm the trainee has acquired the skills to perform basic interventional procedures independently up to the required level of competency.

Procedural competency: Interventional cardiologists

After completion of an interventional training program, early-career interventional cardiologists will not be fully capable of independently performing all types of interventional procedures. It is essential that the early-career junior interventional cardiologist has the availability of a senior operator to help develop and enhance his/her interventional skills for at least 2 to 5 years after training, and for many complex procedures even longer.

Introducing new procedures requires that the interventional cardiologist perform several procedures under the supervision of a senior operator with adequate experience in the procedure. The organization should have a clearly documented process in place that monitors outcomes of these procedures once the operator performs these procedures independently.

An adequate procedural volume is important. Maintaining competency for operators may be challenging if less than 75 interventional cardiac catheterization procedures are performed as a first operator per year, or if the program performs less than 150 cardiac catheterization procedures in pediatric and adult patients with CHD.

Procedural competency: Nonphysician staff

Every team member participating in a congenital cardiac catheterization procedure should have the appropriate skills to perform the role-specific tasks that may be expected of him or her. Competency is acquired through experience. In laboratories offering pediatric cardiac catheterization, a minimum number of cases should be required for nonphysician staff: at least 75 congenital cases per year per staff member (50 of which should be in pediatric patients).

Considerations for ACHD patients

- Primary operators performing ACHD catheterizations and interventions should possess extensive knowledge of CHD.
- Recommendations for ACHD interventional training include participation as a first or second operator in a total of 150 ACHD procedures (100 interventional), with at least 10% of cases (but no more than 25%) performed in children.
- Caring for ACHD patients requires a different skill set than caring for patients with coronary artery disease (CAD) or structural heart disease. As such, occasional practice should be strongly discouraged. As such, procedures must only be performed by operators who also have the required training and background in CHD. This will require either dedicated interventional pediatric cardiac training, formal ACHD interventional training, or (for experienced operators coming from a nonpediatric and non-ACHD background) to have performed at least 300 ACHD cases of wide variety and complexity.
- Operators wishing to perform cardiac catheterizations in adult patients with CHD should maintain an adequate annual procedural volume. As an ideal standard, these operators should perform at least 50 ACHD cases, with 30 ACHD being of interventional nature.
- Procedure-specific minimum case numbers need to be performed under guidance of an experienced ACHD operator prior to performing any of these cases independently.

Considerations for resource-limited environments

- Formal training requirements may be difficult to implement.
- Specific volume requirements may not be achievable.
- The availability of a senior operator to help develop and enhance the interventional skills of a junior interventional cardiologist may be limited.

The ideal pediatric and congenital cardiac catheterization laboratory suite

General considerations

While exact dimensions of a procedure room may vary based on individual cath lab equipment configurations, appropriate workflows are rarely achievable with a procedure room of less than 500 square feet (46 square meters), and ideally at least 1000 square feet (93 square meters). Beyond the in-room requirements, cath lab have a myriad of structural requirements, such as the need for higher ceilings, ceiling reinforcements, and lead lining for walls and the control room window. Other supporting rooms should be positioned immediately adjacent to the main cath lab room. This includes a control room with an unobstructed line-of-sight to the procedure room, a fluoroscopy equipment support room, a scrub area, and sufficient access to extra storage space. Additional

requirements will need to be met relating to heating, ventilation, and air conditioning (HVAC).

A hybrid cardiac catheterization suite has several additional requirements beyond that for a standard cath lab. Most importantly, a hybrid suite should have an addition 200 square feet (19 square meters) of procedure room footprint, plus a dedicated table that can be locked securely, allowing left/right tilt of ideally 30°, as well as head up/down to approximately 30°.

Equipment

For pediatric and congenital cardiac catheterization laboratory (PCCL) procedures, biplane imaging is extremely valuable allowing for imaging complex anatomy in complementary projections, while minimizing exposure to both ionizing radiation and contrast. As such this is the ideal standard for most laboratories. Modern angiographic data outputs should ideally be fully digital. An important element of the x-ray equipment is the size of the flat panel detector, the choice of which will be determined by case mix (balance of adult vs infant patients), resources, and number of rooms. Maintenance and servicing are necessary to ensure ongoing optimal performance and to avoid unexpected outages. X-ray systems should be replaced on at least a 10-year cycle (ideally an 8-year-long cycle) for the PCCL, where many pediatric patients have higher longevity (when compared to older patients) to manifest the secondary effects of radiation exposure.

Consumables and supplies

To accommodate the range of patients and procedures, a wide range of consumable supplies are required. While equipment does not need to be manufacturer-specific, it is important to accommodate specific equipment characteristics requested by operators, who often by training differ in the way that procedures are performed. Laboratories should maintain a stock of consumable equipment to keep up with anticipated demand whereby a minimum number of each consumable product is maintained. The PCCL laboratory manager should maintain detailed lists of all inventories and periodic automatic replenishment (PAR) levels of items that should always be in stock for congenital cases. It is never acceptable that a specific intervention cannot be performed because supplies were not available during a case.

Storage

Storage environments for PCCL equipment are specialized spaces, which should be temperature and humidity-controlled, as many items may deteriorate in suboptimal conditions. Rapid access to the full range of available supplies is necessary for safe practice. Inevitably, some combination of in-room, adjacent, and more distant fixed storage is necessary for almost all laboratories. However, the arrangements of these items should ideally be done in such a way so that staff leaving the laboratory during a procedure to fetch equipment is minimized.

Adult congenital patients

- Larger detector sizes are preferable.
- Procedure tables need to accommodate a higher weight limit.

Resource-limited environments

- Operators may have to utilize single-plane laboratories due to lack of availability of a biplane laboratory.
- Alternative strategies are necessary to meet the supply demands for specific cases.
- Resterilization may be required.

Facility requirements

General considerations and types of facilities

Types of facilities that provide congenital cardiac catheterization services include the following:

- A children's hospital within an adult facility of a larger tertiary medical center
- A children's hospital adjacent to an adult facility of a larger tertiary medical center
- A children's service line within an adult facility
- A free-standing children's hospital
- A free-standing (pediatric and adult) cardiac hospital

Furthermore, in nongovernment-funded health care systems, there are different administrative and financial models to support congenital cardiac catheterization programs.

At the ideal end of the spectrum, there is the fully independent children's hospital with all service lines fully supported within the children's hospital but located within a larger combined child-and-adult facility in a larger tertiary academic medical center. In theory, this offers the best possible arrangement, as it has all the benefits of a free-standing children's hospital, while also having all adult support services in the same building complex. Beyond this theoretical "ideal" setup, specific arrangements need to be made at all other facility models, to accommodate and plan for inherent shortcomings and limitations.

Facility and organizational requirements for the pediatric and congenital cardiac catheterization laboratory

Facility requirements to support a congenital cardiac catheterization program require access to core cardiac services which include the PCCL, echocardiography (including transesophageal echocardiography [TEE]),

electrophysiology, cardiac surgery, cardiac anesthesia, congenital cardiac critical care (pediatric and adult), neonatal care, postanesthesia care unit (PACU), and telemetry beds. Ideally, cardiac services are in close proximity.

Important noncardiac support services include access to blood bank and transfusion, laboratory services (including appropriately sized tubes for pediatric patients), radiology (computed tomography [CT], and magnetic resonance imaging [MRI] with specialists trained in CHD), 24/7 consulting services for important subspecialties, as well as other support services.

Organizational, departmental, and divisional requirements include a formal congenital case management conference, dedicated policies for surgical and extracorporeal membrane oxygenation (ECMO) backup, transportation, a radiation safety program, a QA, and QI program, as well as specific protocols and multidisciplinary support for rare procedures such as fetal interventions.

Considerations for ACHD patients

- For ACHD procedures, areas within the hospital for periprocedural admission and postprocedure care need to be available.
- Hospital mandates such as age restrictions will need to be accommodated.
- ACHD centers require sufficient resources to properly care for the ACHD population.

Considerations for resource-limited environments

- Prioritization of resources for the most fundamental components of the service must be made: operating room (OR), PCCL, intensive care unit (ICU), and imaging.
- Given that facilities must often operate with older equipment, emphasis must be placed on preventive maintenance of equipment.

Surgical backup and circulatory support/extracorporeal membrane oxygenation

Backup with ECMO, without also having cardiac surgical backup availability, is rarely appropriate for any congenital cardiac catheterization procedure. Furthermore, an established ECMO program is not necessarily a requirement for backup, if circulatory support using cardiopulmonary bypass can be provided. Backup categories include the following:

Surgical backup categories:

- Standby: The surgical team is present within the cath lab to render surgical support immediately.
- Rescue: Surgical backup is available on site and can be rendered rapidly (expectation to be able to make an incision within <15 minutes).
- Deferred: A surgeon may be off campus or scrubbed in a different procedure but is available so that a surgical incision can be made within 1 hour of activation.
- No backup: Surgical backup is not available.

Extracorporeal membrane oxygenation/circulatory support categories

- Standby: Expectation of establishing circulatory support/ECMO flow in <10 minutes from activation and/or ECMO team on standby in the cath lab.
- Rescue: Expectation of establishing circulatory support/ECMO flow on average in <30 minutes and in no more than 1 hour from activation.
- Deferred: Expectation of establishing circulatory support/ECMO flow within 1 to 3 hours from activation.
- No backup: ECMO backup or circulatory support is not available.

Extracorporeal membrane oxygenation/circulatory/surgical backup recommendations

A variety of operator, patient, and procedure-related factors need to be considered for deciding the availability of ECMO and surgical backup: age, weight, hemodynamic vulnerability, preprocedure risk scores, previous cardiac surgery, single ventricle vs 2-ventricle, presence of a shunt, associated genetic conditions, and the type of intervention and the most likely expected adverse events (AE). In addition, for surgical backup, consideration should be given to how easily and how effectively an injury can be temporarily controlled by interventional methods. Other factors include the presence of high-risk conditions and anatomic features, salvage procedures, and situations where a patient may not have any possibility of treatment being offered that includes ECMO or surgical backup within the geographical area due to resource limitations.

While many catheter procedures require rescue surgical backup availability, there are certain procedure types where deferred surgical backup is acceptable: diagnostic procedures, biopsies, standard septostomy, noncritical valvuloplasty, and device or coil occlusions. These considerations apply even more so to the provision of circulatory/ECMO backup, where in contrast to surgical backup, usually patient-specific criteria (rather than procedure types) dictate the need for more rapid availability of circulatory support or ECMO backup.

While a dedicated congenital heart surgeon is the ideal standard for surgical backup, it is acceptable that another surgeon provides backup for a specific case if there is documented recent experience (<12 months) in

performing surgical procedures with all the following characteristics:

- The same type of surgery
- A similar size of patient
- A similar overall anatomy
- A similar status of previous cardiac surgeries

Preparedness, activation, and other logistics

A formal protocol should describe how surgical and/or ECMO backup is activated. Given the multiple tasks required in an emergency, the entire activation process (including all necessary staff and equipment) should ideally be initiated in a single step by a designated cath lab team member. If a patient can be sufficiently stabilized, in most circumstances a transfer to the specialized cardiothoracic OR is preferable to performing a procedure in a cath lab environment.

Considerations for resource-limited environments

- In settings devoid of surgical expertise and where otherwise treatment could not be offered to a patient, procedures sometimes may need to be performed without an option for surgical backup.
- Circulatory support using cardiopulmonary bypass can serve as an alternative backup method when an established ECMO program is not available.
- Without the availability of ECMO and/or surgical backup, the presence of experienced operators who understand the procedure and associated risks is crucial.

Anesthesia and sedation

Types of sedation and staffing requirements

Most pediatric patients may benefit from moderate-to-deep sedation or general anesthesia (GA) to facilitate successful performance of cardiac catheterization procedures. However, for some cases, minimal sedation with a local anesthetic may be desired for the diagnostic portion of the procedure, such as the assessment of valvar gradients. An artificial airway is recommended for otherwise higher-risk patients and high-risk procedures. Patient safety should be the primary consideration when creating a sedation or anesthetic plan, which should be discussed in advance between the anesthetic and interventional teams. In most patients, modern anesthetic regimens can be conducted in such a way that the effects on hemodynamics can be minimal, even in sick patients.

The most common models for managing anesthesia and sedation for pediatric cardiac catheterization include:

- OMS
- Pediatric anesthesiologist without dedicated cardiac training (or equivalent)
- Dedicated pediatric cardiac anesthesiologist

The ideal standard to manage anesthesia and/or sedation in the pediatric cardiac cath lab is to have a dedicated cardiac anesthesiologist overseeing all congenital cardiac catheterizations. This may not always be feasible, and as such, an acceptable standard is a pediatric anesthesiologist with some experience managing pediatric cardiac catheterization cases.

On occasions, OMS will be employed for selected cases, which has several requirements to be performed safely:

- The operator will need the appropriate training and experience to manage the level of sedation (critical care experience is recommended).
- The operator will need to have immediate access to emergency anesthesia backup.
- The operator will need to have support from an experienced dedicated (nursing) staff member. This individual should ideally be in addition to the regular staff.
- The case selection should ideally be limited to lower-risk cases in hemodynamically stable patients.

Preparation, equipment, and monitoring requirements

In patients receiving GA, standard monitoring, including electrocardiogram (ECG), noninvasive blood pressure (BP), pulse oximetry, end-tidal carbon dioxide (CO_2), and temperature should be used for every case. Temperature monitoring is important in smaller children and infants who are particularly vulnerable to hypothermia. On occasion, near-infrared spectroscopy monitoring and/or transcutaneous CO_2 monitoring may be useful. Consideration should be given to placement of a urinary catheter for potentially long cases. Invasive BP monitoring may be indicated for selected cases.

Communication

Frequent, open communication between the anesthesia providers and all cath lab team members is critical. This is particularly important during the catheterization when changes in hemodynamics are noted, or changes being made that can affect the hemodynamics. Changes in rhythm or hemodynamic status noted by any team member should be relayed to the anesthesia provider promptly (and vice versa). Specific procedures require additional communication, such as prior to and during the performance of 3-dimensional (3D) rotational angiography, and prior to and during any type of intervention, or placement of stiff wires and other manipulations that could have bleeding or other hemodynamic consequences.

Considerations for ACHD patients

- A greater percentage of procedures can be performed using anxiolysis and/or conscious sedation, or local anesthesia without sedation.

- Anesthesia providers managing patients with ACHD should be competent in handling the entire range of congenital cardiac patients and possess a strong knowledge of management strategies to cope with significant (adult) comorbidities.

Considerations for resource-limited environments

- Access to a dedicated pediatric cardiac anesthesiologist may not be available.
- A larger number of cases may have to be performed with OMS.

X-ray imaging and radiation safety

Physics of catheterization laboratory equipment

Several parameters influence image quality and the x-ray dose to the patient and include the following:

- Dose that reaches the detector for each x-ray pulse
- Number of x-ray pulses per second
- Cross-sectional area of the x-ray beam
- X-ray beam filtration
- Beam on time for cine and fluoroscopy

Effects of radiation exposure

Ionizing radiation causes two different types of health effects: "tissue reactions" (deterministic effects) and "stochastic effects." The relative significance of tissue reactions and stochastic effects is different when comparing small children to adults. In children, due to their smaller body size, adequate tissue penetration to visualize cardiovascular structures is usually achieved with much lower skin entry doses than what is required in adults, and, as such, thresholds for tissue reactions to occur are rarely exceeded. The opposite holds true for stochastic effects. Tissue in growing children is more sensitive to the effects of radiation than adult tissue, due to children's overall greater mitotic activity. In addition, children are more susceptible as they have a longer life expectancy and with CHD often require repeated cardiac catheterizations and radiation-based imaging throughout their lives.

Dose reduction strategies

Since there is no dose threshold below which radiation exposure is not a risk for radiation-induced cancer, the "As Low As Reasonably Achievable" (ALARA) principle was developed to ensure that radiation exposure is always maintained "As Low As Reasonably Achievable." Optimization is the principle of using only the necessary amount of radiation for the procedure. Radiation dose delivery is optimized by equipment quality, calibration, operating protocols, and operator conduct.

While operator conduct forms an integral part of dose optimization, it is important to emphasize that staff have an equally important role to play in aiding radiation dose optimization. Prior to and during each case, the operator should employ several strategies to decrease the dose to the patient and medical personnel:

- Select appropriate protocols and settings.
- Assess need for antiscatter grids and table/patient distance to tube and detector.
- Use the lowest acceptable electronic magnification.
- Collimate the image.
- Dim the room lights.
- Limit excessively oblique imaging angles.
- Remove the long bones from the x-ray beam.
- Limit fluoroscopy time.
- Use saved fluoroscopy, instead of cine acquisition, when appropriate.
- Alternate beam angulation.
- Setting and responding to reminders.
- Consider using 3D imaging as appropriate for the intervention.

Radiation safety for patients and staff

Minimizing radiation to patients starts with eliminating unjustified procedures and/or angiograms and with obtaining high-quality diagnostic imaging without using radiation. Protecting pregnant patients is an important element of radiation safety, and in most jurisdictions, a pregnancy test should be performed in patients of menstrual age prior to a fluoroscopic interventional procedure.

Medical personnel should not be exposed to the primary x-ray beam. The amount of scattered radiation that medical personnel are exposed to is determined by distance from the x-ray source and the effectiveness of shielding. Equipment to mitigate radiation exposure is vital and includes lead aprons, thyroid shields, and eyewear for all staff entering the cath lab. Use of lead glass shields mounted on adjustable props can further reduce scatter and radiation exposure for both the patient and staff.

Oversight and monitoring

It is important that radiation dose is monitored in real-time during a procedure and to inform the operator when agreed limits are reached. Electronic and radiological service engineers should be responsible for routine care and maintenance of radiological equipment, and a qualified medical physicist should ensure optimal image quality while limiting radiation exposure to staff and patients.

Exposure to radiation by medical personnel must also be monitored. A badge must be worn outside of the

protective garments at the collar level on the left side. It is the cath lab manager's responsibility to designate a staff member to collect, return, and replace the badges on a regular basis. Specific accommodations apply to pregnant staff.

Considerations for ACHD patients

- ACHD patients are at higher risk of tissue effects due to higher skin entry doses being required to penetrate tissue in larger patients.
- It is important that specific congenital protocols are used (instead of coronary protocols).

Considerations for resource-limited environments

- Maintaining up-to-date and modern cath lab equipment is often not possible.

Quality and safety

Internal data and records

QA cannot occur without data; thus all centers performing congenital cardiac catheterization must maintain an internal database to track performance and outcomes.

Targeting quality assurance and quality improvement: Adverse events in the pediatric and congenital cardiac catheterization laboratory

Full capture of all AE regardless of severity allows a program to recognize event patterns and identify opportunities for improvement. AE reporting should include a detailed narrative, providing opportunities for improvement and facilitating internal review and discussion among all members of the catheterization team.

Interventional cardiologists should continuously evaluate their practices, monitor outcomes, and work with local multidisciplinary teams to establish rigorous strategies to ensure that the highest quality of patient care is provided. Establishing processes to analyze and display data will allow for close monitoring of progress.

"Key Conferences," including Morbidity and Mortality (M&M) and Serious Safety Event Reviews facilitate practice improvement, continuing medical education (CME), and professional development.

Continuous quality improvement

Continuous QI (CQI) involves an iterative system of improvements in processes, safety, and patient care. One example of a common methodology for CQI is the US Institute for Healthcare Improvement's (IHI) Plan-Do-Study-Act cycle, which allows process changes to be made, studied, and refined over time. Improving quality in the system of care is a team effort and requires individuals offering differing perspectives on the delivery of care.

External performance measurement, risk adjustment, and comparative reporting

Evaluating local results is essential, but it is equally important to compare outcomes against established benchmarks. This allows a program or operator to determine how institutional results compare to peers. Risk-adjusted outcomes, such as standardized AE ratios, are imperative for QA as they allow for comparisons between centers and operators in the heterogeneous population of congenital cardiac catheterization.

Considerations for resource-limited environments

- The International Quality Improvement Collaborative (IQIC), dedicated to improving care in low- and middle-income countries launched a (free) congenital cardiac catheterization registry in 2019, with streamlined variables focused on patient risk and procedure outcomes.

Preprocedural management

Patient selection: Congenital case management discussions

All interventional procedures that are either complex, carry significant risks, have potential alternative treatment options, or where there are questions about the preprocedural or postprocedural management, or the most suitable operator(s) performing the procedure, should be discussed at regular occurring combined case management conferences. These should include a congenital heart surgeon, a congenital echocardiography specialist, a pediatric cardiologist, a congenital axial imaging specialist, and ideally a pediatric electrophysiologist and a representative from pediatric cardiac anesthesia. Depending on the planned procedure type and age of the patient, additional presence of other services may be required.

Procedure-specific case preparation

While case selection and some case-specific decisions are often initiated at the time of the case management discussion, many elements that are important for the specific planning of a procedure follow afterward and are usually coordinated and supervised by the interventional cardiologist and the extended team.

The interventional cardiologist needs to be inherently familiar with all aspects of the patient's cardiac and past medical history, medication, as well as comorbidities. All pre-existing surgical and cardiac catheterization data, imaging data, as well as laboratory and other testing, need to be thoroughly reviewed.

A thorough risk assessment should be performed using preprocedural risk calculators such as the catheterization risk score in pediatrics (CRISP) and the information used to plan periprocedural resources, including post-procedural recovery. The precatheterization review also

needs to include procedural timing/urgency, the anticipated hospital stay, and the expected location following the procedure, so that appropriate resource arrangements can be made.

Preprocedural consults may be needed on a case-by-case basis. Additional preprocedural testing may include nonlaboratory testing such as vascular ultrasounds, pulmonary function tests, or stress tests. Most laboratory testing in healthy children can be obtained on the day of the procedure once vascular access has been obtained. A pregnancy test is recommended in all females of menstrual age. Patients with renal impairment, allergies, and thyroid dysfunction may require additional preprocedural considerations.

Blood may need to be accessible quickly (either in the room or close by) for certain types of procedures. These might include, for example, balloon angioplasty and/or stenting, transcatheter valve replacement, some procedures in premature infants, hybrid procedures, valvuloplasty procedures in critical aortic valve stenosis (AS), and critical pulmonary valve stenosis, as well as some ventricular septal defect (VSD) closure procedures.

The need and timing for involving other subspecialty services (such as TEE), consulting services (including industry support), a second interventional cardiologist, and surgical backup should be assessed and coordinated in advance.

Informed consent

Informed consent is crucial and legally required prior to performing any procedure (except for life-saving emergency interventions). Such consent should always be obtained by direct communication between the operator and the legal caregivers or the adult patient. A thorough discussion of the planned procedure, indications, alternative treatment options, likely benefits, and risks should occur. Patients and caregivers should be informed about the expected intermediate and long-term outcomes and the need for additional procedures that may be required.

Precase clinical review and "nil-by-mouth" guidelines

All patients planned to undergo cardiac catheterization should be clinically evaluated with a full history and physical examination in advance of the procedure (ideally within 30 days). During the clinical precatheterization assessment, information on when to stop eating and drinking must be provided. Generally, the 2-4-6-8 hour rule for clear liquids, breast milk, formula, and solids respectively is utilized.

Transportation

Transportation to and from the cath lab will be unique in every institution. In general, transportation should be conducted efficiently with adequate staffing and resuscitation supplies and medications readily available during the transportation. Intravenous access should be reviewed prior to transportation.

For children who are transported awake, assessment should be made regarding their anxiety and fear of separation from parents, and ideally, considerations be given to allow parents to accompany the child to the cath lab. Pretransport sedation may be needed in some patients.

Specific arrangements need to be made for transportation of ventilated patients, as well as patients on ECMO, ventricular assist device (VAD), or high-frequency oscillatory ventilation (HFOV) support.

Preprocedural team huddle

In addition to the immediate preprocedure timeout, or "safety briefing," a team huddle adds additional safety elements to a procedure. However, this may not be practical in many institutions. The team huddle should ideally be performed with all team members in attendance and prior to the patient being transported to the cardiac cath lab. With the team present, a brief discussion of all relevant clinical and procedural information is provided. Most importantly, a detailed discussion needs to focus on the most likely and important periprocedural AE and their mitigation.

Adverse-event preparation

Catheterization laboratories performing congenital intervention should develop clear protocols for management of common AE that may occur because of a cardiac catheterization procedure. Important elements include the precase review of potential AE and discussion of mitigation strategies, delineation of key roles for personnel during resuscitation and emergencies, a defined activation process for emergency backup teams, training in resuscitation by all team members, considerations for adjuvant imaging, and specific protocols for airway bleeding and vascular hemorrhage.

Considerations for ACHD patients

- Considerations for conditions more common in ACHD patients include arrhythmias, failing Fontan physiology, plastic bronchitis, renal disease, diabetes mellitus, chronic lung disease (CLD), and hypertension.
- If the procedure is being done in a free-standing pediatric facility, a postprocedure recovery plan should be coordinated.

Intraprocedural management

Time out

As in other procedural settings, a formal "time out" at the start of the procedure should be routine with reconfirmation of the patient's identity, procedural plan, and

confirmation of valid consent. This is different from the preprocedural huddle and occurs with the patient in the cath lab. However, the operator should reiterate any unusual procedural aspects, specific equipment requirements, and other important crucial elements of the procedure.

Infection prevention

Infectious complications from cardiac catheterization are rare; however, careful adherence to sterile technique should be routine and is especially important for hybrid and valve implant procedures. Systemic antibiotics are reserved for procedures where foreign material is implanted.

Patient positioning

Patient positioning at the commencement of the procedure is important, recognizing vulnerabilities relating to pressure areas, safety, and risk of hyperextension, plus the need to maintain a sterile field and preserve patient body temperature. Special precautions need to be taken to avoid corneal injuries as well as brachial plexus injuries.

Vascular access

The use of ultrasound to facilitate access is encouraged and is considered the ideal standard of practice. While femoral access remains the most used form of vascular access, alternative routes such as access via the radial artery, axillary artery or vein, carotid artery, jugular veins, or transhepatic access are frequently needed in patients with CHD. Appropriate positioning is crucial to success in vascular access.

Intraprocedural documentation

Formal documentation of the procedure by anesthesia, nursing, medical, and technical staff is mandatory via a written or computerized record. Documentation should be sufficiently detailed to accurately describe the hemodynamic condition of the patient throughout the procedure, the steps undertaken to perform the procedure, equipment utilized, personnel present, the hemodynamic and angiographic findings, and outcome of any intervention performed. Any AE must be clearly documented.

Intraprocedural drug administration

All solutions on the table should be labeled and drawn up in standard and agreed concentrations. Preprinted labels for common medications are useful. Medications frequently used during a procedure include contrast agents, local anesthetic agents, heparin and alternative anticoagulants, antibiotics, dobutamine, intravenous fluids, and pulmonary vasodilators.

Vascular hemostasis

In pediatric practice, it is common to obtain hemostasis by direct pressure once sheaths are removed at the end of the procedure. In larger patients, closure devices or a "figure-of-8" suture may be considered. Careful consideration should be given to reversal of heparin with protamine.

Postprocedural management

Patient destination

The patient destination site post catheterization will vary from one cardiac center to another depending on the location of the catheterization suite relative to the primary recovery area. Direct transfer from the catheterization suite to an intensive care setting may be needed in selected cases.

Overnight observation is usually required for certain procedure types, such as angioplasty, stent/valve implantation, closure of atrial septal defect (ASD) or VSD, transseptal puncture, vascular/valvar perforations, and hybrid procedures. Additional patient characteristics that may warrant overnight monitoring include age <1 month, hemodynamic vulnerability score ≥ 2, CRISP score ≥ 5, patients with systemic to pulmonary shunts or ductal stents, pulmonary atresia with intact ventricular septum with coronary anomalies, William's syndrome, biventricular outflow tract obstruction, and patients on vasodilator therapy for pulmonary hypertension.

Patient handoffs/transfer of care

Communication to the next care team following a catheterization procedure should be clear, distraction-free, consistent, and comprehensive. Communication should summarize the patient's diagnosis/history and details of the procedure, including AE and potential issues that may occur in the recovery period. A written and/or electronic medical record (EMR)-based brief procedure summary to direct immediate postprocedure care should be created prior to transfer to the initial recovery area.

Postprocedural monitoring for adverse events

The patient's respiratory status must closely be monitored, especially in the early stages of recovery. There should be continuous monitoring of arterial oxygen saturation with pulse oximetry. Baseline systemic saturation prior to the procedure should be known for those patients with continuing cyanotic heart disease. Blood returned during airway suctioning should merit vigilance. Large fluid shifts may be encountered in patients over the course of the procedure. Medications used during sedation/anesthesia may have a myriad of effects on recovery.

Vascular access sites used during the catheterization procedure should be frequently monitored during recovery. Postcatheterization arterial thrombosis pathways

should be developed and utilized. Following particularly long cases, intentional evaluation for pressure injuries and brachial plexus injuries is important. Acute neurologic changes should be assessed frequently following a catheterization procedure and if encountered should result in quick escalation to determine the cause.

Bedrest guidelines

Recommendations for lie flat times post cardiac catheterization vary widely from institution to institution and can be as short as 2 to 3 hours, even though 6 hours is a more commonly used time adapted at many centers. The use of vascular closure devices may allow ambulation postprocedure in as little as 1 to 2 hours. Prolonged sedation may be necessary in selected patients.

Structured procedure reporting

A comprehensive structured congenital catheterization report is needed for all patients and procedures, ideally completed within 24 hours where feasible. Summary details should be provided so other health care providers can easily understand indications, outcomes, and complications encountered.

Outpatient discharge planning and instructions

A significant proportion of patients undergoing congenital cardiac catheterization will be able to be discharged to home the same day, provided they have fully recovered from sedation/anesthesia, have returned to baseline oxygen saturation, and have been able to tolerate enteral fluid intake, without any concerns at the vascular access sites. One should consider seeing most patients within 4 to 6 weeks of the procedure, while some patients will require earlier follow-up after 1 or 2 weeks.

Considerations for ACHD patients

- The ACHD team needs to be involved in the periprocedural care of the patient.
- The team needs to arrange postprocedure consultation with internal medicine specialists for any significant comorbidities.
- ACHD imagers should conduct predischarge cardiac imaging.

Procedures requiring specific preparations and setup

Hybrid procedures

Hybrid procedures combine surgical and interventional techniques, such as intraoperative stent placements, perventricular VSD closure, intraoperative placement of transcatheter valves, and hybrid palliation of hypoplastic left heart syndrome (HLHS). Hybrid procedures can be classified as follows: (1) adjuncts to traditional surgical interventions, (2) alternative forms of vascular access to aid transcatheter interventions, and (3) true hybrid procedures that offer alternative treatment options to traditional surgical or catheter-based approaches.

Hybrid procedures can be performed in a variety of environments and settings. The choice of location depends on the type and provided strategy of hybrid procedure being performed and the specific equipment and imaging demands of the interventional and surgical teams. A dedicated hybrid OR is the ideal environment for adjuncts to surgical interventions (such as intraoperative stenting), and perventricular VSD closure, while a hybrid cath lab is the ideal environment when carotid cutdown is required for procedures such as balloon aortic valvuloplasty (BAV) or patent ductus arteriosus (PDA) stent placement. Hybrid palliation of HLHS should ideally be performed in a hybrid OR hybrid cath lab if bilateral pulmonary banding and ductal stenting are performed as a singular procedure.

Personnel for hybrid procedures should include all members of the surgical and catheterization teams necessary to perform their individual procedural tasks. Hybrid procedures utilize a variety of equipment in different environments. Thus, staff will need to be trained to function in those environments and utilize available equipment.

Additional considerations apply to programs planning to offer hybrid palliation for patients with HLHS. It is recommended that only centers that have sufficient preprocedure and postprocedure experience with Norwood and Sano-type palliations should embark on starting such a hybrid program. Follow-up after hybrid stage I palliation should ideally be limited to a few cardiologists with accumulated experience within a center.

Procedures in premature infants

Premature infants, especially those in the very low birth weight (VLBW) category (<1500 g) represent some of the most fragile patients undergoing cardiac catheterization and intervention. To minimize the time in the cardiac cath lab, some programs arrange for endotracheal intubation and appropriate intravenous access to be obtained by the neonatal intensive care unit (NICU) staff prior to transportation to the cardiac cath lab. Elective preprocedural transfusion of packed cells may be considered for those determined to be anemic.

Transportation of VLBW infant is a complex undertaking due to their fragile physiologic state, particularly with regard to the ability to maintain core temperature. Ideally, the neonatologist should accompany the infant during transportation (in addition to the anesthesia team, if used). The ambient temperature in the cardiac cath lab should be increased to at least 23-24 °C (75-76 °F).

Procedures done outside the catheterization laboratory

Sometimes patients are too unstable to be transported to the PCCL, and as such, occasionally cardiac catheterizations and intravascular procedures need to be performed by pediatric cardiac interventional cardiologists outside of the PCCL. In those scenarios, workflows for emergencies need to be defined in advance, so that all team members know how to get support if needed, and to be sure emergency bailout equipment is readily available.

Fetal interventional procedures

Currently performed fetal cardiac interventions are as follows:

1. BAV of the aortic valve in severe AS
2. Atrial septal stenting in HLHS with intact or highly restrictive atrial septum
3. Less commonly, perforation and BAV of the pulmonary valve in pulmonary atresia with intact ventricular septum

These procedures require a dedicated multidisciplinary team including, at a minimum, a maternal-fetal-medicine specialist, an anesthesiologist to care for the mother (and the fetus), a fetal echocardiographer to guide the intervention and a pediatric cardiac interventional cardiologist.

While definitive requirements to start a fetal cardiac intervention program are lacking, published data suggest that large volume centers are in the best position to provide the environment to reach a high rate of technical success with reasonably acceptable risk to the fetus and low risk to the mother. Even though a program's surgical volume alone is not the sole determinant for predicting the long-term success of these procedures, initiating such a program at a center with a low annual surgical volume can be fraught with risk and such practice should be discouraged.

Coronary interventions in pediatric patients

There are multiple, rare congenital coronary artery (CA) lesions that may lead to myocardial insufficiency and perfusion abnormalities, potentially requiring collaboration with adult coronary specialists.

Coronary artery dilation/stent

Very few pediatric cardiac catheterization laboratories will have anywhere near comparable training and experience with interventional treatment of CA obstructive lesions as their adult CA interventional counterparts. Therefore, when catheter procedures for CAD are conducted in pediatric patients, pediatric cardiologists are strongly advised to collaborate with expert CA interventional cardiologists. Whether the procedure is to be performed in a pediatric or adult cath lab will depend on factors such as operator comfort level, availability of equipment, catheterization, and recovery staff qualifications, as well as potential hospital age restrictions.

Coronary artery fistula occlusion

Most significant CA fistulas are diagnosed in children; thus, pediatric interventional cardiologists have built a wealth of experience and technical expertise in treating CA fistulas by intravascular occlusion. CA fistulas that meet indications for closure are rare, though, consequently, collaboration between pediatric and adult interventional cardiologists performing these procedures may aid in increasing their collective experience.

Other considerations

Privacy, confidentiality, and data protection

Internationally agreed standards for protecting patient data do not exist. In the European Union (EU), the General Data Protection Regulation (GDPR) has been in place since 2018. In the US, data protection is covered by the Health Insurance Portability and Accountability Act initiated in 1996. Patients have rights in relation to their own data and transparency, which is a key principle of the GDPR and requires that any information about the processing of a patient's personal data must be easily accessible and easy for them to understand.

Occasionally, it may be necessary to share patient data, particularly when seeking a second opinion or if the patient's care is being transferred to another institution. Data-sharing agreements may be in place. Furthermore, seeking permission from the patient and ensuring the patient's confidentiality are paramount.

Each health care institution under the umbrella of the respective national regulatory body will have guidelines for processing and protecting patient data. This should be overseen by a data protection officer.

Participation of industry

Interaction with representatives from industry, including clinical specialists, can facilitate an optimal patient experience and may ultimately improve patient outcomes. However, clear guidelines should exist in relation to professional conduct and are usually developed by the regulatory body within the region. Participation from industry representatives may vary from ensuring necessary equipment is available, providing some guidance around the technical aspects of the equipment, and finally preparing the medical device for the implant.

Introduction of new technologies or devices may also require proctoring by industry representatives and more experienced physicians. The scope of practice and case participation of a proctor is usually agreed to between the industry representative and the physician being trained;

local regulations for allowing proctor participation will need to be followed.

Taped cases and live cases

Live case transmissions (and the presentation of taped cases) can provide a unique learning opportunity but require detailed planning and a careful consideration of many different aspects of those cases.

4. INTRODUCTION

The practice of cardiac catheterization in pediatric patients and adults with CHD has evolved significantly over the past 5 decades, from a mainly diagnostic modality to one with a predominance of transcatheter interventions that complement, and in some instances, replace the need for a surgical intervention.

Notably, CHD patients have procedural requirements very different from those of adult patients who undergo coronary interventions or interventions for structural heart disease. They also have different requirements in almost all areas that affect the working of a PCCL: laboratory layout and equipment, staffing requirements, procedural competency and training, surgical backup, anesthesia and sedation, and many other important periprocedural aspects of care.

However, despite these different and often unique needs, there have been limited practice standards focusing on cardiac catheterization in this patient population. In 2021, an expert consensus update was published under the umbrella of SCAI,[2] without any section dedicated to patients with CHD. In 2012, the SCAI/ACC Expert Consensus Document on Cardiac Catheterization Laboratory Standards dedicated 4 out of 76 pages to "Special concerns for the pediatric cardiac catheterization laboratory."[1] Additionally, existing recommendations are often broad and nonspecific, and do not address variations in regional, national and international practices and resources. This problem is further compounded by significant local, regional, national, and international variability in practices for these patients, with no clear guidance on "best practice" recommendations.

These factors have created practice heterogeneity, resulting in considerable difficulty when approaching hospitals and administrators to provide an environment that allows safe and efficient care for these patients. Frequently, practice has had to be modified to be in line with the needs of noncongenital adult patients, rather than what are the safest and best practices for the congenital cardiac patient population.

Given these limitations, in October 2020, the PICS Society Quality Improvement Committee decided to evaluate the possibility of developing an expert consensus document focused on cardiac catheterization in pediatric patients and adults with CHD, to aim for standards that can be applied on a global level, with support from multiple international societies.

4.1. Writing committee

The PICS Society Board of Directors approved the proposal and scope of this project in October 2020. The chair and cochairs of the PICS Society Quality Improvement Committee assumed the same positions on this project's WC. International societies that oversee the care of (transcatheter) therapy for patients with CHD in different global regions were identified. These societies included other societies beside PICS: AEPC, APPCS, CSANZ, SCAI, and SOLACI. Subsequently, each society was approached with a detailed description of the proposed project and its scope, inviting them to participate and nominate up to 2 representatives for each society. Where needed, specific requirements for either partnership with or endorsement by each individual society were solicited. Each society then followed its own individual process to review the proposal, often requiring a review by the respective research and publication committees. Approvals were received from each society between November 25, 2020, and February 18, 2021. Representatives from the CCAS and the AAPM joined the project in January 2022 and March 2023, respectively.

Once nominations were received from each society, the chair and cochairs of the WC determined additional potential candidates for participation, based on the need to cover expertise in a variety of areas, while also representing different geographical regions and health care settings around the globe. Additional WC members were added to include representation for cardiothoracic surgery, cath lab nonphysician staff, ACHD, congenital interventional cardiology training, radiation physics, cardiac anesthesia, and critical care.

All initial WC members were asked to provide their relevant RWI. Subsequent candidates were selected in a manner to include the necessary expertise while assuring that less than 50% of the WC members had relevant RWI. Individual updates to RWI of all WC members were sought at various stages during the project. The chair of the WC remained without any relevant RWI throughout the entire project's duration. All relevant relationships with industry (including those without any financial interest) are listed for the WC members (Appendix A).

4.2. Project timeline

An initiating WC meeting was conducted through 2 zoom meetings in March 2021. At this meeting the background and rationale for the project was presented, with the project scope and projected timeline discussed and finalized. The WC was split into different groups of 3 to 5 individuals for each section, paying attention to

preferably having representation from Europe, USA, and an additional region in each group. In addition, subject matter experts in areas such as cardiothoracic surgery, nursing, anesthesia, and ACHD were assigned to the relevant groups. Each section group then prepared an initial outline for their specific section. The WC chair and cochairs then modified outlines to avoid content duplication. Subsequently, each section group produced the written content for their individual section, which was then reviewed by 2 reviewers from the WC who were not involved in the specific section. All drafts were then combined into a single document and thoroughly edited and revised into a publishable format by the WC chair and distributed among the WC for review, with communication via email and scheduled zoom meetings. In addition, external reviewers and content experts that were not part of the WC reviewed and commented on the document (Appendix B). After several iterations of this review process, a final document was approved by all WC members and then distributed to all societies for societal approval.

4.3. Evidence and consensus

Wherever possible, the document included and referred to existing evidence-based data. However, the WC recognized that for most recommendations, higher-level evidence-based data was limited or absent, thereby requiring expert consensus among the WC. Throughout the project, consensus was reached through multiple iterations of review and group email discussions on topics where a difference in opinion was identified among WC members. Where necessary, complex topics were discussed in detail via live zoom meetings, with all such differences resolved by consensus.

4.4. Project scope and goals

The project goal has been to provide a comprehensive cath lab standards document focused on cardiac catheterization in pediatric patients and adults with CHD, a document that can be applied across a wide range of geographical regions and health care settings. The need for individualized and personalized treatment of patients based on different transcatheter strategies remains unaffected by the recommendations in this document. When it comes to specific recommendations and standards, 3 different descriptions were used throughout the document:

Qualified recommendations (based on the consensus of the WC):

- Acceptable standard/practice recommendations: considered acceptable standard/practice by (almost) all operators and in all countries, with no risk of malpractice suits
- Ideal standard/practice recommendations: a step up from an acceptable standard and considered ideal standard/practice by (almost) all operators and in all countries

Other recommendations:

- These include specific guidelines/recommendations that do not lend themselves to multilevel qualified recommendations.

The primary consideration for all recommendations was safety and quality of care. It was emphasized to all members of the WC that this document would not automatically endorse all current practices. Recommendations were created in such a way to be applicable throughout the globe in different health care settings with an understanding that some national laws and regulations may not allow practicing according to the recommended standards in this document. It is believed that this document will provide additional strength and support for congenital cardiologists to educate local/regional/national authorities as to what medical experts believe to be acceptable, and preferably ideal, care for these patients. The document will also form the basis for advocacy efforts urging those authorities to make the legislative, regulatory and policy changes needed to achieve this goal.

Throughout the document, all recommendations, specific accommodations, and modifications from the described standards were made for 2 specific groups and circumstances:

1. Resource-limited environments
2. Adult congenital patients

4.4.1. Resource-limited environments

The authors acknowledge that regional, cultural, and religious practices may influence some aspects of patient care. Most importantly, ideal practice often requires substantial financial resources, which may not be available in resource-limited environments. For example, resterilization of equipment may not be admissible in some countries but vital in resource-limited environments (see Section 7.7). As such, specific subsections were added where applicable to some sections of the document, to highlight the specific perceived limitations for resource-limited environments. For topics that are clearly resource-intensive, such as hybrid and fetal interventions, no subsections were added for resource-limited environments.

Importantly, the listed limitations are solely related to financial resources and while it is difficult to provide an exact definition of what one would consider a center operating in a resource-limited environment, it is clear

that no center operating in a country that is ranked in the top 30 of gross domestic product per capita would fall into this category.

Most recommendations in this document do not depend on financial resources, but instead, a willingness of the cath lab team and hospital leadership to adopt what is considered as best practice standards. It is envisaged that even resource-limited environments, with time, will work toward adapting some of the more resource-demanding recommendations. The standards in this document should provide a good benchmark to aim for improving their practice in the future. All practices that need to be employed in resource-limited environments that may fall short of recommended standards should be reviewed and regulated at institutional and/or regional/national levels, to ensure adequate standards are achieved and maintained, and to identify any breaches of those standards that may put patients at risk.

4.4.2. ACHD patients

4.4.2.1. The need for a special focus on ACHD patients

Based on improvements in diagnostic tools, treatment, and follow-up, the life expectancy of patients with CHD has markedly increased. Most patients born with even complex CHD are expected to reach adult age.[3,4] As of the year 2000, in the USA, the estimated number of ACHD patients outnumbered children with CHD, and by 2005, the estimated total population of ACHD patients had grown to over 1 million.[5] The increasing numbers of this unique population have spurred development of a medical discipline devoted specifically to their care.

This was recognized and implemented in different stages for different countries. As an example, in 2012, the field of ACHD received accreditation, through the American Board of Internal Medicine and the Accreditation Council of Graduate Medical Education (ACGME). Consequently, physicians could gain certification after completing specified training and examinations beginning in 2015. The care of patients with ACHD requires highly specialized clinical care as well as advanced multimodality cardiac imaging, in which cardiovascular catheterization and cardiac intervention play an integral role.

Though the underlying anatomic lesions and most interventional techniques used are similar, there are notable differences in needs and requirements encountered with ACHD patients undergoing invasive procedures compared to procedures for children with CHD. For example:

- Adult patients may have undergone outdated or now seldom used surgical procedures such as Potts/Waterston-Cooley Shunt, Senning/Mustard atrial level switch, classic Glenn and Fontan, Fontan modifications including the Bjork or lateral tunnel, etc.
- For nonsyndromic patients, significant comorbidities are more frequently present in the ACHD population.
- Acquired CAD and acquired cardiac dysfunction complicate underlying congenital cardiac lesions.
- Age-related heart disease including valvular insufficiency and/or stenosis may be present.
- Resuscitation methods, techniques, and equipment vary, including types of mechanical support options.

Concurrent with the development of ACHD medicine, advancements in minimally invasive technologies to treat CHD and structural heart disease have increased, and so has the number of interventional procedures applicable to ACHD. Historically, these procedures were performed with pediatric cardiologists as the principal operators. As more adult cardiologists became involved with ACHD and as procedures and technologies developed for structural heart disease (SHD) interventions were applied to ACHD patients, adult-trained cardiologists became more involved with ACHD invasive procedures, frequently without any training or expertise in treating patients with CHD.

Currently, in many centers ACHD interventions are performed by both pediatric and adult interventional cardiologists, most often working independently. Most of these procedures are performed at major medical centers where the pediatric and adult facilities are in close proximity.[6] Even though invasive procedures for ACHD patients are expanding and have bridged disciplines, recognized accreditation for this work does not currently exist. Significant gaps in standards of practice and training guidelines have been recognized.[6] Subsequently, there have been efforts by cardiac organizations to bridge these gaps, providing a framework for ACHD interventions.[7,8] Specific issues surrounding training and expertise needed to perform cardiac catheterization in patients with ACHD are further discussed in Section 6.4.

4.4.2.2. Scope of ACHD recommendations

The intent of the recommendations made in this document is not to be a comprehensive statement on every aspect of ACHD catheterization but to highlight specific aspects of these procedures that differ from pediatric cardiac catheterization. As such, each of the major sections will include (where applicable) a specific subsection that comments on important differences between ACHD and pediatric patients. Unless stated otherwise, all recommendations and requirements in the general section will also apply to ACHD patients. Section 17 is further devoted to coronary interventions in pediatric patients using a collaborative approach with adult coronary specialists.

5. CATHETERIZATION LABORATORY MANAGEMENT AND ADMINISTRATION

5.1. Physician leadership

5.1.1. Director of the congenital cardiac catheterization program

Leadership and lines of accountability are important elements of any successful cardiac catheterization program. The director/head/lead of the congenital cardiac catheterization program is an essential requirement for laboratories practicing CHD catheterization and intervention. The congenital catheterization director should assume overall responsibility for all catheter-based procedures in patients with CHD within the institution, preferably regardless of patient age.

Being the director of the congenital cardiac catheterization program though, does not equate to being the director of the respective cath lab. While a dedicated cath lab leadership for all patients with CHD is clearly desirable, in practice this may not be feasible in all organizational structures, for example, where the CHD program is embedded within a larger adult facility with shared cardiac catheterization laboratories. In these organizational structures, it is important that the director of the congenital cardiac catheterization program maintains an associated cath lab leadership role, with regular shared leadership meetings with all parties that utilize the cath lab, to discuss all aspects of cath lab operations. Without those shared leadership structures, there is a risk of pediatric and congenital requirements not being considered, and adult-based decisions being made that may have a potential negative impact on the congenital catheterization program.

The director of the congenital cardiac catheterization program should be a fully trained and certified (where available) congenital interventional cardiologist (the exact certification depends on the country of jurisdiction) with significant clinical experience, ideally >5 years from completion of fellowship or similar training, with a verifiable experience of at least 500 congenital cardiac catheterization cases performed as a first operator after training completion. The breadth of skills required in this role are wide-ranging and the individual should have strong management and interpersonal skills.

The director should have robust, up-to-date knowledge of transcatheter congenital cardiac procedures, in particular, those being performed in his/her laboratory. Although the director is likely to be the lead operator for many types of procedures, it is not reasonable to expect that he/she be the primary "expert" in all interventions. In certain instances, the director may not perform specific procedures at all, particularly in large-volume programs, where there may be several operators with various interests.

The director is responsible for the overall clinical performance and strategic direction of the congenital cardiac catheterization program. The director should strive to create a constructive, supportive, and reflective working environment across all aspects of clinical care within the service. There must be a demonstrable commitment to standard setting and objective QA with a primary focus on encouraging and supporting safe, high-quality practice within the unit.

Other responsibilities and skills required of the director include but are not limited to the following:

1. Role model: The program director is expected to act with utmost professionalism and as a role model within the program. Procedural results and technique need to be excellent and adhere to all required cardiac catheterization standards.
2. Respectful teamwork: The director is expected to foster a culture that enables cooperative and constructive working among all laboratory staff groups.
3. Mentoring: The director is expected to act as an approachable mentor to all members of the cath lab, in particular trainees and junior operators.
4. Privileging: The director is responsible for ensuring that physicians catheterizing in the laboratory meet agreed-upon standards and engage in regular performance reviews. There should be a cycle of formally reviewing and renewing privileges for practice within the laboratory, preferably no less frequently than every 2 years.
5. Training: A commitment to training and developing physicians at all stages (consultant/attending level and trainees) and other laboratory staff is essential. Most importantly, the director should facilitate and support the training aims and objectives of the program fostering a positive and supportive learning environment.
6. Keeping practice current: Congenital cardiac intervention is a complex and continuously changing specialty. It is essential the director acts as the driver to keep the service current and ensures that his/her team does the same. This includes, for example, participation in national and international meetings where the current "state of the art" relating to procedures and techniques are openly and objectively discussed.
7. QA and QI: The program director is ultimately responsible for establishing and maintaining active QA and QI efforts (Section 12). This also includes supervision of M&M conferences.
8. Data sharing and outcome reporting: The director is responsible for maintaining accurate data on all procedures performed, to be able to satisfy data reporting

requirements at the hospital, local, regional, and national levels (Section 12.5).

9. New procedures: The director is responsible for establishing and following protocols for introduction of new procedures into the laboratory environment (Section 6.2.2).
10. On-call/out-of-hours coverage: The director is responsible for ensuring there is adequate, evenly distributed, and consistent 24/7 coverage for the laboratory service that provides safe and consistent care for patients and takes account of institutional and program characteristics.
11. Protocols: The program director (together with the cath lab manager) is responsible for supervising and ensuring adherence to existing protocols and facilitating distribution and easy access to all protocols within the cath lab environment.
12. Performance management: The program director is expected to participate in managing performance issues for all members of the congenital catheterization team in accordance with institutional policies and (where needed) with human resource experts. Where applicable, this responsibility is shared with the cath lab manager.
13. Fiscal and strategic responsibility: The program director is expected to have a thorough understanding of the financial and operational details of the program. In this context, the director will act as a primary medical link with the administrative and institutional executive management to ensure laboratory service resource requirements are understood and addressed in a timely manner.
14. Grievance and counseling: The director should be available to all who have contact with or work within the laboratory about complaints and feedback, particularly patients and their families.
15. Collaboration: The program director is expected to foster a working environment that strongly supports collaboration with other subspecialties and services, such as vascular surgery, adult cardiology, interventional radiology, pediatric surgery, anesthesia, neonatal and pediatric intensive care.

5.1.1.1. Reporting and support

Given that experience is a key requirement for the role of the program director, many will serve in the role for several years. There should however be a regular "cycle" of review through the institutional or divisional leadership leading to reappointment or replacement based on prior agreed-upon metrics, as well as the general responsibilities outlined for a program director. There should be clearly defined institutional reporting structures to support and where necessary guide the congenital cath program director.

5.1.1.2. Protected time

The role of congenital cath program director requires considerable commitment which in most cases will be in addition to clinical service provision. As such, a program director should be given sufficient time to fulfill these responsibilities, which ideally should be 0.2 FTE or more of protected time, but at the minimum is expected to be 0.1 FTE of protected time.

5.1.2. Substantive catheterizing physicians

Within a congenital cath lab, there will be a core group of accredited, substantive physicians (in most regions termed either consultants or attendings) who are individually responsible for procedures conducted on their patients. This group will have considerable expertise. While the director is the primary leader of the program; the individual catheterization physicians are responsible for those patients under their care. Consultant/attending level physicians should constructively work with the director (and vice versa) to ensure smooth, effective, and safe running of the program. Institutional support must be available if difficulties are encountered with those relationships.

Depending on the size and volume of a program, there may be a need for a deputy or associate program director role, to share responsibilities where necessary, and to ensure there is coverage during periods when the primary program director is away. Regular meetings with all substantive catheterization physicians should occur to ensure that important programmatic information is shared and that there is group responsibility and action on important issues. In general, these meetings should occur at least once every 3 months, but for smaller programs with just 2 substantive catheterizing physicians, these meetings can usually be conducted informally and more frequently.

5.2. Nonphysician leadership

5.2.1. Catheterization laboratory manager

A cath lab manager or equivalent is a desirable ideal standard for any cath lab but may not be a standard employed in all countries and regions. The cath lab manager functions as a team leader for the nursing and technical staff, also working collaboratively with the medical director of the congenital cardiac catheterization program. In many institutions, the cath lab manager will function both as the leader of the clinical team and as a participant in the cath lab's participate in administrative leadership.

Given the variety of roles for nurses and technical staff within a congenital cardiac cath lab, there can be no absolute "blueprint" for the structure of this leadership function. In general, the cath lab manager or team leader

will be a senior staff member (nurse or technical staff) with considerable experience and understanding of the congenital cardiac catheterization team and the processes of the catheterization service and laboratory environment. Ideally, this individual would also possess an advanced degree. The cath lab manager/team leader and medical program director of the congenital catheterization program should maintain a strong teamwork approach to ensure a positive work culture and good patient outcomes. This relationship is especially important where the cath lab is embedded into an adult cardiology service.

Responsibilities of the cath lab manager in many aspects overlap with those of the director of the congenital cardiac catheterization program and include the following:

1. Safety and compassion: To ensure that patients are cared for safely and compassionately.
2. Role model: Being a role model for the cath lab team, acting with utmost professionalism and integrity.
3. Accreditation: Ensure all team members working within the congenital cardiac catheterization team are appropriately trained and accredited for the roles they are expected to perform.
4. Training: Ensures that (new) staff receives adequate general and procedure-specific training.
5. Maintaining competency: Ensure an individual's skills are objectively maintained and that there is a process of regular competency reviews and professional development to support this.
6. Sedation and monitoring: Confirm that additional appropriately qualified staff and protocols are in place for cases performed under sedation without an anesthesia team.
7. QA and improvement: Engage the cath lab team in quality and safety initiatives.
8. Staffing levels: Maintain nurse and technician staffing levels in line with agreed-upon standards and/or jurisdiction regulations. This includes an adequate out-of-hour (on-call) schedule to provide adequate coverage to safely deal with (emergent) procedures.
9. Protocols, policies, and procedures: The cath lab manager (in conjunction with the medical director) is responsible for supervising and ensuring adherence to protocols and policies, and facilitating distribution and easy access to those protocols within the cath lab environment. The cath lab manager also oversees the team's adherence to hospital policies and regulatory requirements (such as infection control).
10. Communication: Ensures the cath lab team maintains open and clear communication within the team, and with patients and families, before, during, and after catheterization.
11. Inventory and equipment management: Oversees inventory management as well as participates in the coordination of equipment maintenance.
12. Strategic directive: The cath lab manager collaborates with the program director and executive management to develop and support new unit protocols and objectives for the congenital catheterization program.
13. Grievance procedures: Ensure that a complaints procedure protocol is in place and that concerns raised are examined and followed through to an appropriate conclusion.

5.2.2. Administrative leadership

Very large congenital cardiac catheterization programs with multiple cardiac catheterization laboratories should ideally have dedicated administrative and management support. All modern laboratory services have myriad needs that, if incompletely addressed, can lead to inefficiency or at worse impact patient safety. An effective administrative management structure ideally includes effective communication with higher executive leadership. This will ensure that the overall institution understands the program's needs, objectives, opportunities, and challenges.

Management structures may vary among centers, regions, and countries. In some, the cath lab manager will have part of the higher-level administrative responsibilities, while in others, certain higher-level tasks may be handled by administrative leadership that does not have clinical responsibilities. Irrespective of the location or facility, for a congenital cardiac cath lab to be fully effective there should be:

1. Administrative support for the program and specifically for the program director. Lines of accountability and responsibility should be clear. There should be regular communication between the administrative leadership and the program director.
2. The administrative leadership should collaborate with clinical leadership in closely managing and monitoring processes for stocking and timely reordering of consumables.
3. A clear plan and process for timely repair and replacement of important clinical equipment in the laboratory setting (eg, fluoroscopy equipment) that has a relatively predictable lifespan.
4. Cooperative working relationship with the program director and cath lab manager to provide the latest technology and medical devices.
5. Management and support of the financial aspects of the cath lab to ensure the most efficient use of resources.
6. Ensure an open and responsive system where clinical staff can rapidly register (or document) errors or

important problems through the management structure, to enable the institution to implement improvement strategies.

5.3. Catheterization laboratory staffing

5.3.1. General staffing considerations

5.3.1.1. Congenital catheterization team composition

Minimum standards will vary across jurisdictions and from case-to-case depending on complexity, but programs should always include sufficient personnel to safely assume the roles of a scrub assistant, circulator, and recorder/monitor. Irrespective of the individual roles, all staff members have the responsibility to maintain the renewal of their individual licensure or certification (which should be confirmed by the cath lab manager).

The specific job titles, qualifications, and training requirements for staff in the cath lab vary from country to country. What is consistent though, is that the main roles that need to be covered in a congenital cath lab include a scrub assistant, a circulator, and a recorder/monitor.

Scrub assistant: This is a staff member who assists the operator at the table. Having a fellow or second physician scrubbed in during a case does not necessarily eliminate the need for a procedural scrub assistant, who is, in particular, helpful during emergencies. The scrub assistant must possess an understanding of and maintain sterile technique when setting up a table, draping a patient, and handling supplies and equipment throughout the procedure. Additional functions include the following: preparing and flushing transducers, sheaths, and catheters; housing wires; assisting in maintaining wire position; and preparing balloons and devices under the direction of the interventional cardiologist.

Circulator: The function of the circulator is to assist in the room during a procedure, obtain needed cath lab equipment items, understand and maintain sterile technique when opening items, run point-of-care testing, blood gases, and saturations. A wide variety of items are needed for congenital cases, thus it is important for the circulator to have an awareness of the stages of the procedure and be knowledgeable as to the laboratory's inventory, which will allow anticipation and availability of needed supplies.

Recorder/Monitor: The task of the recorder/monitor is to perform hemodynamic recordings, complete the procedure log, and help with x-ray acquisition and storage. Most importantly, the monitor should alert the physician of any changes in ECG or other hemodynamic data and vital signs. It is the recorder's responsibility to ensure all necessary documentation is completed in a timely manner. This includes the technical report, radiation exposure, and procedural logbooks. The function of the monitor/recorder is not to obtain cath lab consumables and items during a case, as this limits the ability to focus and complete the other tasks listed above.

As such, it is recommended that a minimum of 3 nonphysician staff members are available to support each case (not including the anesthesia team). Ideal staffing would require 2 circulators, as this staffing model allows for help during strategic points in a case and also provides needed support in case of any emergencies/complications.

5.3.1.2. Complex cases

Cases identified before the procedure as either high-risk and/or complex may require additional staff over and above standard practices, and some may benefit from 2 fully qualified operators (see Section 5.3.1.4). Complex procedures, such as for example bilateral simultaneous pulmonary artery stenting, may need more than 1 experienced assistant. Complex procedures may also require additional knowledgeable members of staff circulating to obtain equipment quickly and efficiently and to help with point-of-care testing, all of which allow the procedure to be performed with an adequate safety margin. Any hybrid procedure where a combined surgical and catheter-based approach to a problem is employed will require larger teams with competence to manage each element of the case.

5.3.1.3. Cases with operator managed sedation

This topic is discussed in Section 10.

5.3.1.4. Cases with 2 fully trained and qualified operators

The field of congenital interventional cardiology has grown considerably in recent decades with many complex procedures being performed on a regular basis. For some complex congenital interventions (such as some transcatheter pulmonary valve replacement, ductal stents, interstage interventions on the Sano conduits or modified Blalock-Taussig-Thomas [m-BTT] shunts in desaturated patients, etc.), having 2 qualified and fully trained operators for selected cases can facilitate favorable outcomes and expedite a case while reducing radiation exposure.

A core fellow or even an advanced interventional fellow does not necessarily provide the same safety margin that a fully trained operator does. However, this does not uniformly apply to all cases at all institutions. The decision to arrange cases with a second fully qualified operator should be initiated by the main operating physician.

Even though some procedures such as pulmonary valve implantation may often benefit from the presence of 2 qualified operators, for the majority of procedures, the need for 2 fully qualified operators cannot always be determined solely by the diagnosis and planned procedure. One must also consider the hemodynamic

vulnerability of the patient, the potential need for rapid action in case of an AE, the urgency of the procedure, past difficulties performing a procedure in the patient, and/or unusual anatomy for the specific diagnosis.

When 2 qualified operators perform a procedure together for clinical reasons, it is important to recognize the second operator is not simply a procedural assistant, but rather is a fully trained operator. As such, hospitals should provide the necessary staffing and FTE support so that procedures can be performed with 2 qualified operators if and when deemed necessary. In those circumstances, the additional physician should be reimbursed for his/her time and/or where applicable recognized in work "Relative Value Units" or other similar measures in the country and institution involved. Not doing so impedes patient safety as many procedures are then performed without a second qualified operator, when in fact it would be important to do so.

For any case that benefits from a second fully qualified operator, appropriate documentation will be required in the procedure reports (which should also name 1 primary responsible physician clearly identified in all the records). An appropriate forum to make decisions about the need and benefit of a second fully qualified operator could either be a documented case management discussion, or a formal (documented) precatheterization review by the primary interventional cardiologist outlining the need for a second fully qualified operator.

5.3.1.5. Cross-training and coverage

Ideally, all personnel should either be licensed or certified and at a minimum, possess an associate degree or its equivalent. Local or state regulations dictate allowable job responsibilities based on the discipline's licensure. However, many nonphysician catheter laboratory roles are relatively generic, and many skills are interchangeable between different professional groups. While some jurisdictions may have rules or even laws around a particular professional scope of practice and need (eg, the need for a radiation technologist [RT] or radiographer for direct supervision of the use of fluoroscopy, the scope for nursing to administer medication such as for sedation), outside of these specific requirements, a competence-based system for assigning roles is appropriate and indeed desirable for maximum efficiency. As such, unless prohibited by regulatory requirements, cath lab staff ideally should be cross-trained to manage at least 2, preferably all 3 roles needed in the cath lab (scrub assist, monitor, circulator). Without cross-training, it would require many staff to have sufficient support for each of the 3 functions, which as a result would lead to a dilution of professional expertise, particularly, in programs with a lower volume of congenital catheterization procedures. What is of primary importance is that competencies are demonstrated and maintained.

5.3.2. Team members of the congenital cardiac catheterization laboratory

5.3.2.1. Primary physician operators

Every procedure performed in the laboratory must be under the care of a primary substantive catheterizing physician (consultant or attending level). Training and competency requirements are discussed in Section 6 of this document. Primary physicians must be credentialed by the institution for invasive congenital cardiac catheterization.

Although primary catheterizing physicians are not expected to personally undertake every aspect of patient care, they are ultimately responsible for all aspects of patient care including the safe preparation, conduct, and recording of cases conducted under their name. In the majority of cases, the primary cardiologist will be scrubbed at the table for the procedure, but this is not mandatory for all cases. For example, in cases where there is a senior trainee with appropriate competencies to perform selected procedures under supervision, it is appropriate for the primary physician to observe and if necessary, advise from within the cath lab, with the ability to scrub-in whenever difficulties are encountered. Primary physician operators carry responsibility for communication with patients, their families, and other clinicians such as referring colleagues.

5.3.2.2. Procedural assistants

In general, cases should not be conducted without an assistant. Depending on the complexity of the case, an assistant may be another substantive catheterizing physician, a trainee (fellow), or a nonphysician assistant trained to scrub-in and assist at the table in catheterization cases. In many cases, there may be more than 1 assistant. Under those circumstances, it is important that specific roles and expectations are discussed and agreed upon prior to the case. Assistants should be recorded in the procedure log.

It is important to emphasize there is a difference between cases where a second physician assists due to the lack of an otherwise qualified (nonphysician) assistant, vs procedures that require 2 fully qualified physician operators to perform the procedure safely (Section 5.3.1.4).

5.3.2.3. Trainees

Trainees/fellows occupy important roles in many institutions (see also Section 6). Even though trainees may participate in cases, the primary concern must always be to maintain patient safety.

While there are instances where it is appropriate for a senior trainee to directly conduct a procedure or elements of a procedure as the first operator under direct supervision of the substantive physician operator, for the

purposes of records, a trainee must always be considered a secondary and not the primary operator.

5.3.2.4. Nonphysician assistants

In most laboratories, nonphysician assistants will scrub-in to assist in cases. Different countries have varying requirements for these roles, and in some jurisdictions, a nonphysician assistant may be mandatory. In many countries, the assistant will be a trained catheterization nurse, and in others a trained cardiac technologist or radiologic technologist. In some countries, there may be a qualification directed specifically at assisting cardiac catheterization procedures (such as registered cardiovascular invasive specialists [RCIS]). Increasingly in many units, physician assistants and nurse practitioners (or equivalent professional titles) perform scrub assistant roles. While respecting different local rules and regulations, of primary importance from the perspective of this expert consensus document is that staff in these roles have adequate training and experience for the role, and just as importantly, that competencies are maintained.

5.3.2.5. Noncatheterizing physicians

Successful congenital cardiac catheterization and especially intervention relies on high-quality and accurate noninvasive imaging, particularly echocardiography. Noninvasive cardiologists and echocardiography technicians with expertise in this area are a key part of a catheter laboratory team. Provision is volume-dependent but in large programs, echocardiography guidance in the laboratory can be an almost full-time occupation.

Physicians providing noninvasive support in the laboratory should be trained and certified as per their jurisdiction in cardiac imaging including TEE and if appropriate to the setting, intracardiac echocardiography (ICE). There is logic, where possible, in concentrating catheter laboratory image guidance in the hands of a small number of the overall imaging cardiology team to ensure the best quality imaging (based on knowledge of procedural requirements) and communication during procedures. It is important that high-quality, modern echocardiography equipment including the necessary transthoracic echocardiography (TTE), intracardiac echo, and TEE probes are available in the laboratory.

5.3.2.6. Nursing staff, advanced practice nurses and physician assistants

Nursing staff have varied skills and can occupy many different roles in congenital catheterization laboratories, ie, circulators, monitors, and scrub assistants. Nurses involved in the care of children should be adequately trained and credentialed in the care of pediatric patients. In some countries, there are expectations around the importance of direct nursing care for a child at every point in the patient journey such that direct nursing handover of a child to a designated nursing colleague at various junctures is a requirement. While for many countries and centers, it would be unusual for a congenital cardiac catheter laboratory not to have a requirement for a nurse in the laboratory when cases are performed; this clearly depends on regional and institutional requirements and may not be the case in all jurisdictions.

In the broader congenital catheterization team, advanced nurse practitioners, physician assistants, or equivalent professionals frequently manage caseloads or specific aspects of the patient pathway. This may include logistic elements of care including preprocedural, procedural, or postprocedural patient management, relating to smooth and effective running of the service. These roles are highly skilled and are important aspects of patient care, safety, education, as well as patient and family satisfaction.

Given the differences between nursing and practitioner roles, cath lab services and responsibilities will vary. What is essential is that: (1) clinical responsibilities and expectations of the nursing staff, and advanced practice providers within a service are clear; (2) training is appropriate to the role expected; (3) there is accountability and support for nursing staff and advanced practice providers through a clear management structure; and (4) licensure and certification are maintained for the appropriate practice.

5.3.2.7. Technologists

Broadly, by training, there are 3 types of technologists (or equivalent), who may be working in the catheterization environment:

1. Radiologic technologists (or Medical Radiation Technologists [MRT])
2. Cardiac technicians or cardiac physiologists
3. RCIS or equivalent (with a training background focused on intraprocedural assistance and hemodynamic monitoring)

In some instances, these roles may overlap, whereas in other instances, regulations may stipulate that an appropriately qualified nonphysician professional takes full responsibility for certain tasks, such as for example operation of x-ray-producing equipment, making this a specific full-time role in its own right.[1] Other examples may include local regulations where dedicated training as an RCIS (or equivalent profession) is required to scrub assist during procedures.

As is the case with nursing, these technical specialists frequently may perform other clinical roles including but not limited to procedural assistance, circulator for inventory and point-of-care testing, and procedural monitoring and documentation. Some scrub assistants/RCIS

take on responsibility for setting up and handling equipment less commonly used in pediatric procedures including intravascular ultrasound (IVUS), fractional flow reserve (FFR), embolectomy systems, and others. Irrespective of role distribution, there must be a reporting relationship of all those individuals to the cath lab manager, to ensure best use of available staff and resources.

5.3.2.8. Anesthesia

Discussed in Section 10.

5.4. Policies and guidelines

Written policies and procedures in a health care organization serve several important purposes. They facilitate adherence with recognized professional practices; promote compliance with regulations, statutes, and accreditation requirements; standardize practices across areas within the institution; and serve as a resource for staff, especially new personnel. Policies should be designed to be applicable (and relevant) across the institution. They are broadly grouped into those related to providing patient care and those related to providing a safe and well-managed organization. The latter covers areas such as health and safety of the hospital environment, biomedical equipment management, and administrative and human resource issues. It is important that the manager of the congenital cath lab disseminates the knowledge of relevant and important policies and procedures to all members of the congenital cath lab team.

The list of policy, procedure, and guideline documents that are important for the congenital cardiac cath lab needs to be adapted for each institution, and in consideration of other general institutional requirements. Selected examples of important documents include:

1. Full-time cover for emergencies
2. Activation of extra support for emergencies in the cath lab
3. Checklists for equipment that may be required with urgency
4. Emergency chest open in the cath lab
5. Transfer of patient to OR for emergency surgery post cardiopulmonary resuscitation (CPR) and stabilization
6. Emergency institution of ECMO or other circulatory support
7. Introduction of new devices and interventional procedures
8. Acquisition of new technology
9. Handoff of patients to other units

5.5. Considerations for ACHD patients

In areas where local regulations dictate that adults must be treated by adult cardiologists, procedural staffing models that also include pediatric and/or ACHD cardiologists should be adopted. In those circumstances, close collaboration between adult and pediatric cardiologists is essential.

In facilities where the adult congenital interventional cardiologist and pediatric cardiac interventional cardiologist report through separate (adult and pediatric) leadership structures, regular meetings of the entire congenital interventional team are important, to discuss and align all aspects of the congenital cardiac program. The decisions made in those meetings can then be brought forward to the joint cardiac cath lab leadership team, which will require representation from congenital team members to advocate for the specific needs of adult congenital patients.

Some ACHD catheterizations and interventions may require additional staffing. This is particularly important for cases performed under sedation without aid from the anesthesia team, which is a much more frequent occurrence in adult patients (see also Section 10).

Currently, most procedures are performed by operators working independently,[6] but complex adult congenital interventions may need 2 fully trained and qualified interventional cardiologists for selected cases, similar to complex pediatric patients (see Section 5.3.1.4). Optimally, having multidisciplinary operators with pediatric and adult backgrounds collaborating adds additional perspective and expertise as well as helps to bridge any deficiencies. ACHD and pediatric operators need to be credentialed and carry privileges in each institution where they treat patients, and often require privileges in different departments within the same institution.

Nonphysician staff qualifications and training will often have additional requirements to those of an isolated pediatric program. Staff members may require additional credentials and certifications to treat adult patients (such as for example advanced cardiac life support) and should have a thorough knowledge and experience with adult congenital cardiac procedures. It is often beneficial to limit the number of team members for adult congenital procedures to centralize experience. Depending on whether procedures are performed in a children or adult facility, they will require collaboration with team members of the adult team (pediatric facility), or the pediatric team (adult facility), especially when knowledge and experience with ACHD patients are not adequate, or when procedures are performed that are less common for the specific institutional setting. It may also require specific imaging support that may not be available at a specific facility (for example, when overlay is being used), or where the experience to perform congenital echocardiography is limited.

5.6. Considerations for resource-limited environments

- The staffing models and qualifications suggested in this section will need to be adapted to a resource-limited environment. While staff may not always have the formal training and qualifications, the focus instead lies heavily on cross-training staff adequately to assist in any specific role during a procedure.
- Physician and nonphysician staff may have multiple roles to fill within the same institution.
- For many centers in resource-limited environments, a qualified scrub assistant may not be available, and in many instances, an operator may have to perform a procedure with limited assistance during a case.

6. PROCEDURAL TRAINING AND COMPETENCY

6.1. Providing minimum case number requirements

One of the greatest challenges when it comes to training, experience, and competency is to provide minimum case number requirements. The main reasons are the following:

- Meeting specific target numbers does not necessarily signify competence, for a program or an individual operator. The definition of target numbers, in fact, may pose a potential problem in that numbers alone may be used as a surrogate for competence or quality.
- Some operators may achieve competency more rapidly than others, and as such may not require the case experience suggested for an average operator.
- Applying target numbers retroactively to trained operators who have been successfully performing procedures for many years, may potentially prevent skilled operators from continuing to undertake work for which they have established competence and expertise.
- Regional and country-specific constraints may be prohibitive to being able to meet specific minimum case number requirements.
- Not providing specific minimum case numbers would make it very difficult to prevent dangerous occasional practice or practice by nonqualified operators.

Given the above considerations, the WC agreed to use an approach where low minimum case numbers are provided, numbers which on their own do not guarantee competence, but below which, it is extremely unlikely that an operator would have the required competence.

This was combined with other assessment tools and requirements that further supplement the competency requirements. Furthermore, additional comments were included in this document to highlight any country- or region-specific aspects that would make these specific minimum case requirements difficult to achieve.

6.2. Procedural training: General cardiology core and interventional trainees

6.2.1. Introduction

Training requirements and approaches vary across the world, and as such, a full description of training methods and objectives applicable to each country is beyond this document's scope. The purpose of this section is to summarize general training recommendations for both the core trainee (also called "categorical pediatric cardiology trainee") and those who wish to pursue a dedicated career in interventional cardiology for CHD. Several previous publications form the basis of these recommendations.[6,8,9-13] The recommendations outlined in this section must be considered in the context of local, national, and international regulations (as well as clinical governance structures), and are intended as a guide toward best practice.

While the knowledge base and scope of practice for pediatric cardiology have grown over the past few decades in all subspecialties, the available time in each subspecialty during the general (core) training program has not. As such, and due to the judgmental and technical sophistication now required in interventional cardiac catheterization procedures at all ages, it is not appropriate to expect a graduating core trainee to be qualified to perform any type of cardiac catheterization procedure at the completion of a general training program.

While advanced training in interventional cardiac catheterization is available in many institutions around the world, there are substantial variations in the total experience, educational structure, and scope of practice. Various societies and regulatory authorities have recognized the importance of such advanced training and have put forth consensus guidelines and assessment tools for such training.[6,8,9-13] It is important for pediatric cardiologists who wish to perform cardiac catheterizations to prove proficiency through a minimum of 1 (or more) additional postcore year(s) of dedicated interventional training. During this advanced training under the supervision of an experienced interventional cardiologist, it is expected that with increasing case complexity, the trainee will achieve competency as a sole or primary operator. Trainees would then be able to advance their skills independently and progressively with varying and increasing case complexity through a lifetime learning model. Most trainees will maintain mentorship links far beyond their training years (see Section 6.2.1).

6.2.2. Prerequisites for training

The prerequisites for procedural training for the core trainee in pediatric cardiology are admission to a pediatric cardiology training program, the exact details of which may vary between different jurisdictions. Admission

requirements to general pediatric cardiology training are therefore not discussed in this section.

Instead, this section will focus on those interested in pursuing a career in congenital interventional cardiology including both pediatrics and/or ACHD.

Trainees will come from diverse backgrounds. Most trainees will have completed a general pediatrics and pediatric cardiology training program as specified by the country in which they practice. Prior to entering an advanced interventional training program, trainees should have acquired a thorough understanding of cardiac anatomy, pathophysiology, and various treatment strategies including an understanding of the natural and unnatural (modified) history of all congenital heart defects.

During their core training (and preceding the advanced interventional training), trainees should have acquired introductory experience in the basic principles of cardiac catheterization. This should include an understanding of the basic procedures involved in catheterization: indications for the procedure, basic acquisition and interpretation of hemodynamic and angiographic data, and the overall place of interventional catheterization in the treatment algorithm. The early catheterization experience should have focused on acquisition and interpretation of hemodynamic and angiographic data while minimizing use of radiation. It is expected that trainees pursuing an advanced interventional fellowship will have acquired an introduction to basic technical skills (vascular access, catheter manipulation, and limited exposure to device use), enabling the trainee and mentor to assess whether a trainee may have the necessary skills to pursue a career in advanced interventional cardiac catheterization.

It is important that a thorough assessment and selection process should be put into place prior to offering an opportunity for an advanced interventional fellowship. Completing such training does not equate to competency, and it will need to be emphasized to trainees upfront that starting an interventional fellowship does not guarantee a successful sign-off at the end of the training year. The selection process should be structured to limit the possibility that trainees who are selected do not have the skills to succeed as interventional cardiologists, an outcome that would be devastating to the professional career of a trainee.

The duration of advanced training may vary but should ideally be a minimum of 1 year, with each program having the infrastructure and volume to provide trainees exposure to and experience with a wide variety of representative techniques and procedures, to achieve the competencies listed below. While recommendations for total case numbers have their limitations (Section 6.1), any program that wishes to offer an interventional training program should include a minimum of 200 congenital catheterizations per year (per advanced fellow being trained) to be drawn upon (with at least 150 interventional cases). However, this must be taken in the context of regional training requirements and center-specific volumes. A minimum of 200 cases may be difficult to achieve in some countries where there are a limited number of very large volume centers. At the opposite end of the spectrum, in larger programs where a fellow may be exposed to a very large procedural volume, a training period of just 6 months may be adequate, if the fellow meets all volume and other requirements that are expected from a 1-year training program.

Programs offering interventional training should be committed to mentoring and supporting junior cardiologists and should have the ability to measure the outcome of their training efforts. Competence assessment schemes are presented below as a guide for trainers and assessment committees to consider.

6.2.3. Assessment of training progress and competency

The following comments apply to in-training core and interventional fellows whether following a pediatric-focused pathway, an ACHD pathway, or both. It is the training programs' responsibility to monitor core and dedicated interventional fellows in all aspects of their training, using clinical competency committees to review performance and provide feedback on the achieved milestones. The curricular competencies that require mastery include systems-based practice, practice-based learning and improvement, professionalism, and interpersonal and communication skills.

Several assessment methods have been utilized over the years to determine training progress and competency. The traditional framework emphasized a time or case-number-based approach (Section 6.1). However, this has been replaced by an educational and assessment framework focused on processes and (more importantly) outcomes, with specified levels of achievement. All trainees must have a named training supervisor appropriate to their training aims and environment. The trainee's supervisor should set and review the learning objectives for each training level.

A similar format that has become central in medical education is the shift to what is called *"competency-based training or competence by design."* This construct requires the trainee to achieve an expected level of competency in predefined clinical and academic tasks rather than simply spending a defined amount of time in the subspecialty service or performing a certain number of procedures to be considered fully "trained."[14,15]

6.2.3.1. Entrustable professional activities

Several methods exist to assess competency, including case-based assessments, structured observation, and assessment of practical skills. On a global scale, several

licensing boards and licensing authorities[16-18] have required training programs to utilize these "entrustable professional activities" (EPA) as the framework to evaluate a trainee's ability to practice. EPA are observable and measurable, and map the competencies and milestones of trainees as they move through the stages of acquiring fundamental interventional skills. Using this assessment format, the trainee is "entrusted" to move through levels of learning, demonstrating competencies in both the technical and academic components of congenital interventional cardiac catheterization. Achievement of competency as entrustable activities should be measured, monitored, and documented throughout the entire training curriculum (logbooks may complement this process).

Requirements and demands from the core fellow rotating through the cath lab should be viewed to establish the critical base of information required by the general cardiologist in assessing the diagnostic and interventional modalities of the cath lab. As such, their assessment as learners will be different from the dedicated interventional fellow. A suggested template for assessment of a core fellows' interventional rotation is given in Supplementary Appendix S1, and a similar template is provided for the advanced interventional trainee in Supplementary Appendix S2.[19,20]

6.2.4. Staged procedural competency: Trainee

A program offering training in pediatric and adult congenital catheter-based interventions must ensure assessment within the domains of learning: knowledge, skills, and attitudes. The foundation of a successful career will depend on the learner's knowledge and acquisition of interventional techniques, the evidence base for intervention, the concepts of interventional practice, and the ethical foundation toward concepts such as informed consent.

These can be structured in several formats, including as an example the format outlined by the AEPC. That format outlines 3 levels of accomplishment, ie, basic (level 1), intermediate (level 2), and advanced (level 3) with 3 domains within each level: medical knowledge, patient and procedural skills, and interpersonal/communications skills.[11] The trainee under this construct must demonstrate proficiency in level 1 skills before moving on to dedicated interventional training in levels 2 and 3. Alternatively, training can be viewed as a continuum from the core fellowship (basic concepts) through advanced training in interventional catheterization as detailed below.

6.2.4.1. Basic (core) level of procedural competency and training

The basic level is recommended for all pediatric cardiology trainees (**Table 1**). The goal of such training is to provide basic knowledge of hemodynamics, angiography, radiation safety, indications, risks, and benefits of interventional procedures in children and adult congenital patients. The core trainee should be comfortable in interpreting basic hemodynamic and angiographic data including an understanding of disordered hemodynamics and angiographic findings, an ability to perform basic hemodynamic calculations (cardiac output calculations, flows, pressure gradients, and vascular resistances), and an understanding of how they apply to the clinical status of the patient.

The trainee should understand the basic techniques in transcatheter interventions: valvotomy, arterial and venous dilations, device and stent implantation, and procedures performed in an emergency. The trainee should be comfortable with assessing the outcomes of an intervention, including recognizing residual hemodynamic or anatomic abnormalities, device stability, and assessment of radiographic and echocardiographic studies related to the intervention. The trainee should be capable of evaluating children presenting with symptoms of complications that could be attributable to the intervention.

TABLE 1 Core Curricular Competencies and Evaluation for Pediatric and Congenital Cardiac Catheterization

Medical knowledge

- Prepare yourself as if you were primarily responsible.
- Know the risks and benefits of catheterization and specific interventions.
- Know the indications and contraindications for catheterization and specific interventions.
- Know procedural techniques for catheterization and specific interventions.
- Know the principles of radiation safety.

Evaluation tools: direct observation, conference participation and presentation, and in-training examination.

Patient care and procedural skills

- Have a clear pre-cath plan regarding the goal of the procedure and delineate the procedure step-by-step including the probable supplies needed, and preparation for possible emergencies.
- Have the skills to interpret waveforms, determination of pressures, and gradients.
- Have the skills to apply thermodilution and the Fick principle for flows and resistances and know the methodic limitations.
- Have the skills to recognize normal and abnormal hemodynamics.
- Have the skills to interpret angiographic information.
- Have the skills to assess interventional outcomes, both successful and unsuccessful.
- Have the skills to assess the limitations of a procedure and to recognize and manage complications.

Evaluation tools: direct observation. The trainee is encouraged to keep a list of cases performed (which may include procedural details to document technique, equipment, and outcomes).

Interpersonal and communication skills

- Always remember the procedure is for the patient and not for an individual's training.
- Obtaining procedural consent.
- Counseling patients and families regarding the procedure's rationale and results.
- Effectively communicate catheterization data, both orally and in written form.

Evaluation tools: direct observation, faculty evaluations.

Adapted from Armsby et al.[10]

TABLE 2 Recommended Training and Experience to Perform Adult Congenital Heart Disease Interventional Procedures

Specialty	Training and experience	Comments
Pediatric interventional cardiology	■ 12 mo of advanced pediatric cardiac interventional fellowship (or 6 mo in large volume centers) ■ Meets proficiency criteria for pediatric interventional cardiology (Sections 6.1, 6.2, and 6.3) ■ Meets at least minimal procedural ACHD experience/volumes (Sections 6.4.3 and 6.5.4.1)	■ ACHD certification or ACHD specialist available for consultation during case ■ ACHD-focused case management discussion recommended (see Section 13.9) ■ Consider discussion with and participation of ACHD interventional cardiologist in the procedure ■ Ability to arrange combined procedures with adult PCI or adult structural interventional cardiologist on a case-by-case basis
ACHD interventional cardiology	■ Formal training and/or certification in clinical ACHD ■ At least 12 mo of advanced adult congenital cardiac interventional fellowship ■ Meets proficiency criteria for congenital ACHD interventional cardiology (SCAI position statement[8]) ■ Meets at least minimal procedural ACHD experience/volumes (Sections 6.4.3 and 6.5.4.1)	■ Consider collaboration with pediatric interventional cardiologist on cases with high complexity ■ ACHD-focused case management discussion recommended (see Section 13.9) ■ Ability to arrange combined procedures with adult PCI or adult structural interventional cardiologist
Adult interventional cardiology (non-ACHD)	■ Meets proficiency criteria for adult PCI or structural interventional cardiology ■ Experience of having performed at least 300 ACHD procedures of varying complexity (including Tetralogy of Fallot, Fontan, and Mustard) ■ Meets at least minimal procedure-specific ACHD experience/volumes (Sections 6.4.3 and 6.5.4.1)	■ Participation of pediatric or ACHD interventional cardiologist in the case is strongly encouraged ■ ACHD-focused case management discussion required for all cases (see Section 13.9) ■ Ability to arrange combined procedures with adult PCI or adult structural interventional cardiologist on a case-by-case basis

ACHD, adult congenital heart disease.

These competencies should be acquired through clinical exposure and experience but do not require a minimum number of catheterization procedures during the core fellowship years. Rather, they are demonstrated by achieving the competencies as outlined in **Table 2**. The trainee's role during the basic level of training should be as an active participant—being given the opportunity to scrub into the procedure and to use the equipment in accordance with the individual's manual and technical skills.

It is important to recognize there are times when having an unskilled assistant operator at the table can be a distraction and potential danger to a patient. Thus, it is important to emphasize that core training to required levels of competency can be provided without the trainee necessarily scrubbing into every case during the catheterization rotations.

However, while in general, active hands-on experience and a minimum case volume are not a requirement for core pediatric cardiology trainees, there are some important national and regional differences. For example, in a health care system where specialized centers cover large geographic areas (such as Australia), there is a benefit of giving even core trainees who have no intention of performing interventional procedures (but the basic skills to do so), enough hands-on experience to be able to provide emergency procedures (eg, a balloon septostomy, pericardiocentesis) when an immediate transfer to a larger regional unit is not possible, or would significantly delay treatment.

Those core trainees who show an interest in catheterization should be encouraged to participate in more cases over their core training years, to identify whether the trainee may possess the skills to pursue advanced interventional training. The trainee should participate in preprocedural preparation and postprocedural care, including monitoring and managing complications, report generation, and communication of the findings to the referring physicians. Core trainees should actively participate in QI activities, including M&M conferences specific to the rotation in interventional cardiology.

6.2.4.2. Intermediate and advanced levels of procedural competency and training

The eventual practice of pediatric and adult congenital interventional cardiology without supervision requires the mastering of a set of fundamental technical skills, which will require additional year(s) of dedicated training following the standard core fellowship.[9,11,21] During these training year(s), assignment of trainee's cases should be of increasing complexity under the supervision of an attending interventional cardiologist, with an increasing role in the procedure.[9,11] In general, the dedicated trainee undergoing advanced training should be afforded a greater experience and level of independence in the procedures than attained during the core competencies (**Table 1**). It should be emphasized that this skill set forms the foundation for acquisition of further skills that can be applied to more complex procedures.

While there is a large variety of procedures performed in patients with CHD, at a minimum, it is expected that focused instruction should be provided in (but not limited to) the following procedural categories:

- Vascular access: use of ultrasound, large bore entry, and small infants (preemies)
- Aortic and pulmonary valve dilations including indications for rapid pacing
- Aortic (coarctation), pulmonary artery, and systemic and pulmonary vein dilation
- Use of stents in the pulmonary arteries, aorta, and other vessels
- Urgent procedures such as balloon atrial septostomy and left atrial decompression with stents and balloons (including experience with transseptal puncture)
- Use of closure devices including vascular plugs and coils, for treatment of septal defects, fenestrations, the patent arterial duct (including premature infants), and abnormal vascular communications and fistulas
- Endomyocardial biopsies
- Pericardiocentesis
- Percutaneous pulmonary valve implantation
- Hybrid procedures

In addition to these procedural activities, the trainee should understand available equipment in use in the laboratory, and an understanding of complementary imaging (3D TEE, CT, MRI, rotational angiography, etc.) used to support the procedure.

6.2.4.3. Conclusion of an advanced training program

At the conclusion of a trainee's program, it will be the program director's (or training supervisor's) responsibility to confirm whether the trainee has acquired the skills to perform basic interventional procedures with no guidance up to the required level of competency. Depending on the size of the training program and the number of trainees, an interventional fellow might not achieve exposure to all desired procedure types at an adequate volume during the year of training. If, as a result, procedural competency in certain procedural categories cannot be assessed by the program director at the end of the advanced training, such cases should be performed with a senior interventional cardiologist while working as an independent operator until adequate competency can be documented. In such instances, it should be made clear to the trainee and documented that more training is required in certain procedure types.

If a trainee does not meet the expected skills required for an interventional cardiologist, thought should be given to a different area of subspecialization. In this context, it is the program director's responsibility to identify early in-training individuals who are performing poorly through frequent competency assessments as outlined, to avoid situations where at the end of training, performance is suboptimal. This may require working with educational supervisors or educational program directors to support both the catheterization director and trainees with career redirection.

6.3. Procedural competency: Interventional cardiologists

Maintaining competency for the physician operator after formal training can be divided into 2 general categories: ongoing procedural training, and ongoing education. With each passing year, the types of available equipment and cardiac lesions that can be percutaneously addressed increase. As such, it is encouraged that the practicing interventional cardiologist remains abreast of innovative developments by participating in procedural training seminars or webinars. As a corollary to in-house learning, attendance at educational conferences and online resources can be useful to increase knowledge. Documentation of CME is integral in many national licensing jurisdictions and can be a part of the ongoing competence assessments.

6.3.1. Ongoing procedural training

After completion of an interventional training program, early-career interventional cardiologists may not be fully capable of independently performing *all* interventional procedures. While advanced skills have been acquired in training, maintenance, and enhancement of competency continue beyond the training years. Improvement in—and acquisition of—new skill sets is a lifelong process involving collaboration with interventional cardiologists at various levels of training. Acceptance of mentorship and interactions with experienced operators is essential for continued acquisition of skills. The degree of case-specific support will vary with the individual, the years of experience, and the complexity of cases. However, it is an ongoing process that continues even for senior interventional cardiologists. It is encouraged that the early-career junior interventional cardiologist has the availability of a senior operator to help develop and enhance his/her interventional skills, for at least 2 to 5 years after training (and for some even longer). In most cases, the junior interventional cardiologist should be allowed to perform independently, with a senior interventional cardiologist available to guide or participate in the catheterization on a case-by-case basis (which may also include inviting external interventional cardiologists to participate in selected procedures).

6.3.2. Introducing new procedures

Introducing new procedures (including participation in device trials) to an operator requires a clear and transparent process within an organization. It is expected that the interventional cardiologist will perform several procedures under the supervision of a senior interventional cardiologist with adequate experience in the procedure. The exact number of procedures required to demonstrate competency varies from operator to operator and should be guided by the assessment of the senior supervising

interventional cardiologist. The organization/hospital should have a clearly documented and transparent process in place that monitors outcomes of these procedures once the operator performs these procedures independently.

The process of introducing a new procedure type to an entire organization is even more complex. It will require the same kind of senior operator supervision listed above (usually with the aid of a proctor familiar with the new procedure or device). Additionally, there should be a written "new procedure" protocol within the congenital cardiac laboratory specifically focusing on patient safety and clinical governance. Engagement with wider institutional "new procedure" requirements and transparency with patients/families should also be demonstrated. Procedural outputs should be recorded such that relevant outcomes can be scrutinized where necessary. Often this process is time-consuming and requires participation from other specialists who may be involved in the care of these patients, including in-service training specific to the role of the staff being trained. Specific procedural simulation is often required to increase team competence and patient safety.

6.3.3. Case-specific requirements

Recommendations for total case numbers and type-specific procedural numbers have their limitations (Section 6.1). However, when providing thresholds for an acceptable (but not ideal) standard, it is important to recognize that maintaining competency for operators may be challenging if less than 75 interventional cardiac catheterization procedures are performed as a first operator per year, or if the program has less than 150 cardiac catheterization procedures in pediatric patients and adults with CHD. However, in some countries with a limited number of centers providing interventional services, it may be necessary to accept a lower per-operator volume to avoid an entire service line for a region relying on a single operator.

6.4. Procedural competency: Nonphysician staff

6.4.1. General competency

Section 5.3 describes the roles of each type of cath lab staff. In terms of competency, All team members who participate in a congenital cardiac catheterization procedure should have the appropriate skills and competencies to perform all tasks that may be expected of them. All team members should possess baseline knowledge of CHD, types of procedures performed, arrhythmias, normal and abnormal pediatric hemodynamics and physiology, blood gas analysis, signs of patient decompensation, emergency management and inventory anticipation, and types of inventories that may be needed in emergencies.

6.4.2. Case-specific requirements

Overall responsibility for conduct of the case falls on the fully trained interventional cardiologist performing the procedure.

Catheterization volume and case complexity influence the staff's comfort level with equipment and complex cases. In laboratories offering pediatric cardiac catheterization, a minimum number of cases is required for the nonphysician staff, and should be set to at least 75 congenital cases per year per staff member (50 of which should be in pediatric patients). This requirement does not apply to staff that is rotating through pediatric and congenital cases to gain experience, provided there are at least 3 additional staff members (monitor, circulator, scrub assistant) present during the case who meet the experience and volume requirements.

With increased procedural complexity with new case types and devices, it is imperative that in-service presentations are incorporated into the laboratory educational curriculum and that standard guidelines for introducing new procedures are being followed (see Section 6.2.2).

6.4.3. Continued education and training

Ongoing education and annual competencies should be focused on building and maintaining the staff's knowledge base. There are several opportunities in the cath lab setting to offer staff education, including participation in case management conferences, mortality and morbidity conferences, and quality review discussions. In addition, preprocedure huddles and/or time-outs can be used as patient-specific teaching opportunities. Utilizing these opportunities will allow staff to be better prepared and engaged in the daily workload, which increases staff competency. Cath lab staff should be encouraged to participate in didactic teaching provided to cardiology trainees. Additional opportunities for staff education include participation in local and national conferences, as well as online webinars. Yearly competencies on safety and quality use (eg, defibrillation, cardioversion, rapid right ventricle (RV) pacing, or pressure wire setup) should be part of the ongoing staff educational program. Staff also should complete yearly competency reviews and assessments for procedures that are high in complexity but low in utilization. Mock codes for emergency management are beneficial for improving effectiveness and delineating roles during an AE. All laboratory team members should be certified in both pediatric and adult CPR (depending on whether ACHD cases are performed in the laboratory).

6.5. Considerations for ACHD patients

6.5.1. General operator background

Primary operators performing ACHD catheterizations and interventions should possess extensive knowledge of CHD: native and postoperative anatomy, natural history of the disease in adults, hemodynamics, appropriate diagnostics, optimal medical therapy, application and outcome of invasive therapies, and procedural and perioperative expertise and skill sets. Optimal outcomes for ACHD patients are achieved through teamwork between trained congenital cardiac specialists including imaging specialists, interventional cardiologists, and congenital cardiac surgeons. Practice outside this framework is suboptimal and should be discouraged. Currently, physicians performing interventional procedures in patients with ACHD have diverse backgrounds, training, and procedural prospective.

Pediatric interventional cardiologists

- Possess extensive knowledge and experience with CHD and possess the expertise and skillsets for CHD interventions.
- May be lacking in knowledge and experience with adult-acquired heart disease, CAD and coronary interventions, adult comorbidities, pregnancy, and structural heart interventions.

Adult congenital interventional cardiologists

- Possess extensive knowledge and experience with ACHD based on training and/or experience and possess the expertise and skillsets for ACHD interventions. Also, they have experience with adult comorbidities and pregnancy.
- Depending on the volume of an ACHD center, the number of interventions performed in patients with CHD may be lower than CHD interventions performed by pediatric interventional cardiologists.
- If not formally trained in CAD and structural interventions, the provider may be lacking in knowledge and experience with coronary revascularization, structural heart intervention, and CHD interventions primarily performed in children.

Structural heart disease interventional cardiologists

- Possess extensive knowledge and expertise with CAD and coronary interventions, acquired structural heart disease interventions (transcatheter aortic valve replacement [TAVR], transcatheter mitral valve repairs, etc.)
- May have limited exposure to closure of ASD compared to pediatric cardiologists
- Have experience with adult comorbidities
- May be lacking in knowledge and experience with ACHD and may not have full expertise and skill sets for many ACHD interventions

Adult interventional cardiologist (primarily CAD intervention)

- Possess extensive knowledge and experience with adult-acquired heart disease, CA revascularization, and adult comorbidities
- May be lacking in knowledge and experience with clinical ACHD
- May have limited expertise and skillsets for ACHD interventions and are further hindered by a lack of expertise in SHD interventions

Many physicians who performed ACHD invasive procedures trained prior to more structured education in catheterization for ACHD patients existed, as these types of programs have only relatively recently been created. Physicians gained their knowledge and developed expertise through varying degrees of exposure to these procedures during their training and then continued experience and education while caring for these patients in their practice.

Currently, there are programs offering training in ACHD catheterization and intervention, with the majority incorporating these procedures as part of more broad training in pediatric interventional cardiology or adult interventional cardiology fellowships. There are a small number of fellowship programs dedicated to ACHD interventional training with specific curriculum and procedural guidelines. Yet, while some societal guidelines have been published, at this time there is no recognized accreditation of this discipline.[8,22] As a result, the training in these programs is nonuniform and the experience gained may be quite varied. This situation has become recognized, with expert consensus publications attempting to provide guidance for facility infrastructure, multidisciplinary ACHD team composition with patient-centric mindset, and adequate knowledge and expertise of the physician mentors.

While newer ACHD interventional training guidelines recommend 150 procedures during training, this is usually provided in the context of a formal training program with an experienced operator and mentor, and with a wide selection of procedures. This cannot be considered the same as experience performing a limited selection of ACHD procedures over a period of 20 or more years without ever having received any formal guidance. As such, it was felt that an experience level of at least 300 ACHD interventional procedures was required for noncongenital trained interventional cardiologists to perform procedures in patients with CHD.

6.5.2. Occasional practice

Caring for adult patients with CHD requires a skill set very different from caring for patients with CAD or structural heart disease. As such, occasional practice should be strongly discouraged. Procedures should be performed only by operators who have the required training and background in CHD. Just as it is inappropriate for a pediatric cardiologist to perform occasional percutaneous coronary interventions without support of those performing these procedures regularly, it is inappropriate for an adult cardiologist without congenital expertise and skill set to perform ACHD procedures (for example, transcatheter pulmonary valve implantations), unless very specific criteria are met, which are outlined in this section. Not practicing according to these recommendations will ultimately lead to poor procedural outcomes (including longer procedure times or unsuccessful procedures), which would be difficult to defend if engaged in such practice without the necessary skills and qualifications.

6.5.3. Requirements for performing ACHD interventions

Table 2 provides the training and experience requirements for those wishing to perform ACHD interventional procedures, separated by the specific track and background (pediatric interventional, ACHD interventional, non-ACHD).

Providing specific requirements for operators without any formal adult or pediatric congenital training, but who have been performing these interventions for a considerable amount of time, is challenging. However, to safeguard patients, the most important requirement for these recommendations is to eliminate occasional practice, or practice by someone not sufficiently experienced in performing these procedures.

6.5.3.1. Procedure-specific volume recommendations

Minimum procedure-specific volume requirements (experience) prior to performing these procedure types independently are listed in Table 3.[8] When not meeting individual procedural minimum volume requirements, a safe practice requires for an experienced adult congenital interventional specialist to be present and assisting during these cases, until the recommended minimum requirements have been achieved and the necessary skills have been attested. Only then will the operator be able to independently perform these specific procedure types. It is important to emphasize that meeting minimum case volume requirements alone (without attestation by an experienced operator) does not necessarily guarantee competency.

6.5.3.2. Maintenance of competency

To maintain competency, further knowledge acquisition, and eliminate occasional practice, operators performing cardiac catheterizations in adult patients with CHD should maintain an adequate annual procedural volume.

As an ideal standard, these operators should perform at least 50 ACHD cases with 30 ACHD being of interventional nature, in addition to performing a total of at least 75 interventional procedures of all types per year (pediatric, ACHD, CAD, structural).[8] In addition, it is important to track procedural volumes and outcomes, specifically tracking and evaluating all complications and participation in national and/or international registries (also see Section 12). Additionally, the ACHD interventional specialist should participate in major interventional conferences with a focus on ACHD interventions, build collaborations with other ACHD interventional cardiologists, engage in peer-to-peer training, and follow the appropriate protocols when introducing new or rarely performed procedures.

TABLE 3 Minimum Interventional Procedure-Specific Experience for Adult Congenital Heart Disease Interventional Cardiologists[a]

Device closures
Atrial septal defect ≥15
Patent foramen ovale ≥12
Intracardiac echocardiography to guide septal closure ≥20 cases[b]
Ventricular septal defect ≥5
Patent ductus arteriosus ≥8
Angioplasty/stenting procedures
Coarctation with stent ≥8
Pulmonary valve implant ≥12
Right ventricular outflow tract, conduit, or branch pulmonary artery stents ≥10
Aortic valvuloplasty ≥3
Pulmonary valvuloplasty ≥5
Stent implantation in venous vessels ≥5
Stents baffles ≥5
Pulmonary vein stents >2
Fontan baffle fenestrations >2
Other procedures
Balloon atrial septostomy ≥2 (can be with other left atrial procedures)
Transseptal catheterization ≥10
Perivalvular leak closure ≥5
Ultrasound-guided access ≥100
Large vessel vascular closure techniques ≥30
Radial artery access ≥20

Adapted (with some modification) from Aboulhosn et al.[8]
[a]In addition, operators need to meet the training and experience requirements outlined in Table 2, as well as the requirements for maintaining competency, Section 6.5.3.2.
[b]In facilities and locations where ICE is not available or the cost is prohibitive, TEE can be used instead.

6.5.4. Dedicated ACHD interventional training

Competency-based training in ACHD interventional fellowship follows closely that of pediatric cardiac interventional training and the concepts discussed in this section. More details are provided in SCAI consensus

document by Aboulhosn and colleagues, from which many recommendations in this section have been adapted.[8] Considering few programs can provide the entirety of ACHD interventional training, continued strong collaboration between pediatric and ACHD interventional cardiologists is strongly encouraged. The aim of ACHD interventional training should be acquisition of foundational knowledge and skillsets for safe and effective procedural implementation and the recognition that ACHD intervention requires lifelong education, mentorship, and collaboration.

Given the length of training already required prior to embarking on dedicated adult congenital interventional training (which includes general ACHD training as well as interventional training required to perform cardiac catheterization in adult patients), it seems appropriate to require no more than 1 year of additional dedicated ACHD interventional training, which is in keeping with a previously published consensus document.[13]

6.5.4.1. Volume recommendations for ACHD training

Volume recommendations are adapted/modified from a recent SCAI consensus document by Aboulhosn and colleagues and include the following[8]:

- Participation as a first or second operator in a total of 150 ACHD procedures with at least 100 of those being interventional in nature. This is in addition to noncongenital case numbers that are required during adult (noncongenital) invasive training.
- At least 10% of cases (but no more than 25%) should be performed in children, given that certain interventional procedures are uncommon in the ACHD population; based on an overall training volume of 150 cases, this equates to at least 15 pediatric and 135 ACHD cases.
- Minimum procedure-specific volume requirements are listed in **Table 3**.[8] It is important though to emphasize that not meeting these procedure-specific volume requirements does not necessarily prolong the ACHD interventional training but requires the same additional mentoring and training for these procedure types that is required from experienced operators prior to performing these cases independently.

6.5.5. Cooperation/collaboration with adult cardiologists experienced in structural heart disease and coronary artery disease

Technological advancements over the past 25 years have produced an explosion in the number and scope of interventional procedures in the fields of CHD, structural heart disease, and CAD. As these individual disciplines increased in the required expertise and experience, the application of these technologies across disciplines has also continued to increase. Expanding new procedures to include different patient populations is accomplished optimally by collaboration between operators with pediatric and adult expertise. This allows an operator who has experience with the technology to perform the procedure with operators best suited to manage care for the patients. Collaborative management of procedures often portends optimal patient safety and outcomes, allowing each operator to work to their strengths and obviate deficiencies. It also facilitates collective knowledge acquisition and experience by both operators where each operator can act as a mentor to the other.

Pediatric and ACHD interventional cardiologists should collaborate with adult interventional cardiologists when ACHD patients require SHD procedures such as TAVR, transcatheter mitral valve repairs, aortic pseudoaneurysm exclusion, and CA revascularization (especially in older patients with significant comorbidities). With the aging of the ACHD population, more patients will also need treatment for acquired heart diseases.

These attributes of multidisciplinary collaboration hold true even in complex procedures where all parties have experience; examples include paravalvular leak occlusion and especially postmyocardial infarction VSD closure. The collaborators should work amicably with a common, patient-centered focus, keeping personal interests and egos in check to provide best patient outcomes. In centers of excellence performing these procedures, collaboration of cath lab professionals involves more than the primary operators and extends to all staff members involved in these cases. Additionally, this high level of collaboration extends to the institutional level and hospital administrations. The institutions need to facilitate the ability for all members to work fluidly through (often multiple) hospital systems; these professionals must be allowed to carry privileges in each institution.

6.6. Considerations for resource-limited environments

- The recommended training structures for pediatric and adult congenital interventional cardiologists have a significant (human) resource requirement that may be difficult to meet in resource-limited environments.
- Equally, specific volume requirements may not be achievable and operators may need to perform procedures sometimes without the type of volume experience one would expect and demand in more resource-rich environments, where patients have easy alternative access to skilled high-volume operators and centers.
- The availability of a senior operator to help develop and enhance the interventional skills of a junior interventional cardiologist for at least 2 to 5 years after training may not be possible in resource-limited environments. This is even more so the case as there are centers in poorer countries that have only 1 or 2 cardiologists in

total, with often only 1 cardiologist who performs cardiac catheterization procedures. In such cases, it is recommended to have a senior interventional cardiologist to be available for at least remote (virtual) consultation for complex cases. This may however not always be feasible when a remote proctor/mentor is in another country.

7. THE IDEAL PEDIATRIC AND CONGENITAL CARDIAC CATHETERIZATION LABORATORY SUITE

The PCCL suite consists of the cath lab proper (the procedure room), a control room, storage space, space to scrub, as well as ancillary space needed to support technical equipment. The PCCL is a unique environment within a hospital, requiring a sterile/semisterile space with room for a catheterization table, apparatus for x-ray imaging (fluoroscopy and angiography), hemodynamic monitoring equipment, and equipment for anesthesia delivery. Moreover, each piece of equipment ideally must function in patients ranging in size from premature infants (<1 kg) to large adults. Flexibility is needed to incorporate a host of other equipment that may be needed: vascular ultrasound, defibrillator/pacing equipment, echocardiography (transthoracic, transesophageal, or intracardiac), a radiofrequency generator, and various forms of mechanical circulatory support. This section outlines some of the requirements for layout, supply, and storage of the PCCL (Table 4).

7.1. General considerations

7.1.1. Layout and size of the pediatric and congenital cardiac catheterization laboratory

7.1.1.1. The pediatric and congenital cardiac catheterization laboratory procedure room

In his seminal textbook, Dr Charles Mullins states that the optimal size for a cardiac cath lab procedure room is 32 feet (11 m) in length and 24 feet (7.3 m) in width with 14 feet (4.3 m) high ceilings to accommodate suspension systems for the x-ray equipment.[23] These dimensions are required to accommodate the 2 fixed pieces of equipment: the catheterization table and the x-ray equipment (both, the x-ray generating equipment and the supports to allow for rotation along both left to right and cephalad to caudal axes). In current practice, catheterization lab sizes are highly variable, especially when comparing a PCCL to a laboratory predominantly used for adult coronary interventions. The 750 to 850 ft^2 (~70-80 m^2) lab described in early documents is relatively small for a PCCL, compared to some modern labs. It is similar though to the space of 800 ft^2 which was suggested for TAVR procedures.[24] Ideally, PCCL procedure rooms should have a size of 1000 ft^2 (~93 m^2) or even larger, to provide more flexibility and greater ease when conducting complex procedures, including those which require ECMO or support of the surgical team. However, local building limitations in older facilities can constrain the size and layouts of some laboratories.

An extra-long (6.5 ft or 2 m) table is necessary both to accommodate taller adult patients and also to provide enough working space for exchange-length wires, sheaths, and delivery systems. If necessary, the working length of the table can be extended with extra supports at the foot end of the table. The room should be configured to allow the lateral gantry (of a biplane setup) to be moved away from the patient to allow for access during transfer. The required room width must accommodate a table wide enough for large patients, the lateral x-ray gantry, and the capacity to rotate both planes, as well as accommodating rotational angiography, which has been identified to be helpful to guide many complex interventions in patients with CHD.[25] It also needs to have sufficient space to accommodate the anesthesia team and its equipment, the echocardiography team, and potentially the perfusion team in patients receiving mechanical circulatory support or for hybrid procedures.

Around these fixed pieces of equipment, there needs to be sufficient space in the laboratory for pressure recording equipment (including wires and connections), an extra equipment table that may be needed for hybrid or valve procedures, resuscitation cart/defibrillator, machines to analyze saturation and blood gas data, a power injector for contrast, adjustable spotlights or OR lights, and a set of electronic monitors. Important considerations also include the arrangement of ceiling or floor-mounted radiation shielding, not just for the operator but also for other staff members such as anesthesia and echo teams. To fulfill its purpose, shielding needs to be installed so that it is not cumbersome to move or utilize. Space should also be provided to store protective aprons to maximize their longevity.

Whether composed of a single large panel or an array of smaller screens, the arrangement of monitors must have sufficient screen area for fluoroscopy, review of angiograms, monitoring of hemodynamic data, and potentially other imaging (including echocardiography and overlays from tomographic sources). Additional monitors should be provided that allow the anesthesia team as well as echocardiographers to visualize images.

In addition, there must be sufficient clear space around the patient for circulating staff to operate safely and efficiently and sufficient room to allow for the patient to be safely and efficiently transported from the catheterization table to either a hospital bed or other conveyance while maintaining a flat supine position. Though not mandatory, there are several equipment modifications,

TABLE 4 Summary of Recommendations for Physical Layout and Supply of the Pediatric and Congenital Cardiac Catheterization Laboratory[a]

Catheterization lab layout	
Size	Acceptable standard: ■ The procedure room should have sufficient space (in all 3 dimensions) to allow for the table, x-ray equipment, anesthesia equipment, and adjuvant imaging equipment and personnel as well as space for circulating staff to move unencumbered. ■ Exact dimensions may vary based on the bulkiness of the equipment and the flexibility of the table and x-ray equipment to be moved, but usually require a minimum of 500 square feet (46 square meters). Ideal standard: Procedure room size being at least 1000 square feet (93 square meters).
Layout	Acceptable standard: ■ In addition to the main procedure room, space for a control room, x-ray power source, and scrub rooms.
Heating, ventilation, air conditioning	Acceptable standard: ■ Regardless of resources, the PCCL should be separated from nonprocedural areas with some consideration for air exchange and filtration. Ideal standard: ■ Operating room level ventilation and air filtration.
Considerations for multiple use	Acceptable standard: ■ When there are multiple disciplines that use the laboratory, at minimum acceptable standards should be maintained for all disciplines. ■ Careful planning is necessary to ensure different operators/services priorities do not impede optimal performance of all services using the space. Ideal standard: Ideal standards for all disciplines that will use the laboratory should be maintained.
X-ray equipment	
Biplane vs single-plane	Acceptable standard: single-plane laboratory with the ability to perform 3D rotational angiography. Ideal standard: a biplane X-ray setup allows for imaging complex congenital defects and minimization of exposure to both X-ray and contrast.[1] The availability of image overlay is desirable.
Maintenance	Acceptable standard: local biomedical technicians supported by vendors with a service contract provide appropriate routine maintenance and as-needed support for optimal performance. Ideal standard: as above but with a requirement to limit laboratory downtime to less than 48 h.
Longevity	Acceptable standard: x-ray equipment should be replaced at no less than every 10 y to reduce the risk of failure, minimize radiation, and improve image quality. Ideal standard: x-ray equipment should be replaced at least every 8 y to reduce the risk of failure, minimize radiation, and improve image quality.
Non-x-ray equipment	
Vascular ultrasound	Acceptable standard: ultrasound guidance available for selected patients if needed (with advance notice and arrangements) Ideal standard: 2-dimensional (2D) and color vascular ultrasound available and used for all patients, to reduce the risk of vascular injury and improve speed of vascular access.
Physiologic data	Acceptable standard: The following should be available: ■ Machines to measure oxygen saturation, blood gas analysis, blood glucose, and activated clotting time. ■ Transducers for recording pressures and waveforms. Ideal standard: digital setup to facilitate recording and presentation of oximetry and pressure data, documentation/storage, and sharing of potentially important data in real-time.
Echocardiography	Acceptable standard: timely access to echocardiography is necessary for emergent evaluation as well as procedural guidance.
Radiofrequency generator or other device(s) to perform tissue perforations	Acceptable standard: patients who may need this equipment are transferred to a different facility. Ideal standard: equipment should be available to facilitate perforation of tissue (such as perforation of an atretic valve.
Consumables	
Stocking	Acceptable standard: ■ Stock of consumable supplies should be maintained to match expected demand for a wide variety of procedures and to allow operators to respond to unexpected findings. ■ A complete documented inventory of consumables that may be needed for pediatric and congenital cases (including equipment shared with adults) is maintained (including PAR numbers) and stock cross-checked at least once per month.
Storage	
	Acceptable standard: ■ Regardless of the storage arrangement, a clear plan is necessary so that supplies can be accessed in a timely fashion without the need for operators to descrub during a procedure. ■ Consumables may be stored outside the lab in mobile carts dedicated for pediatric/congenital cases that can be moved in and out of the lab as needed. Ideal standard: ■ All nondevice and nonballoon equipment should be stored in carts that are located within the PCCL procedure room. ■ Most balloons are stored in carts within the PCCL procedure room. ■ All equipment and devices that may be needed for bailout are stored in carts within the PCCL procedure room.

[a]Ideal standards also include all requirements for acceptable standards that are listed.

PCCL, pediatric and congenital cardiac catheterization laboratory.

such as rotating tables and fluoroscopy machines that can make this easier and more efficient.

In many countries, PCCL procedures are commonly performed in conjunction with an anesthesiologist.[26,27] As such, there must be adequate space at the head of the table to allow for the anesthesia team and their equipment, including wall attachments for medical air, oxygen, and suction as necessary, as well as machinery for the delivery of inhalational anesthetics. In planning the space, allowances for access to the patient's neck (jugular vein access) and/or arm (radial or subclavian) from either the side or the head of the table are important. In certain circumstances, repositioning the patient in a foot-first, supine position allows for easier manipulation of catheters placed for carotid or subclavian artery access.[28-30] Space for additional imaging teams (eg, echocardiography or bronchoscopy) on the side opposite the anesthesia machine is a key consideration.

Beyond the in-room requirements, catheterization laboratories have a myriad of structural requirements, such as the need for higher ceilings and special ceiling reinforcements to accommodate the weight of the ceiling-mounted imaging equipment. In addition, walls should have lead lining, as should have the window to the control room.

7.1.1.2. The pediatric and congenital cardiac catheterization laboratory supporting rooms and space

The procedure room alone does not provide all that is needed for the functioning of the PCCL. Thus, other supporting rooms should be positioned immediately adjacent to the main cath lab room. The following key areas need to be included in the design process of any PCCL:

1. Control room: A control room adjoining the laboratory is essential. This room will need to accommodate key staff, eg, nurses and technologists who record data outputs from the case as well as provide real-time feedback to the operating physician and staff. The control room must have adequate space (ideally 200 square feet [19 square meters]) to house computers for recording hemodynamic data and storage of angiograms, reviewing the electronic medical record and a variety of imaging data, as well as ideally providing space for postprocedural documentation without having to leave the PCCL to perform those tasks. Given the variety of tasks that will need to be performed in the control room, it should ideally be separate from the cath lab, allowing the staff to review, document, and record, without lead or personal protective equipment. Uninterrupted lines of sight between the recording staff member and the procedural team at the table is an essential requirement for any PCCL. Equipment (eg, microphones and personal or room mounted speakers) may be necessary to ensure clear communication.
2. Fluoroscopy equipment support room: Modern fluoroscopy equipment requires a relatively large power supply within a temperature-controlled space to allow it to function optimally. This space requirement should not reduce the footprint required for the procedure room.
3. Scrub: Ideally, a separate scrub area outside of the cath lab should be provided for operators to scrub prior to the case without inadvertently contaminating the field or other equipment. However, it is acceptable and not uncommon for scrub sinks to be included in the catheterization lab room when there are space constraints.
4. Storage: Ready access to supplies is vital as is an efficient storage plan to accomplish that (Section 7.5).
5. Other areas: Catheterization laboratories are working environments. Sufficient space for staff (lavatories, break and touchdown space) is important if a high-functioning service and morale are to be maintained.[31]

7.1.2. HVAC

In general, the risks of PCCL procedure-related bloodstream and site infections are low,[32] especially compared to those following congenital heart surgery.[33] To our knowledge, no studies to date have evaluated the relative risk of nosocomial infection based on the ventilation systems in catheterization laboratories. However, regulations governing HVAC have been incorporated into modern infection control practice.

Air quality in a confined indoor space is measured by the following: (1) room pressurization (eg, positive pressure to prevent contamination by air from other areas), (2) number of air changes per hour (ACH) expressed in total ACH, and the volume of outside air brought in (outside ACH), (3) the air distribution, and (4) filtration measured by the minimum efficiency reporting value rating (MERV) between 1 and 20.

There is no consensus on the exact air quality requirements in the PCCL. As an example of specific recommendations, the 2006 US guidelines for adult catheterization laboratories recommend 15 ACH, of which at least 3 should be fresh air.[34] Current US standards are set by the Facility Guidelines Institute[35] which relies on HVAC design standards for facilities set by the American Society of Heating, Refrigerating, and Air-Conditioning Engineers (ASHRAE), the American Society for Healthcare Engineering (ASHE), and the American National Standards Institute (ANSI).[36] In those standards, proscriptions for "interventional imaging" areas (positive

pressure ventilation, 15 total ACH, 3 outdoor ACH, and MERV-14) are set less stringent than those for OR (positive pressure, 20 total ACH, 4 outdoor ACH, and MERV-16). While the above provides some guidance, recommendations will likely vary between countries and localities (and whether applying to new or existing equipment).

Historically, standards set for catheterization laboratories serving adults were similar to OR, but as cutdowns have been replaced by less invasive vascular access techniques, this requirement has gradually been amended. However, with more frequent implantation of transcatheter valves in the PCCL, it may be important to again more closely adapt air quality standards of the OR.[37] The room pressurization and air circulation will also be dictated to some extent by the specific location of the PCCL: if connected to (cardiac) OR, then a shared OR level ventilation system is most appropriate. Equally, hybrid PCCL will require OR standard air circulation that may not be needed for a standard PCCL. Given the lack of data supporting a clear "ideal standard," regulations and requirements will likely differ from country to country. Importantly, paying close attention to establishing appropriate air exchange, temperature control, and filtration for any PCCL is essential. In all settings, the cath lab space should have appropriate doors, which should be closed to other less sterile areas to minimize potential contamination.

7.1.3. Considerations for multiple use

The above recommendations refer to a PCCL suite exclusively used for diagnostic and interventional cardiac catheterization procedures. There are several scenarios where sharing of PCCL space with other services is needed.

A common scenario is a room in which both PCCL procedures and electrophysiology procedures are performed. A separate set of (potentially bulky) equipment and computers is necessary for diagnostic electrophysiology studies, 3D mapping, and ablation procedures, each of which occupies significant space in the procedure room as well as the control room. Less commonly, particularly in primary pediatric hospitals, the PCCL team may share a space with interventional radiology as well as perform procedures together with the cardiac surgery teams in so-called hybrid rooms (Section 7.1.4).

In all these cases, additional space and equipment are necessary. While shared-use laboratories are attractive to optimize "room utilization" and hospital revenue, it is important that adequate considerations are given to additional requirements for space, room layout and ergonomics, supporting equipment, and storage, all of which will need to be significantly up-scaled and go beyond the basic requirements of a single use PCCL.[31]

7.1.4. The hybrid pediatric and congenital cardiac catheterization laboratory

Hybrid procedures are discussed in Section 16.1. When considering a dedicated hybrid catheterization suite, there are several important design elements that are listed in this section.[38] To be considered a true hybrid PCCL, it must meet all requirements of a standard congenital cardiac cath lab, and several additional requirements:

- An additional 200 square feet (19 square meters) of procedure room footprint to that of a standard PCCL, to accommodate the additional team members and equipment required for these procedures.
- A dedicated table that can be locked securely, allows left/right tilt of at least 15° (ideally 30°), as well as head up/down to approximately 30°.
- Additional ceiling-mounted monitors for viewing fluoroscopic and other imaging modalities from all sides of the table and by all team members.
- Appropriately located gas supply to accommodate the cardiopulmonary bypass and/or ECMO circuits.
- Sufficient quantity and location of electrical power outlets to accommodate all surgical and catheter equipment.
- Easily movable storage cabinets to facilitate cleaning.
- Equipment and other booms/fixtures designed and placed to facilitate movement of staff and equipment while providing workable ergonomics for all participants to assess images promptly.
- Monolithic ceiling design (no fissures or cracks), air exchanges of OR standards, scrub sink placement outside the room, and OR-specific temperature and humidity control.
- Location preferably near cardiac surgical OR and the ICU.

7.2. X-Ray equipment

7.2.1. Single plane vs biplane

X-ray equipment remains central to the cardiac cath lab for both procedural guidance and recording of angiographic data. For PCCL procedures, biplane imaging is extremely valuable,[1,39] allowing for imaging complex anatomy in complementary projections, minimizing exposure to both ionizing radiation and contrast. Single-plane systems remain in use in general hospitals, even those with large structural and congenital programs. When capable of utilizing 3D rotational angiography, these systems may work well for many congenital cardiac catheterization cases. However, biplane imaging is the ideal standard, and in most settings, a single-plane system is usually an inferior alternative to a biplane system. This is important to consider when the congenital

catheterization suite consists of just a single laboratory. Whatever system is used, it must be able to achieve a full range of projections and coverage of the patient's entire body.

7.2.2. Output/storage/analysis

Modern angiographic data outputs should ideally be fully digital. The near-instantaneous availability of high-quality images can facilitate rapid communication with consulting or referring physicians and potentially improve efficiency. This obligates centers to invest in information technology infrastructure for data storage.[1] Remote access to these data is not available in all areas but is a potentially useful tool to facilitate communication and shared decision-making. Digital systems underscore the importance of in-lab monitors of sufficient quality for interpretation of angiographic data. Digital systems include software to facilitate rapid and accurate analysis of angiographic data (for example, digital calipers to measure vessel diameter) with many including automated systems designed to precisely measure diameters of vessels along their entire length using autocalibration features.

7.2.3. Equipment features

X-ray equipment is 1 of the major capital investments in a cath lab. Thus, it is important that x-ray equipment be sufficiently flexible to handle the entire range of patients and procedures that can be expected. Key to this is the size of the flat panel detector. Choice of optimal flat panel size will be determined by case mix (balanced of adult vs infant patients), resources, and number of rooms. Modern x-ray systems also facilitate integration of CT and MRI datasets (as well as rotational angiography) onto which live x-ray imaging may be overlain. The potential benefits of using image overlay techniques in a subset of transcatheter interventions have been well described.[40-44]

7.2.4. Maintenance

Maintenance and servicing are necessary to ensure ongoing optimal performance and to avoid unexpected outages. Service contracts with the manufacturer are important as the cost of ownership can be as much as twice the purchase price over 10 years of use.[44] Biomedical technicians or engineers working in conjunction with vendors can provide routine and additional service as needed, and ideally, servicing and testing should be performed at least once every 2 years (or more frequently if/when required by jurisdictions in states/regions/countries). However, the quality of vendor support is a key part of decision-making when purchasing an x-ray system. This is particularly true for services with no institutional support.[45]

7.2.5. Longevity

X-ray equipment regardless of maintenance has a finite lifespan. The Canadian Association of Radiologists and European Society of Radiology have endorsed life-cycles for cardiac cath lab equipment of between 8 to 12 years depending on utilization (<1500 to >3000 cases/year).[46,47] However, utilization based on case numbers alone, may not be sufficient to adequately reflect the usage within a PCCL, where case times are longer, and labs rarely accommodate much more than 500 cases per year per lab.

There is no evidence to our knowledge that PCCL procedures are more taxing on x-ray equipment than fluoroscopy in other settings. However, research and development of x-ray equipment continue to improve to provide equivalent image qualities with lower radiation exposure, which are a critical consideration in growing patients and to reduce the exposure of cath lab personnel. Research detailing accumulated radiation in PCCL patients and estimated risk of related M&M[48-52] underscore the importance of mitigating exposure. Since replacement of x-ray equipment is associated with significant reductions in radiation exposure,[53] x-ray systems should be replaced on at least a 10-year cycle (ideally an 8-year-long cycle). This is specifically important in pediatric patients who have a longer life span to manifest the secondary effects of radiation exposure (see Section 11).

7.3. Non-x-ray equipment

7.3.1. Vascular ultrasound

Small portable vascular ultrasound machines are increasingly common in PCCL suites, allowing for detailed visualization of target vessels and the ability to inspect with color flow whether there is upstream occlusion. While not a substitute for vascular access skills, use of vascular ultrasound likely improves the speed of obtaining access, improves accuracy, and potentially reduces the risk of vascular complications. As such, the use of 2-dimensional (2D) ultrasound is considered "ideal practice" for vascular access in the PCCL.[54]

7.3.2. Physiologic and laboratory data

Equipment to measure oxygen saturation, blood gas, lactate, and glucose should be available within the PCCL procedure room. This is important for the evaluation of physiology (ie, saturation run for the detection and quantification of shunts and/or calculating cardiac output) and for rapid evaluation of hemodynamic stability in potentially fragile patients in a cath lab environment. Regular upkeep of monitoring equipment should be performed in conjunction with hospital laboratory leadership. To ensure adequate anticoagulation, a machine to

measure activated clotting time (ACT) should also be available within the procedure room.

Pressure measurements are generally performed through external transducers connected to catheters via an external manifold isolating it from the sterile field. These systems require calibration prior to each case. Transduced pressure measurements and captured images of waveforms are typically recorded using a hemodynamic monitoring system with purpose-built software. Ideally, digital recording should be used to facilitate standardized reporting and calculation. Having the ability to utilize pressure wires can be beneficial to measure pressures distal to tight anatomic stenosis. Pressure wires have also been proven useful to assess the FFR in, for example, patients with an anomalous origin or course of a CA.

7.3.3. Echocardiography

Echocardiography provides real-time imaging of the heart and surrounding structures, which is a useful adjunct to fluoroscopy and an essential component for the safe conduct of many interventions. Rapid access to transthoracic echocardiography is necessary for emergent evaluation of the pericardial space and cardiac function. For echocardiography-guided procedures, a high-end ultrasound machine with an appropriate selection of probes (transthoracic and transesophageal) is required. ICE is an alternative imaging modality for some cases but is more commonly used in adult patients.

Ultimately the choice between transthoracic, intracardiac, and TEE depends on the patient (size and anatomy), procedure, and operator/institutional preference/expertise. Ideally, echocardiographic images are displayed so that both the imaging and interventional cardiology teams can see the images in real-time. In the ideal setting, images can be displayed on the main display monitor.

7.3.4. Radiofrequency generator

Devices that generate radiofrequency energy are helpful equipment for perforating tissue in some situations (eg, the atretic valve plate in pulmonary atresia with intact ventricular septum). Availability of a system (generator and accompanying wires and catheters) to deliver radiofrequency energy and exchange for conventional wires is important to perform these procedures. Other alternatives can equally be considered, such as for example dedicated wires used to recanalize chronic total occlusions.

7.3.5. Intravascular ultrasound

Developed to evaluate accumulated atherosclerotic plaques in coronary disease, IVUS has been used sporadically in PCCL to evaluate coronary arteries, such as part of surveillance after orthotopic heart transplant,[55] even though not as part of the recommended standard screening regimen.[56] IVUS has also been used to assess the vessel wall in some patients with aortic lesions, as well as a research tool to understand changes in vessel walls during and after interventions for stenoses.[57-60] While ideal to have this available in a PCCL, it is not established routine practice.

7.4. Consumable supplies

7.4.1. General considerations

To accommodate the range of patients (sizes and anatomies) and procedures, a wide range of sheaths, catheters, wires, and devices are necessary. The frequency with which each piece of equipment is used is highly variable, ranging from workhorse catheters to highly specialized equipment whose use is infrequent but vital in that specific context. Consumables vary greatly depending on the spectrum of procedures performed at a specific institution.

Within a practice, individual operators may also have preferences for specific equipment. It is important to recognize that it is not appropriate to mandate that operators use identical equipment without room for variation, given the vast range of training background operators may have at any given institution. Mandating operators to use different techniques and equipment with characteristics that vary from what they are accustomed to, may lead to suboptimal results or longer case times, and should be avoided. While equipment does not need to be manufacturer-specific, it does require that chosen alternatives have closely matched characteristics to those requested by an operator.

Given those considerations, the potential volume and supply of consumables are therefore large and complex, requiring space for storage and systems for accurate and timely reordering.

7.4.2. Approach to stock inventory

Laboratories should maintain a stock of consumable equipment to keep up with anticipated demand while at the same time limiting expiration and waste of supply as much as possible. The PAR system should be used whereby, a minimum number of each consumable product is maintained. When the inventory number drops below the PAR, more are ordered. Ideally, this ensures that both shortages and waste do not occur. Attention to changing patterns of use is necessary for this system to be effective. In addition, PAR numbers should be adjusted whenever the current level is identified as inadequate, to accommodate temporary backorder shortages of specific items. Similarly, if items frequently expire, then PAR levels will need to be adjusted, an exception being

emergency equipment that is rarely used but always needs to be available.

Inventory can be purchased prior to stocking or obtained on consignment. Consignment is especially useful for high-cost items, enabling systems to stock a larger number of the item or a greater variety of sizes than they would if they had to be purchased ahead of time. Ultimately, PCCL staff participation in this process is important to both avoid waste and ensure timely access to desired equipment. As such, in many laboratories, specific staff members (or in busy labs, dedicated full-time inventory specialists) are necessary for managing PCCL inventory.

The PCCL lab manager should maintain a detailed list of all inventories (including PAR numbers) that should always be in stock for congenital cases. For programs that share space with coronary or structural heart programs (as well as interventional radiology programs), crossover in some types of consumable equipment can, if correctly managed, reduce on-shelf inventory within an institution. However, even in those shared laboratories, a dedicated inventory list should be created for all equipment utilized for pediatric and congenital cases (including equipment shared with adult cardiology). With such a list, equipment in carts should ideally be compared to the inventory list on a regular (1-monthly) basis, to avoid equipment deficiencies only being identified during a case.

It is never acceptable that an anticipated intervention cannot be performed because it is recognized that supplies are not available during a case. Equally, a cath lab needs to be sufficiently stocked to be able to address common but unexpected findings. Having a specific inventory list makes it clear to everyone what can be relied upon to be available for a case, and any variations or backorder items need to be communicated to interventional cardiologists in advance so that no surprises are encountered during procedures.

There is some bailout equipment that must always be kept in the cardiac cath lab, and they include snares, covered stents of all sizes (and appropriate long sheaths for delivery), coils and devices for vessel occlusion when hemorrhage occurs, curved orotracheal tubes for selective bronchial intubation, chest drains, and equipment packs for pericardial drainage.

The stock-keeping of consumables is not just dependent on institutional volumes, but also heavily influenced by geographic variations, such as variable access/approval of different devices or equipment, national/regional variations in licensing, and local supply chain issues. These issues are not limited to resource-limited environments; rather, they can affect health care systems across the globe. While the best effort should be made to maintain an inventory that is not susceptible to every supply chain issue, it is not possible to completely eliminate these problems.

7.5. Storage

7.5.1. General considerations

Any plan for storage of consumable and durable equipment is inevitably a compromise between the wide range of supplies necessary for the myriad patient-procedure combinations that comprise PCCL practice and the intense competition for “real estate” in even the most spacious catheterization environments. Storage environments for PCCL equipment are specialized spaces; they should be temperature and humidity-controlled, as many items may deteriorate in suboptimal conditions and become dangerous to patients. Hanging storage as well as carton storage for items of different lengths is essential.

Establishing plans for equipment needed for common procedures in standardized lists and/or preprocedure review and discussion of specific cases can simplify this process. Unexpected findings or changes in patient condition make rapid access to the full range of available supplies an absolute necessity for safe practice. The method for providing ready access to the entire laboratory inventory will vary by center depending on available space, number of labs, their arrangement, and their schedule of use. Regardless of the arrangement, a system to ensure specific equipment can be located rapidly (and for identifying when supplies need to be replenished before they are depleted) is vital for storage to be effective.

7.5.2. In- and out-of-room storage

Inevitably, some combination of in-room, adjacent, and more distant fixed storage is necessary for almost all laboratories. However, the arrangements of these items should be done in such a way so that staff leaving the laboratory during a procedure to fetch equipment is minimized (if not eliminated altogether), in particular for emergency and bailout equipment items. Ideally, all nondevice and nonballoon equipment, all emergency equipment, and most balloons should be stored in carts located within the PCCL procedure room. In shared adult (coronary, structural) and pediatric/congenital laboratories, all equipment needed predominantly for pediatric cases should be stored in dedicated (mobile) pediatric/congenital cabinets that can be moved in and out of the shared laboratory as much as needed. Some durable equipment that is not used for all procedures (eg, echocardiography or radiofrequency generator) can be mounted on wheels and stored outside the laboratory to free up space. Similarly, mobile carts with collections of equipment for specific procedures (eg, coils for occlusion) that can be moved into a lab for certain procedure types, can

increase efficiency and avoid unnecessary opening of the cath lab doors during the procedure.

7.6. Considerations for ACHD patients

- Usually, larger detector sizes are preferable for adult patients.
- Procedure tables need to accommodate a higher weight limit than what is needed for pediatric patients.
- Standard positioning for CHD interventions using biplane angiography usually requires having arms raised above the head. Restraints are therefore needed to support the arms such that the risk of brachial plexus injury is at a minimum yet allows adequate x-ray gantry movement for proper image projections.
- Adults may require some rescue equipment more frequently than pediatric patients, such as the availability of percutaneous ventricular assist devices (eg, Impella device).
- In addition to standard equipment and supplies, nuanced items specific for ACHD interventional delivery are to be available.

7.7. Considerations for resource-limited environments

- A PCCL is an extremely expensive area within a hospital. As such, many of the recommendations made will be difficult to achieve in resource-limited environments. This applies in particular to the age of x-ray equipment, the size of the lab, storage, and available items such as monitors, extra shielding, and additional modern equipment.
- Furthermore, operators may have to utilize single-plane laboratories without access to biplane technology and may need to use alternate imaging modalities more frequently to complement x-ray imaging.
- In resource-limited environments, alternative strategies are necessary to meet the supply demands for specific cases. It often requires a greater degree of flexibility by the operator, to be using equipment that may not be the most suitable for a specific procedure, but to adapt as much as possible. In those situations, sometimes procedure times may be longer, and procedural success and outcome can be affected by limited equipment availability. Maintaining a large stock of consumables may be impossible. Operators therefore must review available equipment ahead of a case and attempt to purchase items for a specific case whenever possible. Dealing with inevitable unexpected findings or complications can be considerably more challenging in this context.
- In resource-rich settings, resterilization and reuse of catheters, sheaths, and wires are uncommon due to legislation or concerns about medico-legal culpability. However, in resource-limited environments, resterilization is a useful strategy to maintain a supply and reduce costs (such as for example resterilization of ICE probes, which is common practice in many parts of the world). In these settings, establishing protocols for quality control and monitoring is important to ensure equipment integrity, reliability, and patient safety, which also applies to the use of donated and/or expired equipment. These strategies should be guided by local experience since there is little guidance from manufacturers. Frequently, difficult decisions are necessary, balancing the need for access to certain equipment, with the need for reliability of such equipment.

8. FACILITY REQUIREMENTS

8.1. General considerations

Cardiac catheterization, whether diagnostic or interventional, is an important service line in any larger facility providing comprehensive care for pediatric patients and adults with CHD. While the pediatric and congenital cardiac cath lab is at the center of this service line, it cannot function in isolation. Rather, it requires a variety of additional core cardiac services, support services, organizational arrangements, and administrative support to provide efficient and high-quality care for this patient population.

While there are several different facility models to provide care for these patients (with each having different challenges), in order to succeed there is no single care model that is by default superior to all others. If facilities recognize potential shortcomings and make appropriate arrangements to address those challenges, then care can successfully be provided in a wide range of different facility models. Section 8.2 outlines different facility models with their inherent challenges and opportunities, while Section 8.3 discusses all requirements facilities must meet to provide a pediatric and congenital cardiac catheterization service line.

General recommendations related to facility requirements are also greatly influenced by local, regional, and national regulations that often have additional facility requirements to those listed in this section. Those additional requirements need to be accommodated in order to perform cardiac catheterization procedures in pediatric patients and adults with CHD.

8.2. Types of facilities

A variety of facilities are providing cardiac catheterization services for pediatric patients and adults with CHD:

- A children's hospital within an adult facility of a larger tertiary medical center

TABLE 5 Advantages and Challenges of Different Facility Types as They Relate to Care in the Pediatric and Congenital Cardiac Catheterization Laboratory

Facility type	Advantages	Challenges
Children's hospital within an adult facility	■ All the benefits of a free-standing children's hospital and a children's service line within an adult facility.	■ The (administrative) lines between adult and children's facility are sometimes not 100% clear. ■ If conceptionally not fully implemented and designed from the start, then some of the challenges of a children's service line within an adult facility will remain.
Children's hospital adjacent to an adult facility	■ All the benefits of a free-standing children's hospital. ■ Easier access to adult care and support when compared to a free-standing children's hospital.	■ Sometimes administrative leadership structures may result in less independence than for a free-standing children's hospital. ■ Transport of patients between facilities may be complicated if not directly connected. ■ Emergency backup and access to adult providers and services not as easy when compared to a children's service line within an adult facility.
Children's service line within an adult facility	■ All the benefits of a free-standing adult and pediatric cardiac hospital. ■ Pediatric subspecialty support is available. ■ Proximity to maternal fetal and delivery services.	■ Administrative structure usually combined with adult services. ■ Often dominated by adult services. ■ Shared leadership of common resources may not be focused on the needs of pediatric patients. ■ Pediatric cardiac services and inpatient locations usually spread out throughout the facility.
Free-standing children's hospital	■ Administrative independence allowing dedicated care for pediatric patients. ■ All pediatric cardiac and support services are available.	■ Administrative, legal, and clinical challenges in caring for adult patients. ■ Often less experience of the clinical team caring for adult patients. ■ ACHD expertise and adult support services may not be available at all, and/or may need to be arranged on a case-by-case basis. ■ Emergent access to adult support in the cath lab limited. ■ Maternal, fetal, and delivery services not on site.
Free-standing adult and pediatric cardiac hospital	■ All cardiac services are available and dedicated to pediatric and adult patients. ■ Adult patients can be cared for at the most appropriate unit. Depending on age, the cardiac procedure performed and associated medical problems were treated. ■ Continuity of care for ACHD patients. ■ Adult support services are usually available when needed. ■ Emergent access to adult support in the cath lab is available.	■ Challenges of providing noncardiac support services ■ If adult dominant, the pediatric services may not have the same pediatric independent focus that would be expected in a pure pediatric facility ■ Maternal, fetal, and delivery services not on site.

ACHD, adult congenital heart disease.

- A children's hospital adjacent to an adult facility of a larger tertiary medical center
- A children's service line within an adult facility
- A free-standing children's hospital separate from an adult facility
- A free-standing (pediatric and adult) cardiac hospital

Advantages and challenges of each of these facility types are summarized in Table 5. Beyond the clinical scope of these facilities, there is also a considerable impact based on whether these facilities are associated with an academic institution or function as pure clinical service providers. Being associated with an academic center frequently (but not always) provides a larger number of faculty caring for these patients, as academic time is considered in staffing models. Most importantly, academic centers usually have a well-developed research infrastructure, important when trying to gain access to investigational devices. While it is certainly possible to participate in larger trials even as part of a private for-profit institution not associated with an academic center, hurdles are often higher and nonacademic centers do not as frequently have the opportunity to participate in these trials. This can have a considerable impact to the patient population they serve, especially in countries like the US, where sometimes important devices remain inaccessible until device trials at other centers have been completed. A representative example is availability of the covered Cheatham-Platinum (CP) stent, which is well recognized as an important bailout device, yet was inaccessible to nontrial centers until trials were completed and the device approved.[61] In sum, access to (investigational) devices differs considerably between countries.

8.2.1. Leadership structures

The leadership of a facility that provides comprehensive pediatric cardiac care has an important role in establishing and supporting a PCCL, to allow it to meet evolving needs to perform highly complex procedures, while at the same time also being conscious of efficient resource use and compliance with regulatory requirements.

There are several important differences among facilities in the area of administrative leadership structures. By default, leadership structures in stand-alone pediatric facilities focus on pediatric patients and usually have their own administrative and financial structure.

However, given the increasing complexity of pediatric cardiac care, a dedicated focus on pediatric cardiac

patients provides additional benefits. In this context, the model of a pediatric (and/or congenital) heart center provides emphasis on a semi-independent leadership structure and ability to manage resources to the best possible benefit of patients with CHD. However, pediatric, and congenital heart centers are more difficult to establish in combined adult and pediatric facilities. Frequently, this results in general combined adult and pediatric heart centers where adult care may receive a larger number of resources when compared to the care of patients with CHD.

In general, in nongovernment-funded health care systems such as in the US, there are different administrative and financial models to support congenital cardiac catheterization programs that include both an adult and a pediatric facility:

- Children's hospital and adult hospital both operate under a common administrative and financial structure.
- Children's hospital and adult hospital have different administrations but operate under a common ownership umbrella/network.
- The hospitals have different ownership and administration.

Combined leadership structures that oversee adult and pediatric patients have an inherent danger of the needs of the adult population being prioritized over those of pediatric patients, or inadequate compromises being made as it relates to the care of pediatric patients. In facilities with a single overall administrative leadership, it is important that there is adequate pediatric representation at all levels (including the cath lab, Sections 5.1 and 5.2), to advocate for the needs of pediatric patients.

8.3. Facility requirements for the pediatric and congenital cardiac catheterization laboratory

To provide pediatric and adult congenital cardiac catheterization services, a variety of requirements need to be met. These can be differentiated by specific requirements (Section 8.3.1), as well as organizational support structures (Section 8.3.2).

8.3.1. Specific facility requirements to support the pediatric and congenital cardiac catheterization laboratory

The "Guidelines for Pediatric Cardiovascular Centers" published by the American Academy of Pediatrics in 2002 stated that apart from the team with special expertise in the care of cardiac patients,[62] there is a need for additional pediatric specialists for the overall care of patients. This statement is even more important at a time when more and more complex transcatheter interventions are performed in the PCCL, and does not just apply to subspecialty consultations, but many other facility-specific requirements important for the care in the PCCL. This section however is not intended to comment and expand on general requirements for a pediatric cardiac program or general pediatric facility requirements.

Table 6 summarizes specific facility requirements important for the PCCL separated into categories of core cardiac services, support services, facility structures and layout. Requirements for fetal interventional services are discussed in Section 16.4.

8.3.2. Organizational requirements to support the pediatric and congenital cardiac catheterization laboratory

Important organizational, departmental and divisional requirements include a formal congenital case management conference (Section 13.1), dedicated policies for surgical and ECMO backup (Section 9) and transporting premature patients and patients on ECMO support (Section 16), a radiation safety program and supervision (Section 11), a QA and QI program (Section 12), other written cath-specific policies and procedures (Section 5.4) as well as specific protocols and multidisciplinary support for rare procedures such as fetal interventions (Section 16.4, if applicable).

8.4. Considerations for ACHD patients

While it is not the purpose of this document to describe all aspects of an adult congenital cardiac program, there are important aspects that complement the recommendations in this section for pediatric patients.

8.4.1. Facility types and collaboration

Adequate infrastructure and facilities are required to properly perform ACHD interventions. The center, collectively, should not only have the experience and expertise to perform these catheterizations but also handle comorbidities and acquired cardiac disease.

The location of a catheterization suite that treats ACHD patients can be in 1 of several facility types:

- ACHD catheterization suite located within a free-standing children's hospital, collaborating with specialists from an adult hospital.
- ACHD catheterization suite located within an adult hospital, collaborating with specialists from a pediatric hospital.
- ACHD catheterization suite located in a center where the children's hospital is incorporated into a larger adult and pediatric medical facility ("hospital within a hospital").

In addition, the way that the ACHD and pediatric teams collaborate may vary depending on individual facility arrangements:

TABLE 6 Summary of Specific Facility Requirements that are Important for the Pediatric and Congenital Cardiac Catheterization Laboratory

	Acceptable standard	Ideal standard
Core Cardiac Services		
PCCL	■ See also Section 7 ■ Shared with adult noncongenital patients ■ A team that may also perform general adult procedures but meets minimum experience requirements (Section 5.5) ■ 24/7 coverage for emergency procedures	■ See also Section 7 ■ edicated to treating pediatric patients and adult patients with CHD ■ Dedicated congenital team
Echo	■ Section 7	■ Section 7
Electrophysiology	■ Outside EP attending available for remote consultation	■ EP attending as a faculty member
Cardiac surgery	■ Section 9	■ Section 9
Anesthesia	■ Section 10	■ Section 10
ECMO	■ Section 9	■ Section 9
Critical care	■ General PICU ■ Faculty and nursing with experience caring for cardiac patients	■ Dedicated cardiac PICU
Neonatal care	■ General neonatal intensive care unit ■ Faculty and nursing with experience caring for cardiac patients	■ Dedicated cardiac nursing and physician team, separate from the general NICU team
PACU	■ General PACU where some staff have pediatric experience	■ Dedicated PACU that cares for pediatric patients ■ Staff with experience looking after patients with CHD
Telemetry beds	■ Available only within PICU	■ Available outside PICU
Noncardiac support services		
Transfusion	■ Blood can be provided but timely cross-matching may require obtaining blood samples preprocedure ■ Emergency non-X-matched blood availability if/when requested	■ Dedicated blood bank protocol that allows cross-matching of blood within 1 h of receiving a sample (in a patient without antibodies) ■ Emergency non-X-matched blood availability if/when requested
Laboratory services	■ Shared adult and pediatric laboratory ■ Appropriately sized sample tubes available for all patient sizes	■ Dedicated pediatric laboratory ■ Appropriately sized sample tubes available for all patient sizes
Radiology	■ On-site availability of cardiac MRI and CT for pediatric patients ■ Imaging reads provided by a radiologist without dedicated pediatric cardiac training ■ Ability to obtain imaging review by a pediatric cardiac specialist at an outside institution if/when needed	■ 24/7 on-site availability of cardiac MRI and CT for pediatric patients ■ Imaging reads are provided by a dedicated on-site axial imaging expert with training and experience in CHD
Consulting services available 24/7	On site (24/7): ■ General pediatrics Off-site (available within 24 h): ■ Pediatric surgery ■ ENT ■ Hematology ■ (Interventional) radiology ■ Neurology and neurosurgery ■ Vascular surgery	On site (24/7): ■ General pediatrics ■ Pediatric surgery ■ ENT ■ Hematology ■ (Interventional) radiology ■ Neurology and neurosurgery Off-site (available within 24 h) ■ Vascular surgery
Other services	■ (Biomedical) engineering ■ Facility management and cleaning services ■ Information technology ■ Pharmacy ■ Respiratory therapy	■ All services listed under acceptable standard, plus: ■ Child life/play specialists ■ Social worker ■ Physical therapy
Structure and layout		
	■ Cath lab, cardiac OR, PACU, PICU, and NICU, all available but may be distributed over a larger facility ■ Specific workflows and protocols are established on how to transport patients between units that are not in proximity	■ Cath lab, cardiac OR, PACU, PICU, and NICU, all in close proximity and ideally on the same level

CHD, congenital heart disease; ECMO, extracorporeal membrane oxygenation; ENT, ears, nose, and throat; EP, electrophysiology; NICU, neonatal intensive care unit; OR, operating room; PACU, postanesthesia care unit; PCCL, pediatric and congenital cardiac catheterization laboratory; PICU, pediatric intensive care unit.

- ACHD multidisciplinary team housed primarily within a children's hospital collaborating with adult cardiologists and adult consultants.
- ACHD multidisciplinary team housed primarily within an adult hospital collaborating with pediatric specialists.
- ACHD multidisciplinary team housed in a single institution (such as for example a pediatric/adult heart institute).

8.4.2. Multidisciplinary team

An ACHD team is a diverse multispecialty group of care providers and administrators devoted to providing high-quality care to patients with ACHD, including invasive cardiovascular procedures. This heart team may consist of ACHD cardiologists, pediatric interventional cardiologists, ACHD interventional cardiologists, congenital cardiothoracic surgeons, cath lab nursing, RT and RCIS, cardiac anesthesiologist, critical care cardiologists, CHD imaging physicians (TTE, TEE, MRI, CT), ACHD administrator and ACHD interventional trainees.

The entire ACHD care team should have ACHD expertise in their respective disciplines and be knowledgeable about native and postprocedural anatomy, pathophysiology, cardiovascular hemodynamics, natural history, treatment options and techniques as well as possible complications related to these patients. This group should work harmoniously with a common focus on patient-centered care and ACHD program development. This team should be capable of delivering quality care at both children's and adult hospitals if patients require transfer between the facilities.

Accreditation (or its international equivalent) ensures that a program provides the highest standard of care for ACHD patients and is strongly encouraged for centers that provide ACHD interventional cardiac catheterization care. As an example, within the US, the Adult Congenital Heart Association oversees this process, providing specific criteria that must be met to be accredited as an ACHD program.

8.4.3. Other facility requirements for ACHD patients

A well-functioning ACHD program requires multiple areas for clinical work. Important cath-specific areas include inpatient bed space for those requiring admission, especially for those requiring critical care. For these procedures, areas within the hospital for periprocedural admission and postprocedural care need to be structured to accommodate this patient population, which includes areas to provide critical care. Whether ACHD patients are admitted to a pediatric or adult facility depends on factors such as country and regional specific legal requirements, as well as a center's level of expertise, experience with a specific procedure to be performed, or at times patient preference. Centers should maintain a minimum of procedural volumes to maintain overall competency and level of expertise in ACHD care delivery (Section 6.4).

8.4.4. ACHD institutional support

Institutional support is critical to the success of any ACHD interventional program and ACHD center. ACHD centers require sufficient resources to properly care for a patient population that is relatively small when compared to other specialties such as adult cardiology. The ACHD care team is sizable. Members of the team may spend significant time devoted to ACHD patient care, time which may be reimbursed poorly. Even still, their contributions to management of ACHD patients are necessary for a functioning ACHD interventional program and that work needs to be properly supported. In this context, it is important that institutions support ACHD accreditation (or equivalent) in countries where such a pathway is available, as it signifies that a program meets all the staffing and process needs to provide comprehensive ACHD care, including an ACHD cardiac catheterization program.

8.5. Considerations for resource-limited environments

- In resource-limited environments, a large general hospital serving a major city or region usually functions both as a tertiary specialist center and to some degree as a community hospital. Such hospitals provide both adult and pediatric inpatient services through a broad range of specialist and subspecialist services.
- Basic acceptable facility requirements may be difficult to meet in resource-limited environments. As such, prioritization for the most fundamental components of the service must be made (OR, PCCL, ICU, imaging).
- Given that facilities often must operate with older equipment in all aspects of care, it becomes even more important that an emphasis is placed on preventive maintenance of equipment, an aspect that is often overlooked in such an environment.[63]

9. SURGICAL BACKUP AND CIRCULATORY SUPPORT

9.1. Introduction and background

Life-threatening AE occur in about 2% of cardiac catheterization procedures; thus, in some cases, survival of a patient depends on availability of surgical backup and/or circulatory support such as ECMO.[64]

Data on the frequency of urgent ECMO or surgery due to an AE during cardiac catheterization are scarce and mostly limited to single-institution data.[65] The congenital cardiac catheterization project on outcomes (C3PO) reported life-threatening AE (level 4/5) occurring at an

incidence of 2.1%, with 9% of them requiring ECMO support.[64] More recent data from the C3PO registry evaluated the outcome of 268 cases that underwent cardiac catheterization and encountered either a traumatic AE (vascular/cardiac trauma) or technical AE (device/stent/coil embolization/migration).[66] For vascular/cardiac trauma, ECMO was required in 9%, surgery in 20%, and death occurred in 10%. For technical AE, ECMO was required in 2%, surgery in 13%, and death occurred in 2%. For those that required surgery, almost 40% were performed in the cath lab and survival was 68% for cardiac/vascular trauma and 96% for technical AE. Catheter-based interventions, when done within 30 days of cardiac surgery, were associated with a significantly higher incidence of a need for ECMO, surgery, or death after cardiac/vascular trauma. No patient died or required ECMO after coil/device embolization/migration.

9.1.1. Surgical backup vs extracorporeal membrane oxygenation backup

It is important to recognize that backup with ECMO, without also having cardiac surgical backup availability, is rarely appropriate for any procedure. As such, the need for ECMO backup cannot be looked at in isolation. While isolated circulatory support/ECMO may be needed for hemodynamic compromise, many of these same procedures also carry risks of traumatic cardiac or vascular injury that require surgical backup. Furthermore, where cardiac surgical backup is provided, by default it also allows backup with circulatory support if and when needed. While an active ECMO program may allow the cardiac team to be more selective in choosing the type of backup in hemodynamic emergencies, it does not obliviate the need for surgical backup.

For the purpose of this section though, surgical backup focuses on cases that may require surgical repair of trauma and/or device retrieval, while circulatory support/ECMO focuses on cases that may require hemodynamic or oxygenation support.

9.1.2. Surgical backup: Existing recommendations

The 2012 Expert Consensus Document on Cardiac Catheterization Laboratory Standards stated that "Certain therapeutic procedures should still be done only in facilities with cardiovascular surgical backup. These include therapeutic procedures in ACHD and pediatrics."[1] This falls in line with recommendations that are used for accreditations of congenital cardiac catheterization laboratories. The Intersocietal Accreditation Commission (IAC) Standards and Guidelines for Cardiovascular Catheterization Accreditation recommended that "Cardiovascular catheterization procedures on pediatric patients, as well as patients of any age with complex congenital heart defects, should only be performed at centers with experienced cardiovascular surgical staff" and "Centers performing pediatric cardiovascular catheterization should have … an on-site pediatric cardiac surgery program."[67]

Limited specific recommendations have been made for certain procedure types. In 2011, an American Heart Association (AHA) Scientific Statement on the "Indications for Cardiac Catheterization and Intervention in Pediatric Cardiac Disease" recommended the availability of surgical backup for septostomy procedures but emphasized that the standby of an OR was not necessarily required,[68] and in standard practice, most septostomy procedures are performed without surgical backup necessarily being present on campus during the procedure. The WC also recommended that device implantations should only be performed at centers where surgical backup is available.

9.1.3. Extracorporeal membrane oxygenation backup: Existing recommendations

Data on the need for circulatory support/ECMO backup is even more limited. The 2012 expert consensus statement mentioned only that there "should be access to ECMO,"[1] while the IAC standards stated that "The pediatric cardiovascular cath lab should have access to rescue ECMO," without providing a clear definition of what is considered rescue ECMO in this context.[67]

It is important to emphasize that an established ECMO program is not necessarily a requirement for backup if circulatory support using cardiopulmonary bypass can be provided within the recommended time period.

9.2. Backup categories by urgency

Depending on the potential urgency to mitigate an AE, there are different categories of surgical backup and circulatory support that can be provided:

Surgical backup categories (which include circulatory support):

- Standby: The surgical team is present within the cath lab to render surgical support immediately.
- Rescue: Surgical backup is available on site and can be provided rapidly with an expected time to incision within <15 minutes.
- Deferred: A surgeon may be off campus or scrubbed in a different procedure but is available so that a surgical incision can be made within 1 hour of activation.
- No backup: Surgical backup is not available.

Circulatory support categories:

- Standby: Expectation of establishing circulatory support/ECMO flow in <10 minutes from activation and/or ECMO team on standby in the cath lab.
- Rescue: Expectation of establishing circulatory support/ECMO flow on average in <30 minutes and in no more than 1 hour from activation.

- Deferred: Expectation of establishing circulatory support/ECMO flow within 1 to 3 hours from activation.
- No backup: ECMO backup or circulatory support is not available.

In addition to the above categories for circulatory support, it is important to consider planned preprocedural ECMO or circulatory support prior to any intervention for higher-risk cases.

9.3. Extracorporeal membrane oxygenation/circulatory backup recommendations

A variety of operator, patient and procedure-related factors need to be considered for deciding the availability requirements for circulatory support/ECMO backup, such as age, weight, hemodynamic vulnerability (as defined in the Catheterization for Congenital *Heart* Disease Adjustment for Risk Method [CHARM][69]), preprocedure risk scores, previous cardiac surgery (and the timing thereof), single ventricle vs 2-ventricle anatomy, presence of a shunt, associated genetic conditions, and the type of intervention and the most likely expected AE.

A list of acceptable and ideal ECMO/circulatory support availability requirements in relation to procedure and patient-specific characteristics are listed in **Tables 7 and 8**,[70] with rescue ECMO/circulatory support being the ideal backup for most pediatric and adult congenital cardiac catheterization procedures.

ECMO standby or extracorporeal cardiopulmonary resuscitation is usually not required for a successful outcome after an AE, and decisions about its availability should be made on a case-by-case basis. Potential examples where such immediate support may be considered include cases where the anatomy may prohibit effective CPR if an AE were to occur. Whenever such a higher-risk case is identified, then a multidisciplinary discussion should take place among all relevant teams (cardiology, critical care, anesthesia, ECMO team including the cardiac surgeon and cath lab team), to decide whether ECMO should be initiated prior to the procedure, whether a prepared circuit and the full team are present during the critical components of the procedure, or whether a prepared ECMO circuit is to be brought on site once the team is activated. Examples of higher-risk patient-specific characteristics that should prompt consideration of ECMO backup include severely depressed ventricular function, CA abnormalities, critical AS, biventricular obstructions, severe pulmonary hypertension, and Williams-Beuren syndrome, as well as patients with potentially challenging vascular access for ECMO.

TABLE 7 Procedure-Specific ECMO/Circulatory Support Backup Availability Requirements

	Circulatory support availability	
Procedure	**Acceptable**	**Ideal**
Diagnostic procedures (elective)	Deferred	Rescue
Biopsy with coronary angiography	Deferred	Rescue
Standard septostomy in TGA (not HLHS)	Deferred	Rescue
Other atrial septal intervention	Deferred	Rescue
Aortic/pulmonary valvuloplasty (not critical)	Deferred	Rescue
Aortic/pulmonary valvuloplasty (on PGE)	Deferred	Rescue
Perforation of the pulmonary valve	Deferred	Rescue
Stent or balloon: patent arterial duct, shunt	Deferred	Rescue
Device or coil closure	Deferred	Rescue
Balloon angioplasty and/or stent	Deferred	Rescue
Pulmonary valve implantation	Deferred	Rescue

HLHS, hypoplastic left heart syndrome; PGE, prostaglandin; TGA, transposition of the great arteries.

TABLE 8 Patient-Specific Requirements That Impact the Need for ECMO/Circulatory Support and Override Procedure-Specific Considerations

	Circulatory support availability	
Characteristic	**Acceptable**	**Ideal**
Higher preprocedural risk based on a composite score (catheterization risk score in pediatrics [CRISP]) ≥ 10, rCRISP ≥ 10, C3PO precase cardiac status = 3, C3PO estimated hemodynamic vulnerability ≥ 2, American Society of Anesthesiology score ≥ 4)	Rescue	Rescue with ability to prearrange standby for selected cases
A single physiologic parameter that may increase procedural risk above and beyond what is reflected in composite scoring (such as severe pulmonary hypertension, very high LVEDP, etc.)	Rescue	Rescue with ability to prearrange standby for selected cases
Procedural Risk in Congenital Cardiac Catheterization (PREDIC3T) risk category 4 or 5[70]	Rescue	Rescue with ability to prearrange standby for selected cases
Conditions where standard CPR may be less effective (case-by case decisions need to be made): ■ Pulmonary atresia with intact ventricular septum with suspected coronary anomalies ■ Williams-Beuren syndrome ■ Suspicion for high-risk coronary lesion ■ Biventricular outflow tract obstruction ■ Selected shunt/duct-dependent pulmonary circulations	Deferred with ability to prearrange rescue for selected cases	Rescue with ability to prearrange standby for selected cases
Salvage procedures (irrespective of other considerations)	No backup	NA
A patient is not expected to have any possibility of treatment being offered that includes ECMO backup within the geographical area due to resource limitations or transfer being too risky for the patient (irrespective of other considerations)	No backup	NA
Patient weight <1.5 kg	No backup	NA

C3PO, congenital cardiac catheterization project on outcomes; CPR, cardiopulmonary rescucitation; ECMO, extracorporeal membrane oxygenation; LVEDP, left ventricular end-diastolic pressure; NA, not applicable; PA-IVS, pulmonary atresia with intact ventricular septum.

9.4. Surgical backup

9.4.1. General recommendations

As is the case with ECMO backup, a variety of factors need to be considered when assessing the need for surgical backup. Beyond general patient- and procedure-specific factors, consideration should be given to how easily and how effectively an injury can be temporarily controlled by interventional methods while awaiting surgical backup. A traumatic injury of the aorta is much more difficult to control due to high aortic pressures, than an injury to a systemic vein. Management of an injury to the pulmonary artery is often complicated both by blood loss and gas exchange abnormalities that accompany pulmonary hemorrhage. As such, when the ability to control or stabilize a catheter-related complication is limited, then the availability of immediate surgical backup is strongly recommended. A specific list of acceptable and ideal surgical availability requirements in relation to procedure and patient-specific characteristics are listed in **Tables 9 and 10**.

While surgical backup is important and potentially lifesaving, it is clearly not feasible for a surgeon and the surgical team to put all other tasks on hold when cardiac catheterization procedures are performed. Consequently, specific arrangements should be made in advance with the surgical team, to guarantee availability of the required backup. It also requires that direct communication between the cath lab team and the surgical team occur before a patient is called into the cath lab and that the surgeon's availability is confirmed prior to performing the most critical procedural components. Ideally, a procedure with a higher preprocedure risk should be scheduled earlier in the day to guarantee in-house surgical backup. It should be clear which surgeon will provide backup once availability is affirmed. For surgeons performing surgical procedures at the same time, this may entail coordinating the timing of the procedures and potentially assigning team members that could commence the initial stages of a required surgical backup.

For some patients, surgical intervention may not be feasible, despite potentially life-threatening AE. For example, surgical options are limited if a device embolizes or a traumatic rupture occurs during PDA closure performed in patients <1.5 kg. Patients with previous surgical interventions pose another challenge due to the need to enter the chest through the scarred mediastinum, especially if the injured structure is located posteriorly in the mediastinum.

Finally, some cardiac catheterization procedures are performed as a last resort salvage procedure in patients deemed not to be candidates for any surgical intervention if AE occur. Obviously, adequate discussion with parents and documentation thereof is required for those cases.

TABLE 9 Surgical Backup Availability Requirements

	Surgical availability	
Procedure	**Acceptable**	**Ideal**
Diagnostic procedures	No backup	Rescue
Biopsy with coronary angiography	No backup	Rescue
Standard septostomy	No backup	Rescue
Other atrial septal intervention	Rescue	Rescue
Aortic/pulmonary valvuloplasty (not critical)	No backup	Rescue
Aortic/pulmonary valvuloplasty (on prostin)	Rescue	Rescue
RF perforation of the pulmonary valve	Rescue	Rescue
Stent or balloon: patent ductus arteriosus shunt	Rescue	Rescue
Device or coil closure	Deferred, consider no backup in selected cases	Rescue
Balloon angioplasty and/or stent		
Pulmonary artery/RVOT	Rescue	Rescue
Aorta	Rescue	Rescue
Vein	Deferred	Rescue
Other artery	Rescue	Rescue
TPVI	Rescue	Rescue

RF, radiofrequency; RVOT, right ventricular outflow tract; TPVI, transcatheter pulmonary valve implantation.

9.4.2. Surgical operator

It is beyond the scope of this section to specify surgical training requirements and experience needed to perform specific congenital cardiac surgical (rescue) procedures. However, there are some uniform and generalizable minimum requirements that should be met for a surgeon to provide surgical backup for a cardiac catheterization procedure.

TABLE 10 Patient-Specific Requirements That Impact the Need for Surgical Backup and Override Procedure-Specific Considerations

	Surgical availability	
Characteristic	**Acceptable**	**Ideal**
Presence of high-risk lesions: Williams-Beuren syndrome	Deferred, with ability to prearrange rescue for selected cases	Rescue
Suspicion for high-risk coronary lesion		
Surgery within the past 30 d	Rescue	Rescue
Salvage procedures (irrespective of other considerations)	No backup	NA
A patient is not expected to have any possibility of treatment being offered that includes surgical backup within the geographical area due to resource limitations or transfer being too risky for the patient (irrespective of other considerations)	No backup	NA
Patient weight <1.5 kg	No backup	NA

NA, not applicable.

Acceptable standard: The surgeon who provides backup for a specific case should have documented recent experience (<12 months) in performing a surgical procedure with all the following characteristics:

- The same type of surgery that may be needed to aid with a possible AE in the cath lab
- A similar size of patient
- A similar overall anatomy related to the type of (palliated) congenital heart defect
- A similar status of previous cardiac surgeries (unoperated chest vs previous cardiac surgical procedures)

Ideal standard: The ideal standard for primary surgical backup for all pediatric and adult congenital cardiac catheterizations is to have a congenital heart surgeon as the primary backup for all cases.

9.5. Preparedness, activation, and other logistics

9.5.1. Backup activation

A formal protocol should describe how surgical and/or ECMO backup is activated. This protocol should be reiterated in the preprocedure "time out" and/or the preprocedure huddle, for higher-risk cases. Given the multiple tasks required in an emergency, the entire activation process should ideally be initiated by a single designated cath lab team member (and ideally being a 1-step/1-call process). The contact information for this individual (such as phone or pager number) should be posted and clearly visible in the cardiac cath lab. All potentially necessary staff for an emergent situation should ideally be able to be contacted through a single activation method. If that is not possible, an acceptable minimum requirement is to have a regularly updated list of all emergency numbers posted and clearly visible in the control room. This list also needs to be applicable after hours; alternatively, there needs to be specific numbers listed for after-hour support activation. A call for emergency backup should never be a surprise to an unprepared team. Clear communication between the teams is essential.

9.5.2. Backup location

If a patient can be sufficiently stabilized, in most circumstances a transfer to the specialized cardiothoracic OR is preferable to performing a procedure in a cath lab environment. In some cases, this may require initiation of ECMO support in the cath lab prior to transfer to the OR. Other aspects to consider are the availability of a hybrid cath lab, the availability of a free OR, the potential length and complexity of the surgical procedure, the feasibility of running a cardiopulmonary bypass circuit within the cath lab, and the availability of other items such as heat exchangers, bed warmers, and cell saver units.

9.5.3. Equipment

Written protocols need to be established by each institution delineating the type of equipment required and its storage location in the cath lab for surgical and ECMO backup. The surgical and ECMO teams need to be aware of the equipment they are expected to provide when activated, as opposed to equipment that is readily available within the cardiac cath lab.

9.5.4. Training

Providing surgical and ECMO backup in a cardiac cath lab is complicated. The footprint of a standard (nonhybrid) cath lab is often less than 500 ft^2 (46 m^2), and there is limited room for multiple teams to work. Therefore, institutions should work out the logistics and ergonomics for their constrained space and team structure. Simulation of the entire process from initiation to completion and transfer of the patient is the ideal method to identify and correct workflow problems in advance.

9.6. Considerations for ACHD patients

During ACHD catheterizations and interventions, hemodynamic compromise can occur as a result of multiple etiologies. Patients who have pre-existing hemodynamic dysfunction are at particular risk. Resuscitative regimens should include mechanical circulatory support devices including percutaneous ventricular assist devices. ECMO is the most utilized system in this setting. Circulatory support should be available, with a perfusion team, 24 hours a day, 7 days a week.

Other recommendations made for surgical and ECMO backup in this section also apply to adult congenital patients. The femoral vessels are usually the site for cannulation in adults. When there has been prior arterial and venous access, the patency of these vessels should be confirmed prior to interventions, and appropriate alternative sites/plans developed in case circulatory support is required. Percutaneous ventricular assist devices (eg, Impella device) may also be used in certain settings.

9.7. Considerations for resource-limited environments

- Surgical and circulatory support/ECMO backup becomes even more complicated in resource-limited environments. In settings devoid of surgical expertise, interventional procedures may be the only treatment that can be offered. This may result in the dilemma of either not performing a procedure at all (without any other alternative to the patient who then is exposed to the sequelae of the underlying condition) or performing a procedure without surgical backup.
- It is important to acknowledge that the cost of creating and maintaining an ECMO service with the ready availability of blood and blood products may be prohibitive in most cardiac centers performing pediatric

TABLE 11 Ideal Setup Arrangement for Facilities in Resource-Limited Environments Performing Cases Without On-Site ECMO/Circulatory Support and/or Surgical Backup[a]

■ Appropriate inventory of interventional and rescue equipment
■ Meticulous clinical and angiographic selection criteria for procedures performed without surgical and/or circulatory support/ECMO backup
■ Ideally, participation in a multicenter data registry
■ Informed consent to include full disclosure that a procedure will be performed without on-site surgical/circulatory support/ECMO backup
■ Experienced anesthesia, nursing, and technical laboratory staff that is comfortable treating acutely ill patients with hemodynamic and electrical instability
■ A critical care unit and team that has experience managing critically ill cardiac patients
■ Interventional procedures should be performed by experienced operators who understand the procedure and associated risks

[a]Adapted and modified from the 2012 cath lab standards document.[1]

and adult congenital interventions in developing countries. However, circulatory support as a backup using standard cardiopulmonary bypass should be considered for selected cases in centers that have an active cardiac surgical program.

- Despite these limitations, there are many policies and procedures that can be put into place to aid the outcome of cases that are performed without ECMO or surgical backup in resource-limited environments (Table 11). While these may not all be feasible in resource-limited environments, they serve as a guide to which resources should ideally be in place when performing cases without surgical or circulatory support/ECMO backup. Particularly important is the presence of experienced operators (and, where needed, multiple operators) who understand the procedure, the associated risks, availability of resuscitation equipment, and critical care backup. Appropriate tracking and review of AE in those settings is important.

10. ANESTHESIA AND SEDATION

Just as cardiac catheterizations for CHD have evolved from diagnostic procedures to primarily interventional procedures over the past 50 years, so too has the need for sedation and analgesia during these procedures. Historically, many interventional cardiologists were directing the sedation, which often consisted of an intramuscular injection of meperidine, chlorpromazine, and promethazine in the precatheterization area for infants and children.[71] As procedures became longer and more complex, the need for deep sedation and anesthesia increased, and deep sedation or GA began to be performed in most cases. Between 2007 and 2010, 69% of congenital cardiac catheterization cases in select United States centers began with an artificial airway.[72] Consensus guidelines for sedation and anesthesia in the congenital cardiac cath lab, however, were not published until 2016.[73]

10.1. Types of sedation in the congenital catheterization laboratory

The American Society of Anesthesiologists defined levels of sedation and analgesia along a continuum from minimal sedation to GA (Table 12).[74]

Most neonates, infants, and young children, as well as anyone with psychological or behavioral limitations, may benefit from deep sedation or GA to facilitate successful performance of hemodynamic and interventional cardiac catheterization procedures. However, when the indication for intervention relies on catheter-based valvar gradients, Glenn/Fontan evaluation, or duct-dependent systemic blood flow that is significantly affected by the level of sedation (such as for balloon aortic valvuloplasty), minimal sedation with a local anesthetic may be desired for the diagnostic portion of the procedure and can be attempted as tolerated. Minimal (anxiolysis) to moderate sedation may also be appropriate routinely for older more cooperative patients, depending on level of risk of the patient and procedure. The use of spontaneous respiration as an airway management strategy in low-risk procedures in low-risk patients has been shown to be safe and effective with a very low risk of AE.[72] GA may be necessary during long procedures to facilitate patient comfort when the movement of the patient could interfere with the procedure, such as during accurate stent placement.

TABLE 12 Continuum of Depth of Sedation: Definition of General Anesthesia and Levels of Sedation/Analgesia[74]

	Minimal sedation (Anxiolysis)	Moderate sedation/analgesia (conscious sedation)	Deep sedation/analgesia	General anesthesia
Responsiveness	Normal response to verbal stimulation	Purposeful[a] response to verbal or tactile stimulation	Purposeful response after repeated or painful stimulation	Unarousable, even with painful stimulus
Airway	Unaffected	No intervention required	Intervention may be required	Intervention often required
Spontaneous ventilation	Unaffected	Adequate	May be inadequate	Frequently inadequate
Cardiovascular function	Unaffected	Usually maintained	Usually maintained	May be impaired

[a]Reflex withdrawal from a painful stimulus is not considered a purposeful response.

TABLE 13 Patient- and Procedure-Related Characteristics That Pose a Higher Risk Related to Sedation and/or Anesthesia in Pediatric Patients

■ Neonates undergoing patent ductus arteriosus stent implantation[a]
■ Neonates with single ventricle physiology[a]
■ Neonates with left-sided atrioventricular valve hypoplasia or atresia with a restrictive atrial septum undergoing balloon atrial septostomy or stent placement[a]
■ Patients with severely calcified and stenotic right ventricular-to-pulmonary artery conduits who are undergoing conduit rehabilitation[a]
■ Patients with severely depressed systemic ventricular function
■ Patients with compromised CA perfusion issues
■ Patients with severe pulmonary arterial hypertension

[a]These patients may benefit from an artificial airway.

An artificial airway is recommended for selected high-risk patients and high-risk procedures, as these patients are more likely to suffer serious AE for which airway management is often necessary to manage the event. Patient safety should be the primary consideration when formulating a sedation or anesthetic plan. However, this plan should be discussed in advance between the anesthetic and interventional teams, particularly for complex patients. Secondary factors that should be considered and discussed between teams include the degree of patient movement that is acceptable, patient comfort, and the effect of the medications and airway management strategy on hemodynamics and blood gases. **Table 13** lists patients at increased risk of anesthetic complications. Therefore, the risk associated with GA should be assessed in the context of the ability to convert a sedation plan to GA given the ready availability of an anesthesia provider (standby). Provided that care is rendered by an experienced anesthesiologist (or in some circumstances/jurisdictions, an intensive care physician), the pathophysiology of the patient should be the deciding factor as to whether GA is utilized or is better avoided. Even in those higher-risk patients, modern anesthetic regimens can be conducted in such a way, by an experienced practitioner, that the effects on hemodynamics can be minimal, even in the sickest of infants and children.

10.2. Staffing and training requirements

Staffing and training requirements for anesthesia care vary throughout the world. As such, it will be difficult to provide specific training and staffing requirements to directly manage or supervise sedation and anesthesia during pediatric cardiac catheterization procedures. As an example, the American Society of Anesthesiologists states that a nurse trained and credentialed in procedural sedation can provide minimal sedation (anxiolysis) to moderate sedation, under the supervision of an interventional cardiologist.[74] Deep sedation should be administered or supervised by an anesthesiologist or intensivist, whereas GA should be administered or supervised by an anesthesiologist. In addition, intensivists often administer drugs at dosages that constitute general anesthesia.

Similarly, the involvement and independence of certified registered nurse anesthetists (CRNA in the US, or similar professional titles in other countries) varies throughout the world. These staff members can play an important role in managing sedation and anesthesia. Their scope of practice is usually regulated by national and regional guidelines.

The most common models for managing anesthesia and sedation for pediatric cardiac catheterization can be grossly divided into 3 different categories:

- OMS
- Pediatric anesthesiologist without dedicated cardiac training (or equivalent)
- Dedicated pediatric cardiac anesthesiologist

An attempt to provide a generalizable (global) guideline for staffing requirements to supervise anesthesia and sedation, without providing job titles and qualifications that may be country-specific, is listed in **Table 14**.

10.2.1. Operator-managed sedation

OMS has historically been used for many cardiac catheterization procedures in pediatric patients. It is still used today, even in larger centers in developed countries, in part because there is frequently a shortage of dedicated pediatric cardiac anesthesiologists available for all cases. There has been some concern that liberal use of OMS could impact patient safety if not managed and supervised appropriately; thus, attempts have been made in some countries to provide guidelines for this practice.

As one example to address these concerns, consensus guidelines (written in 2016 by representatives of US cardiology and anesthesia societies) guide the use of GA and OMS. They identify qualified individuals to provide sedation/anesthesia based on risk stratification using Catheterization Risk Score for Pediatrics (Section 13.2.2). The guidelines recommend that cases with CRISP scores

TABLE 14 Staffing Requirements for Supervision of Sedation and/or Anesthesia During Pediatric Cardiac Catheterization Procedures

Acceptable standard	Pediatric anesthesiologist without dedicated cardiac training (or equivalent): ■ The anesthesiologist should have some experience in managing pediatric cardiac catheterization cases.
	Operator-managed sedation (OMS): ■ The operator will need appropriate training and experience to supervise the level of sedation and its possible associated AE. ■ Having critical care experience is recommended. ■ The operator will need to have immediate access to emergency anesthesia backup if specific sedation-related complications or AE or airway management difficulties are encountered. ■ The operator will need to be supported by an experienced nursing staff member or other qualified individual who can manage the sedation and monitor the patient, to allow the operator to focus on the interventional procedure. This individual should ideally be present in addition to the regular staff in the cath lab. ■ The case selection should ideally be limited to lower-risk cases in hemodynamically stable patients, in particular, if the operator does not have pediatric and/or adult critical care experience.
Ideal standard	Dedicated pediatric cardiac anesthesiologist: ■ Should have either formal training or extensive experience managing pediatric patients with CHD. ■ Spends at least 50% of his/her work on providing anesthesia care to pediatric cardiac patients.

AE, adverse event; CHD, congenital heart disease.

≥ 2 be staffed, at a minimum, by an anesthesiologist with special expertise in CHD, and cases with CRISP scores ≥ 5 involve a pediatric cardiac anesthesiologist.[73]

However, it is important to emphasize that OMS does not necessarily mean that sedation is provided with a lesser safety margin. In many cases, the care may be provided with equal safety but better efficiency when compared to care provided by a dedicated pediatric cardiac anesthesiologist.[26,75] Determining whether a patient is suitable for OMS purely based on a numerical risk score, may not take into account all nuances of the anatomy, physiology, and clinical status of a specific patient. Clinical case-by-case judgment is equally (if not more) important when selecting cases for OMS.

For OMS to be safe, it is crucial that the interventional cardiologist has adequate experience to supervise OMS, and ideally an additional intensive care background. In addition, individual responses to sedative medications are not predictable; thus, the practitioner supervising the sedation must be adequately qualified to manage the airway and hemodynamic issues associated with all levels of sedation. This includes immediate access to backup from an anesthesia provider if airway issues are encountered that cannot be managed by the practitioner. OMS also requires that the practitioner has support from an experienced nursing staff member or other qualified individual who can manage the sedation and monitor the patient, to allow the operator to focus on the interventional procedure. This individual will need to be dedicated to sedation and patient monitoring and should be present in addition to the regular staff in the cath lab.

10.2.2. Sedation and anesthesia provided by a trained anesthesiologist

While OMS can be equally safe as sedation or anesthesia provided by a trained anesthesiologist, there are clearly specific case characteristics where an anesthesiologist should be present during catheterizations. This includes cases in neonates and most infants, particularly those with low weight (<4 kg), presence of noncardiac comorbidity, or low mixed venous oxygen saturation (<50% in single ventricle disease or <60% in biventricular circulation). These characteristics have been shown to be independent predictors of high-severity sedation- and airway-related AE in US pediatric cardiac catheterization centers.[72]

There are differences in expertise between a regular pediatric anesthesiologist with some (but limited) experience providing care for these cases, and a dedicated pediatric cardiac anesthesiologist. The ideal standard to manage anesthesia and/or sedation in the pediatric cardiac cath lab is to have dedicated cardiac anesthesia providers overseeing all congenital cardiac catheterizations. This ensures that the anesthesia providers have a thorough understanding of the patient's congenital heart anatomy and physiology, critical to maintaining stable hemodynamics throughout the case and managing AE. It is also an ideal standard that a lead cardiac anesthesiologist coordinates the cardiac anesthesia service.

10.3. Equipment and monitoring requirements

Monitoring of patient ventilation, oxygenation, blood pressure, and heart rhythm is paramount during cardiac catheterization. Alterations in any of these lead to changes in and a false representation of the patient's resting hemodynamics, which then can cause incorrect conclusions about the need for intervention or even candidacy for heart transplantation. Monitoring these parameters is the first step toward assuring a steady state during the catheterization. Due to many CHD patients having baseline hypoxemia, it is critical to check oxygen saturation by pulse oximetry at the beginning of the case (prior to any sedation being administered), to establish the patient's baseline. Supplemental oxygen should be avoided for the diagnostic portion of the catheterization if the patient can tolerate room air with acceptable saturations. If supplemental oxygen is added, the interventional cardiologist should be made aware of the fraction of inspired oxygen (FiO_2), as dissolved oxygen may need to be included in the Fick calculations.

While moderate sedation practice guidelines call for periodic monitoring of response to verbal commands,[73,74] both talking and snoring can alter hemodynamic

measurements and should be kept to a minimum. Checking the patient's ability to give a "thumbs up" or other indication of consciousness in response to verbal or light tactile stimulation is a good indication that the patient can control his airway.[74] During moderate and deeper sedation/anesthesia, ventilation should be monitored continually by observation of qualitative clinical signs such as chest movement, but continuous capnography (end-tidal carbon dioxide [CO_2] measurement) and pulse oximetry are ideal. Continuous ECG monitoring and continual blood pressure determinations (eg, at 5-minute intervals) should be made. Once vascular access is obtained, the anesthesia or sedation provider should have an unobstructed view of a monitor displaying pressure tracings. As an ideal standard, the anesthesia or sedation provider should also have access to the live fluoroscopy images.

In patients receiving GA, standard monitoring (including ECG, noninvasive blood pressure, pulse oximetry, end-tidal CO_2, and temperature) should be used for every case. Temperature monitoring (and maintenance of normothermia) is important in smaller children and infants who are particularly vulnerable to hypothermia. Warming blankets, mattresses, appropriate swaddling, and increased room temperature can all be useful to assist in temperature control. On occasion, near-infrared spectroscopy monitoring and/or transcutaneous CO_2 monitoring may be useful, and consideration should be given to placement of a urinary catheter for potentially long cases or for cases in which accurate determination of urine output would be useful. Equally, invasive blood pressure monitoring may be indicated for selected cases. Systems should be in place for recording all the clinical and hemodynamic data, as well as processes to store these data for review.

Meticulous preparation of the patient allows for proper monitoring, adequate intravenous access, arm padding, and no impedance to x-ray arm imaging from equipment. Patient positioning is discussed in detail in Section 14.5. Deairing of the intravenous extension tubing should be performed. The anesthesia provider should monitor for compression of the airway and/or vascular structures by the transesophageal probe.[76] Furthermore, it can never be overstated that there needs to be meticulous attention to avoid any air entry through intravenous lines in patients with (or having the potential for) right-to-left shunt physiology (including the use of filters for such lines). Postprocedural destination and monitoring are discussed in Sections 15.1 and 15.3.

10.4. Intraprocedural communication

Frequent, open communication among the anesthesia providers, the interventional cardiologists, and the entire cath lab team is critical, starting prior to and continuing throughout the procedure. It is important to create an environment where all members of the team are encouraged to voice any concerns at any point and time. The precatheterization huddle is discussed in Section 13.8.

What may be clear to the interventional cardiologists may not necessarily be apparent to other team members. For example, explicit communication around upcoming interventions can prepare the team for variations in hemodynamics, allow technicians to gather any additional equipment, and provide an opportunity to inform the operator of any patient instability anesthesiologists have been managing. Scheduled case pauses also allow providers to assess case progress and reevaluate the plan of care.

Open communication between the anesthesia provider and the other interventional team members is particularly important when changes in hemodynamics are noted and/or treated. Oxygen, volume infusion, change in ventilation mode, and vasoactive medications can affect the hemodynamics, which can alter the catheterization findings, decision-making, and treatment plan. Therefore, the need for these should be discussed with the interventional cardiologist prior to their use, except in cases of emergency. Similarly, changes in rhythm or hemodynamic status noted by any member of the cath lab team should be relayed to the anesthesia provider promptly. When heparin administration is requested, a readback by the anesthesia personnel and confirmation of the dose and volume being given by the interventional cardiologist should be done prior to administration. Background noise and the distances between practitioners often disrupt clear communication among team members in the angiography suite and control room. Use of headsets with microphones can improve communication and should be considered.[76]

Certain procedures require additional communication, such as prior to and during performance of 3-dimensional rotational angiography, as this often requires coordination of a breath-hold, rapid ventricular pacing to decrease cardiac output, contrast injection, and a spinning C-arm during image acquisition. Transcatheter pulmonary valve replacement in RV-to-pulmonary artery conduits often involves serial conduit dilation and CA compression testing, which can produce severe hypotension, followed by catecholamine release in most patients. These types of induced hemodynamic perturbations should be discussed prior to their occurrence, as they usually resolve spontaneously and should not be treated.

During cases of branch pulmonary artery rehabilitation and/or those with stiff wires in the distal branch pulmonary arteries, anesthesia providers should monitor for blood in the endotracheal tube and quickly communicate

this complication to the interventional cardiologist to initiate action. The anesthesia provider should have a high suspicion for this type of complication, as this may go unnoticed for a while with patients often covered by drapes or inability to access the patient when the interventional cardiologist is accessing the patient from the neck. In these cases, the first sign of bleeding will be decreased airway compliance with decreased delivered tidal volume when the patient is ventilated via pressure-controlled ventilation mode or increased airway pressures when volume-controlled ventilation is utilized.

The length of the procedure should also be communicated between teams. In patients with pulmonary hypertension, the risk of AE correlates with greater procedure times.[77] An awareness of the length of the procedure may help decrease case length. Open communication during all cases is key to patient safety, accurate data gathering, and successful interventions.

10.5. Considerations for ACHD patients

Based on the older adolescent's and adult's degree of illness, as well as the potential ability to understand and cooperate, a greater percentage of procedures can be performed using anxiolysis and moderate sedation, or local anesthesia without sedation. These strategies mitigate the detrimental hemodynamic effects potentially caused by deep sedation and GA. They can be used for diagnostic procedures especially when complex hemodynamics need to be defined and for more straightforward interventional procedures (PFO/ASD occlusion using ICE, Fontan fenestration occlusion, etc.).

The staffing requirements for adult congenital patients are generally the same as those listed in Section 10.2. In addition, anesthesia providers managing patients with ACHD should be competent, experienced, and certified (where required) in handling the entire range of congenital cardiac patients, most importantly adults. They should possess a strong working knowledge of cardiac anomalies and hemodynamics, and of management strategies to cope with significant comorbidities that may be seen more commonly in the adult population. Those comorbidities may include, for example, CLD, diabetes, renal impairment, hepatic disease, thyroid disease, and other conditions.

There are some subtle differences in additional requirements needed, based on where the anesthesia provider usually performs the procedures.

Anesthesiology in a children's facility:

- Knowledge and experience with ACHD patients and procedures
- Carry necessary credentials needed to treat adult patients (for example, advanced cardiac life support certification in the US)
- Experience managing mild-to-moderate comorbidities
- Ability to collaborate with adult cardiac anesthesiologists for patients with significant comorbidities

Anesthesiology in an adult facility:

- Knowledge and experience with ACHD procedures
- Ability to collaborate with pediatric cardiac anesthesiologists when knowledge and experience with ACHD patients is not adequate, or for procedures infrequently performed

10.6. Considerations for resource-limited environments

Human resources are one of many limiting factors in resource-limited environments. As such, access to a dedicated pediatric cardiac anesthesiologist may not be available, and a larger number of cases may have to be performed with OMS and support by dedicated nursing staff. It however remains important that a dedicated staff member be present to provide OMS and monitor the patient.

11. X-RAY IMAGING AND RADIATION SAFETY

X-ray imaging is integral to cardiac catheterization procedures. However, the associated radiation dose includes risk of adverse health effects. Therefore, its beneficial use for diagnosis and intervention in the congenital cath lab must be balanced with its incremental risk to both patients and medical personnel. Even though engineering advancements over the past several decades have substantially reduced radiation doses while improving image quality, adequate physician training (resulting in more radiation-efficient use of both new and old equipment) remains the most impactful element of dose reduction strategies. This is even more important, given that interventional catheterizations for CHD have become much more complex, requiring longer fluoroscopy times.[78]

11.1. Physics of the catheterization laboratory equipment

X-ray fluoroscopy units generate controlled x-rays in a vacuum tube. The x-rays form images by passing through the patient and are detected by a flat panel detector (or in older equipment an image intensifier). X-ray tube output is modulated by feedback circuitry from the unit's imaging chain to achieve an image quality that is appropriate for the patient's size.[78]

Several parameters influence image quality and the x-ray dose to the patient. These include:

- Dose that reaches the detector for each x-ray pulse: This is set by the x-ray unit calibration and determines the image clarity and detail.[78] It is important to recognize that increased dose per pulse may not necessarily increase the detail or radiographic contrast, as different

doses per pulse result in varying amounts of noise (presence of artifacts not originating from the original object being imaged) which may affect the visibility of structures.
- Number of x-ray pulses per second: This is selected by the operator and determines the temporal resolution.
- Cross-sectional area of the x-ray beam: This is selected by the operator and determines how much of the patient is seen in the image.
- X-ray beam filtration: The x-ray tube generates x-ray photons that have a spectrum of energies. The lower-energy photons, such as those below 30 kiloelectron volts (keV) do not have enough power to reach the detector and can be filtered out of the beam by interposing layers of aluminum and copper in the tube to prevent them from exposing the patient.[78]
- Beam on time for cine and fluoroscopy: This is the time the operator engages the fluoroscopy/cine pedals.

Patient body habitus also affects the dose, because x-ray systems are calibrated to image with a particular detector dose.[78] In order to achieve that dose to the detector through a large patient, the tube needs to deliver a larger dose to penetrate the patient. This results in a greater dose to the patient, as well as more scatter to nearby health care providers.

Angiography equipment has 3 modes: (1) fluoroscopy: low dose per frame and often low frame rate protocol used primarily for catheter manipulation; (2) cine acquisition: intermediate dose per frame and frame rate used for diagnostic interpretation; (3) digital subtraction angiography: high dose per frame and low frame rate (1-6 frames per second [fps]) protocol used to image noncardiac, stationary vessels.[78]

11.2. Measures of radiation

Radiation exposure and radiation absorbed dose are 2 different metrics used to describe patient radiation burden associated with x-ray fluoroscopy. When x-rays interact with matter, they create free electrons, referred to as ionization. Radiation exposure is the presence of ionizing radiation in the air. It is typically measured in milli-grays (mGy) as air kerma, which is the amount of energy released by the interaction of the radiation with a unit mass of air.[78] Kerma is an acronym for "kinetic energy released in matter." For full-size C-arm systems, it is measured by the x-ray system at the interventional reference point, which approximates the beam entry into the skin (15 cm from the isocenter in the direction toward the x-ray source) and is displayed by the fluoroscopic system in real-time.[78] Procedure total air kerma can be used as a metric of patient radiation (skin entry) dose burden. Because patient skin dose can be assumed to increase as a function of total air kerma, air kerma can be used to establish action levels above which the patient should be assessed for radiation skin injury.

Much of the energy of the x-ray beam incident on a patient is absorbed by patient tissue. The energy which transmits through the patient is used to create the radiologic image at the image detector. In addition, radiation is scattered within and outside the patient, exposing tissues outside of the imaging target and exposing staff.[78] Absorbed dose refers to the magnitude of x-ray energy absorbed in the region of the body being examined and it decreases rapidly as the x-ray beam passes through the patient. Absorbed dose is the quantity relevant to the biological effects of radiation and it is determined by the total exposure, the properties of the radiation, and the volume of tissue exposed; it is also expressed in mGy.[78]

To incorporate the volume of tissue being exposed, kerma-area product (KAP or P_{KA}) or dose area product (DAP) is the product of the beam's air kerma and its cross-sectional area.[78] DAP measures the total amount of radiation delivered to the patient in Gy · cm^2 but may be reported in other units, such as mGy · cm^2 or cGy · cm^2. Traditionally, it was measured by a DAP meter built into the fluoroscopy unit near the collimator. However, newer systems may compute DAP from x-ray and field size factors.

The magnitude of radiation dose to tissues is highly variable, and different tissues and organs have variable sensitivity to radiation effects. Given this variability in tissue dose and sensitivity, the concept of effective dose was developed to correlate partial-body dose with cancer risk. Effective dose uses a tissue-weighting factor, which reflects the tissue's sensitivity to stochastic risk. Effective dose estimates the potential for a biological effect on the entire body (caused by a particular absorbed dose) in milli-sieverts (mSv).[78]

To estimate effective dose, each organ's actual absorbed dose is estimated (in mGy) and multiplied by an organ-specific weighting factor. Then, the sum of the weighted organ doses is calculated to estimate effective dose in mSv.[78] In practice, effective dose is a calculated quantity using standard anatomical models and is not patient-specific. Therefore, it is not an indicator of an individual patient's specific risk. Effective dose allows comparisons between exposure or radiation dose from different x-ray imaging modalities. However, the adult organ weighting factors do not include the increased sensitivity of pediatric tissue to radiation.[79]

Patient-specific estimates of effective dose are not routinely used in clinical practice. Effective dose is used to estimate dose to patients enrolled in research protocols that use x-ray imaging. If effective dose is calculated and reported, it should be accompanied by the actual exposure measurements and the conversion factor used for

estimation, given that it is an estimate involving multiple assumptions.[78]

11.3. Effects of radiation exposure

Ionizing radiation may be associated with 2 very different types of health effects. The first is called "tissue reactions" (formerly called deterministic effects), caused by injury to structural and functional molecules in cells that can lead to cell necrosis.[79,80] If this occurs in enough cells, tissue injury will result. This is typically dose-dependent, requiring a threshold dose to be exceeded. Though uncommon, skin injury following x-ray-guided procedures is possible. Following exposure to a very high skin dose, this may occur with a time delay, as time is required for molecular damage to evolve and cause macroscopic injury.[79] If damage occurs, it often manifests itself 4 to 8 weeks after the exposure and occurs at the beam entry site, which is usually on the patient's back or side.[79] However, for very high doses, late effects often occur well beyond that time period. The second type of health effects is called "stochastic effects" and results from radiation-induced damage to a cell's DNA, which can transform a normal gene into an oncogene. These effects do not have a known dose threshold or dose-related severity. The probability of cancer developing, however, is assumed to increase linearly with dose.[1,78]

The relative significance of tissue reactions and stochastic effects is different when comparing small children to adults. In children, due to their smaller body size, adequate tissue penetration to visualize cardiovascular structures is usually achieved with much lower skin entry doses than what is required in adults. Therefore, thresholds for tissue reactions to occur are rarely exceeded in children.

The opposite holds true for stochastic effects; tissue in growing children is more sensitive to the detrimental effects of radiation than adult tissue, due to children's overall greater mitotic activity. This puts children at increased stochastic effect risk resulting from radiation exposure.[79] In addition, children are more susceptible to radiation-induced illness, as they have a longer life expectancy than adults and more time for the effects to appear. Furthermore, many patients with CHD need repeated cardiac catheterizations and radiation-based imaging throughout their lives. Some patients receive lifetime doses that are associated with a detectable increased risk of cancer.[48-50,52,78,81]

For high radiation dose, cancer risk has been shown to follow a "linear no threshold" model, which states that cancer incidence increases with dose in a linear fashion with no lower threshold.[82] This linear no threshold model is used as a foundation of radiation safety for typical low-dose exposures of patients and staff. Even low doses are assumed to include a small risk of cancer. Females are at increased risk for radiation-induced cancer due in large part to their increased risk of breast cancer.[82] While collectively these factors increase the long-term cancer risk, without these procedures, long-term survival would not be possible for many of these patients.

Interventional cardiologists are exposed to radiation due to x-ray scatter from the patient and the x-ray tube assembly. They are among the health care providers with the highest radiation exposure, with known associated risks such as cataract development.[78] Time spent in the procedure room, the proximity to the patient and x-ray equipment, and the often-seen nonutilization of radiation barriers all contribute to the exposure to staff members. Even though contemporary studies have failed to demonstrate a causal relationship between occupational radiation dose and increased cancer risk, it remains important that safe radiation practices are followed to help minimize risk.[78]

11.4. Dose reduction strategies

Dose management centers around the principles of justification and optimization.[79] The procedure should be justified for each patient, determining that the procedure is indicated and that the anticipated benefit outweighs the risks. Due to the linear no threshold model of cancer risk from radiation dose, it is assumed that there is no dose threshold below which cancer risk from radiation is zero. Therefore, the ALARA principle was developed to ensure that radiation exposure is always maintained "As Low As Reasonably Achievable."[78,83] Optimization is the principle of using only the necessary amount of radiation for the procedure and keeping to the ALARA principle. Radiation dose delivery is optimized by: (1) equipment quality and calibration, (2) equipment operating protocols, and (3) operator conduct.[78] Total dose delivered to the patient is proportional to the product of the dose per frame and the total number of frames during the study. The dose per frame is determined by the equipment quality, calibration, settings, and the size of the patient, while the total number of frames is dependent on the frame rate and total time for which the x-ray beam is on.

11.4.1. Equipment quality and calibration

Since increased radiation dose produces better image quality, a fine balance between image quality and dose must be achieved such that the lowest acceptable image quality is used that will not compromise diagnosis and/or treatment.[78] Acceptability of low frame rates and/or noise varies among operators; thus, it is important that image quality does not adversely impact an operator's ability to perform a procedure safely and efficiently. A procedure that is prolonged due to poor image quality because of a low radiation dose does not result in overall dose reduction to the patient.

Over the past 2 decades, dose reduction and image quality have improved significantly, due to advancements such as flat panel detectors, high-heat capacity x-ray tubes, continuous radiation monitoring and display, virtual collimation, last-image-hold, and retrospective storage of fluoroscopy data.[1] Thus, keeping up-to-date fluoroscopy equipment in congenital catheterization laboratories is critical (Section 7.1).[78]

Dose reduction strategies start with aspects of the imaging equipment's hardware and configuration that must be selected at the time the system is installed, and/or configured.[79] "Out of the box" new fluoroscopy systems are typically configured for adult use, which can result in radiation doses that are not optimized for infants or children.[79] Optimization and configuration of the hardware and software are crucial and should involve close collaboration among interventional cardiologists, cath lab staff, the vendor's design engineers, and qualified medical physicists.[79] A qualified medical physicist should check the equipment calibration periodically. The dose and image quality should be verified, with physics QA staff periodically confirming that the x-ray system is working as expected.

11.4.2. Equipment operating protocols and settings

Preset default programs for several different pediatric weight categories from 1 to 125 kg should be programmed with the lowest dose settings that provide satisfactory image quality. If image quality is unacceptable, the operator can make adjustments to improve image quality. If the default settings provide better image quality than is necessary, however, there is no prompt for the operator to adjust the settings to decrease the patient dose. Therefore, it is preferable to default to a low dose and adjust upward as needed. In addition to selecting the appropriate default settings based on patient size, most x-ray angiography systems provide several different dose rates that are selectable via the table-side-controls for immediate access.

Multiple parameters should be configured for the weight categories. The smallest focal spot should be selected that provides adequate penetration for a given patient size. A small focal spot is required to support the use of geometric magnification without significant focal spot blur.[79] The x-ray pulse width should be short (5 ms) for small children, as this improves image sharpness of rapidly moving objects. Pulse width may be longer (up to 10 ms) for adolescents and adults.[79] The use of low voltages unnecessarily increases patient dose and does not improve image quality. Therefore, algorithms should be used for small children to reduce tube current or pulse width to prevent reduction of voltage <60 kV.[79] Voltage and added filter thickness should be selected automatically as a function of patient weight.[79]

For patients with a lower weight (below 10-20 kg), it is recommended that the antiscatter grids be removed to decrease dose to the patient. In addition to attenuating scatter, antiscatter grids attenuate some of the unscattered x-rays leading the auto exposure controls to increase radiation output.[79] With the exception of newer fluoroscopy systems, when other parameters are left unchanged, removal of the grid will always reduce patient dose. Furthermore, if geometric magnification is clinically needed and used, removing the grid can be important. In children over approximately 20 kg, however, the scattered radiation decreases image quality. The operator must define the body habitus limits at which the image quality is degraded to the point that warrants the use of the antiscatter grid, with approximately a 20 kg upper limit.[79] In selected patients who are slightly larger than this, a nongrid long air gap technique can be considered, provided a small focal spot is used for cine recordings.

Use of the air gap technique, however, can limit the effects of scattered radiation on image quality without the increased dose from the grids.[79] With the image receptor moved approximately 15 cm from the patient, most of the scattered x-rays emitted from the patient bypass the receptor and, do not degrade image quality.[79] All the unscattered x-rays reach the receptor when the grids are removed; this increased dose to the receptor allows the automatic exposure control system to decrease the dose rate delivered. The air gap technique has the added benefit of creating geometric magnification of the image without increase in dose. Fifteen centimeters of air gap approximates a 1-step increase in electronic magnification. It is important to recognize though that the air gap technique can increase patient entrance dose if it is achieved by bringing the patient closer to the x-ray tube. Also, the air gap technique should not be used with the antiscatter grids in place, as this redundancy increases the overall dose.[79]

11.4.3. Best practices of operator conduct

Even though operator conduct forms a crucial pillar of radiation dose optimization, it is important to emphasize that staff plays an equally vital role in radiation dose optimization, and in alerting the operator when suboptimal settings and practices are being used for a procedure.

Prior to and during each case, the operator should employ the following strategies to decrease dose to the patient and medical personnel:

Selecting protocols and settings:

- The operator should select the proper patient size and type of exam to bring forth the configured parameters for dose and image quality optimization that include frame rates for fluoroscopy and cine acquisition, as well as fluoroscopy mode.

- Lower frame rates for both fluoroscopy and cine acquisition translate into lower doses at the expense of temporal resolution. Because the eye has fewer frames to integrate temporally, the noise level appears to increase at lower frame rates. Some systems automatically adjust for this by increasing the dose per frame slightly to maintain a constant level of perceived noise. Therefore, the dose rate reduction may not be directly proportional to the frame rate reduction on all systems.
- Pulsed fluoroscopy should not exceed 15 pulses/second, and acquisition frame rates should not exceed 30 frames/second.[79] Lower frame rates can be used for patients with slower heart rates or when imaging slow-moving structures, such as during venography or balloon inflation.[79]
- Modern x-ray systems also allow the operator to select from a number of fluoroscopy dose rate modes (usually 3-4 modes, such as low/medium/high). The mode determines the radiation dose rate at the image receptor and affects the amount of noise in the image.
- A lower detector dose translates into a lower patient dose but with greater image noise. Using a lower dose mode can potentially reduce radiation exposure by as much as 50% or even more, and, as such, it is recommended to start in the low dose mode and only increase if needed for image quality.

Assess need for antiscatter grids and table/patient distance to tube and detector:

- Remove the antiscatter grids during procedures on small patients (<20 kg) or when the image receptor cannot be placed close to the patient (geometric magnification technique).
- Position the patient at the imaging isocenter and raise the table to increase the distance from the tube to the patient. Table height may be limited by the lateral detector positioning, but increasing the distance between the x-ray tube and the patient decreases dose to the patient's skin by the inverse square law.[79]
- Unless an air gap is being used to mitigate scatter, decrease the distance between the patient and the image receptor.

Use the lowest acceptable electronic magnification:

- The field of view (FOV) is the area of the x-ray field at the entrance plane of the detector. When not using magnification, the x-ray beam irradiates the entire surface of the detector. In electronic magnification modes, there are successively smaller areas of beams to the receptor, which magnifies the image anatomy on the monitor and therefore may improve perceived image resolution. For image intensifiers, the dose rate to the patient increases with a smaller FOV proportionally to the inverse of the FOV change. For example, when the FOV is halved, the patient dose is doubled. While this may not have a significant impact on DAP in pediatric patients, it is an important consideration for tissue effects in larger patients.

Collimate the image:

- Collimation reduces the volume of tissue exposed to the primary beam, thereby sparing the surrounding tissue and organs from direct irradiation (and reducing the DAP in the process), and it also reduces scatter. The reduction in scatter at the detector leads to improved image contrast, which helps to visualize small stents, for instance. Exclusion of radiolucent lung tissue also improves image contrast, due to the automatic brightness control feature of the fluoroscopy unit.[84] Collimators should always be visible within the field.

Dim the room lights:

- Dimmer ambient lighting improves contrast perception and makes the monitors appear brighter.

Limit excessively oblique imaging angles:

- These angles require the beam to pass through more tissue, degrading the image quality and increasing the dose to the patient.[79]

Ensure that the patient's arms are not in the x-ray beam:

- Arms in the beam increase the x-ray path length through the patient, resulting in an increase in patient dose rate. Also, the arms of adult patients can be very close to the lateral plane X-ray tube, resulting in an unnecessary risk of skin injury to the arm.

Limit fluoroscopy time:

- Radiation dose increases with longer fluoroscopy times, and, therefore, the beam should only be on when the operator is looking at the image.

Use saved fluoroscopy, instead of cine acquisition, when appropriate:

- Stored fluoroscopy significantly decreases dose, as the dose rate per frame during acquisition is 6 to 10 times greater than during fluoroscopy.[79]

Alternating beam angulation:

- During long procedures, consider altering the beam angulation to change the area on the patient's skin that is in the direct x-ray field. This is particularly important in larger patients who are at increased risk of tissue effects.

Reminders:

- Where feasible, operators and staff should adapt general and procedure-specific reminders when certain

radiation doses or fluoroscopy times are reached during a case.

Use alternate non-x-ray imaging modalities (such as echocardiography) where feasible.

11.4.4. Three-dimensional imaging

Three-dimensional imaging allows improved understanding of complex anatomical relationships, including vessel-vessel and vessel-airway interactions. 3D rotational angiography (3DRA) has been widely used over the past decade in congenital cardiac catheterization laboratories to rapidly acquire high-resolution volumetric datasets by rotation of the C-arm mounted flat panel detector. This results in a CT-like image or angiographic CT that can be viewed as a 3D volume or in a 2D multiplanar reformation (MPR) with slice thickness <0.5 mm. The 3D reconstruction can be rotated into any angle and allows the interventional cardiologist to find the ideal gantry angles for 2D imaging. The 3DRA can also be fused with live fluoroscopy to provide a 3D roadmap, as the images are automatically registered to or are in geometric correspondence with the C-arm coordinates.[44] Use of 3DRA should be considered during the preprocedural planning to avoid duplication of imaging in both 2D and 3D. Nearly all studies related to this topic have shown comparable or lower radiation exposure rates in cases using 3DRA compared to cases using standard biplane angiographic acquisitions.[44] It is important to work with the vendor and a medical physicist to configure x-ray tube voltage (kV), tube current (mA), pulse width (ms), filtration (material and thickness), and detector dose for 3DRA to ensure sufficient image quality at the lowest achievable radiation dose for various patient weights.[44] Dose protocols based on patient weight should be created and programmed into the system.

The 3D rotational imaging modality is undergoing continued optimization by vendors to reduce the need for contrast while maintaining adequate imaging capability. While newer systems can perform 3DRA with both biplane C-arms spinning together, at this time, no vendor offers biplane acquisition during the rotation. Whether biplane rotational angiography can reduce the spin-time and contrast load remains to be seen. Equally important, operators can improve image quality of rotational angiography by carefully selecting parameters such as a preset x-ray delay following the start of contrast injection, injection site, and the use of rapid ventricular pacing.

3D reconstructions from precatheterization CT and MRI can also be fused with live fluoroscopy. However, this requires registration of a segmented 3D volume with the x-ray system and can be limited by a lack of visible bones for registration and by differences in arm position, respiration, and interval growth of the patient between procedures.[44] Fiducial markers can be placed at the time of the CT or MRI, which aid in registration to the C-arm. 3D image fusion with live fluoroscopy has been shown in multiple studies to improve procedural efficacy and safety, shorten fluoroscopy times, and reduce overall radiation dose and contrast administration.[44,85]

11.5. Radiation safety for patients and staff

11.5.1. Patients

Minimizing radiation to patients starts with eliminating unjustified procedures and/or angiograms and obtaining high-quality diagnostic imaging without using radiation. Diagnostic imaging in the cath lab should be limited to diagnoses that cannot be made by alternative modalities such as echocardiography and MRI. Physicians are responsible for understanding the determinants of patient dose and for keeping to the ALARA principle throughout the procedure, as described in Section 11.4. Fluoroscopy time in minutes, air kerma at the interventional reference point, and DAP should all be reported for each cardiac catheterization.[78] While fluoroscopy time is not a good measure of radiation dose, it is helpful as a surrogate for case complexity and operator and/or trainee efficiency. In addition, when air kerma and DAP decrease with no change in fluoroscopy time, it is clear that an effort to decrease dose by changing equipment, protocols, settings, and/or best practices has been successful.

Air kerma and DAP for every case should be reviewed for internal comparison, as well as compared to national benchmarks.[1,86] Participation in a multicenter QI radiation reduction project has been shown to improve mutual accountability and create a culture of respect for the hazards of radiation (Section 12).[53]

11.5.2. Catheterization laboratory personnel

Medical personnel should not be exposed to the primary x-ray beam and should take great care to keep their hands and extremities out of this primary beam. Therefore, their exposure to radiation comes from scattered radiation emanating from the patient and the x-ray tube collimator assembly.[87] The amount of scattered radiation they are exposed to is determined by the following: (1) x-ray tube output, (2) distance from the x-ray source (x-ray intensity decreases proportionally to the square of the distance from the source), (3) duration of x-ray beam on time, and (4) the effectiveness of accessory shielding.[78] While it is unlikely that occupational exposure for nonoperators is high enough to justify routine use of a heavy 0.5 mm apron, most countries still require protective garments to have 0.50 mm of lead-equivalent coverage.[88] However, this needs to be balanced against weight and orthopedic strain, and as such 0.35 mm lead-equivalent coverage may be more appropriate for many operators and almost all

staff working in the PCCL (where regulations allow). Radiation exposure to the operator is generally greater for internal jugular, subclavian, axillary, and hepatic access than with femoral access.

Lightweight, reusable, or disposable lead-free drapes and pads can be placed on the patient (eg, patient's right thigh) to reduce scattered radiation levels from the patient to the operator. This protection should be considered when the operator needs to be very close to the irradiated volume of the patient.[89] These drapes can substantially reduce the radiation dose to personnel with minimal or no additional radiation exposure to the patient. Their use should be considered in clinical practice.[90] Care should be taken to avoid placing drapes within the primary beam, however, as this can increase both patient and operator exposure.[89,90]

Equipment to mitigate radiation exposure is vital to minimize radiation dose to staff. These include lead aprons and ideally thyroid shields for all staff entering the cath lab where x-ray systems are active. Lead glasses are important for personnel working close to the radiation source and are recommended for any staff having to "scrub-in" for a procedure. Space should be provided to store protective gear to maximize longevity. Protective equipment should undergo regular formal assessment (at least every 6-12 months) for integrity. Lead gloves, radiopaque hand gels, and shielded hats are not in widespread use and generally do not provide any significant additional protection.

The use of lead glass shields mounted on adjustable props reduces scatter and can reduce radiation exposure to staff protected by the x-ray shadow that they cast.

11.5.3. Pregnant staff

The complex cellular processes occurring in the human embryo and fetus are particularly sensitive to radiation effects. In rare circumstances, this can cause fetal malformations, growth retardation, impaired neurological development, and even intrauterine death and may increase the fetus's future risk of developing cancer.[78] However, these effects are known to occur at doses much higher than realized by a performing physician. The shielding provided by a standard protective lead apron is usually sufficient to protect the embryo and fetus from typical exposure to radiation.[88] Women who desire additional protection can wear an additional lead apron or a maternity apron with double-lead inserts over the pelvis. Providing 1.0 mm lead-equivalent over the abdomen could decrease the conceptus's dose by an additional factor of approximately 10 compared with a standard lead apron, even though the absolute dose reduction is minimal.[88]

11.5.4. Pregnant patients

The American College of Radiology (ACR) recommends a pregnancy test be performed in patients of menstrual age (usually 12-50 years) within 72 hours prior to a fluoroscopic interventional procedure.[91] However, this is not required in all countries and jurisdictions. In the very rare event that a pregnant patient must undergo a cardiac catheterization, the abdominal and groin areas should be shielded to avoid the uterus from being in the direct beam, understanding that most of the fetal exposure is from scatter radiation within the body.[1] It is important though to recognize that placing additional shielding on the wrong patient surface could result in increased patient dose (due to automatic exposure control) if the shield is in the primary beam. Efforts to minimize exposure should include using fluoroscopy and echocardiography rather than cineangiography.[1]

11.6. Oversight and monitoring

11.6.1. Oversight

Electronic and radiological service engineers should be responsible for routine, periodical care, and maintenance of the radiological equipment (including verifying equipment performance and calibration). A qualified medical physicist should ensure optimal image quality while limiting radiation exposure to staff and patients and monitoring radiation safety techniques.[1] Oversight also includes a radiation safety officer and engaged physician leaders. However, the exact specifics of the required oversight vary among countries and geographical regions.

11.6.2. Patient monitoring

Although technology exists to create a comprehensive patient dose tracking system, knowing a patient's lifetime accumulated radiation exposure is not thought to provide valuable information for clinical decision-making.[78] The principal value would be in clinical research to define the dose-stochastic risk relationship more precisely.[78]

However, it is important that radiation dose is monitored in real-time during a procedure and to inform the operator when set limits are reached.

While radiation-induced skin injury is rarely a concern in pediatric patients, it remains an important consideration in adult-sized patients undergoing complex interventional procedures. Knowledge of recent prior exposure can aid in predicting the risk of tissue reaction. Single doses of 2 to 5 Gy may cause transient erythema and possible epilation but usually result in complete healing. Doses of ≥5 Gy may result in permanent hair loss and dermal atrophy or induration.[78]

Early recognition of radiation-induced skin injury is important for proper treatment. Making the patient, family, and primary care physician aware of the potential for skin injury is the best strategy for prompt recognition.[78] It is recommended in the ACC/AHA/SCAI 2011 PCI guidelines that all patients who receive an air kerma at the

interventional reference point >5 Gy should be counseled about the possibility of a skin injury and instructed on how to respond to the earliest signs should they occur.[92] It is ideal practice to arrange a follow-up visit 4 to 6 weeks after the procedure for all patients, which allows the physician to examine the patient and identify any tissue reactions that may be attributable to the radiation exposure. Follow-up of patients receiving excessive radiation exposure should be addressed with the assistance of fluoroscopy radiation dose monitoring programs, as those patients require a longer period of surveillance. As an example, when a patient receives either "one shot" or "an accumulation" of a very high dose such as 8 Gy or higher, the patient's skin condition should be monitored and evaluated every 3 months for a period of 6 months.

11.6.3. Staff monitoring

Exposure to radiation by medical personnel must be monitored. Phantoms have been used to create models from which doses are estimated, using personal radiation badges. A badge must be worn outside of the protective garments at the collar level on the left side. This provides an estimation of the dose to the lens of the eye. Another badge may be worn under protective garments at waist level. Effective dose can be estimated roughly from the collar badge reading but can be more accurately estimated by using the readings from both badges.[78] Whether a 1- or 2-badge system is utilized usually depends on local regulations and hospital practice. In addition, some newer systems allow real-time radiation monitoring of staff, which may be a beneficial tool in encouraging best practices.

When a staff member works for more than 1 employer, cooperation among the employers is essential to sum all the doses acquired at each of the facilities into a complete dose record.[89] It is the responsibility of the cath lab manager to designate a staff member to collect, return, and replace the badges on a regular basis. Given that in many laboratories, compliance with wearing radiation badges is suboptimal, a designated staff member should track whether badges have in fact been exchanged and worn. Evidence of nonreturned badges, unworn/sealed new badges, or badges that do not have any dose recording should be documented for each monitoring period, and the relevant staff member should be contacted if there is concern about badges not being worn. Equally important, clear protocols need to be in place if a staff member exceeds defined radiation dose limits. A regular annual medical check-up for the personnel working in an area of radiation is standard in some countries and jurisdictions.

11.6.3.1. Staff monitoring during pregnancy

Regulatory requirements vary between counties and jurisdictions regarding monitoring of staff during pregnancy. In the US, declaration of pregnancy is a personal issue that needs to be decided by the affected individual. In other countries, however, it may be mandatory for the pregnant worker to declare her pregnancy to her employer as soon as the pregnancy is confirmed and staff may not be allowed to work in a radiation area for the duration of pregnancy.[88]

In countries where staff is allowed to continue working in an x-ray environment during pregnancy, the pregnant worker should be provided with an abdominal dosimeter for the fetus and monthly dose reports. The reports should arrive promptly to allow the worker to make changes to her exposure if needed. A worker who is contemplating pregnancy should also be given an abdominal badge if desired, as the fetus is most sensitive to radiation effects between 8 and 15 weeks of gestation.[88]

Data suggest that fetal doses <50 mGy are not associated with a detectable increase in frequency of any adverse fetal outcomes.[78] Phantom studies have shown that an accumulated collar badge dose of 2500 mGy would be required for an exposed worker to receive a uterine dose of 50 mGy.[78] Different national regulatory agencies provide different limits for uterine exposure (eg, The US National Council on Radiation Protection [NCRP] limit is 0.5 mSv/month once pregnancy is known).[88] The pregnant worker should not be discriminated against and, where jurisdictions allow, should not be excluded from working in fluoroscopic environments.[89]

11.7. Training and education

Expert consensus guidelines for safety and effectiveness in cardiovascular imaging stress the "need to augment and standardize the level of knowledge and competence that cardiovascular specialists should hold in radiation safety and management," and that "this knowledge base should be incorporated into training curricula and in physician board certification procedures."[78] Physicians and staff must be knowledgeable in matters of radiation physics, radiation biology, technological developments in x-ray imaging systems, x-ray dose management, radiation protection, and monitoring metrics of patient and personnel exposure.[84] A curriculum covering these topics should be an integral part of every congenital interventional cardiologist's and staff member's training.[1]

All catheterization laboratories should maintain and enforce training and policies regarding monitoring and radiation reduction procedures for pregnant operators and staff.[78] The policies should cover declaration of pregnancy, occupational exposure, dosimeter use and readings, duties, and risk/benefit of additional shielding.[88]

QA for the PCCL is discussed in Section 12.

11.8. Regulatory requirements

Regulatory requirements for radiation-generating equipment vary widely among states, countries, and regions. As an example, the International Commission on Radiological Protection (ICRP) is an independent international organization that advances the science of radiological protection. ICRP does this by providing recommendations and guidance on all aspects of protection against ionizing radiation. The ICRP standards (which are followed in Europe) are more stringent than the NCRP standards in the US.[78] In Europe, limits for occupational exposures are also included in the European Directive 2013/59/Euratom.[93] This directive modifies the occupational dose limit for the lens of the eye to an equivalent dose of 20 mSv/year or 100 mSv in any 5 consecutive years from the previous value of 150 mSv/year. The limit on the equivalent dose for the skin and extremities is 500 mSv in a year.[93] Congenital catheterization laboratories should comply with all local, state, and national regulatory requirements, while always following the ALARA principle.

11.9. Considerations for ACHD patients

Adult patients are at higher risk of tissue effects, due to larger patient sizes and often long procedure times. It is important that specific "congenital" protocols and settings are utilized for these patients, rather than the standard adult coronary protocols/settings since the latter are intended for shorter procedure times and have significantly higher exposure settings than what is desirable for adult congenital procedures. It is also important to emphasize that ACHD patients often have multiple diagnostic and therapeutic procedures involving radiation exposure and have been shown to be at much higher risk for cancers than controls.[82]

11.10. Considerations for resource-limited environments

- The largest limiting factor in reducing staff and patient radiation dose is the difficulty in obtaining up-to-date cath lab equipment, since this is a major cost element in these environments and laboratories may frequently be older than 10 to 15 years.
- Dedicated staff support specialized solely in radiation protection and supervision is usually not available.
- Adequate availability of qualified medical physicists for QA, training, configuration settings, and problem-solving may not be feasible.
- Despite all these limitations, significant dose reduction can be achieved by utilizing best operator and staff practices.[94]

12. QUALITY AND SAFETY

Quality improvement methodology in the congenital cardiac cath lab is essential to providing high-quality care to this complex patient population. It is important that a cath lab develops and sustains a culture centered on providing optimal patient care with a focus on quality, outcomes, and analyses of important safety events. Creating a quality culture does not require significant financial resources but does require a concerted team effort to anticipate vulnerabilities, record outcomes, and review performance.

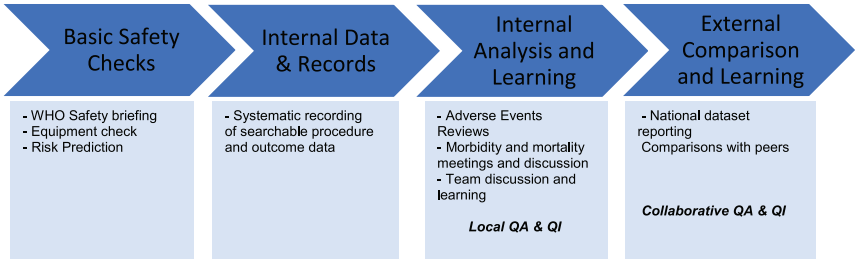
This section outlines minimum requirements for maintaining a quality program and describes activities that promote a culture of quality and improved patient safety. Procedural preparation, risk assessment, and risk management are discussed in detail in Section 13.

Teams can improve performance by adding quality activity and measurement components as they evolve (**Figure 1**).

12.1. Internal data and records

Quality assessment and quality assurance cannot occur without data; thus, all centers performing congenital cardiac catheterization must maintain an internal database to track performance and outcomes. Metric

FIGURE 1 Building a Quality Culture



generation and outcome assessment over time requires a system to record both process and outcome measures. The most basic metrics are the types and numbers of procedures. While accrediting bodies require hospital performance tracking, recording more granular patient and procedural characteristics specific to cardiac catheterization is necessary to understand case mix complexity and adjust for risk factors when assessing outcomes. These outcomes may be procedure-related (such as procedural success, case duration, and radiation usage) or patient-related (such as the occurrence of an AE).

12.2. Targeting quality assurance and quality improvement: Adverse events in the pediatric and congenital cardiac catheterization laboratory

There are many domains to target QI. However, this section focuses largely on AE recording, documentation, and analysis (AE preparation is discussed in Section 13.9) due to the potential to improve practice by learning from experiences through internal review activities.

12.2.1. Recording patient and procedural adverse events

Pediatric cardiac catheterization is an essential component of diagnosis and treatment of CHD. A wide variety of inherently technically complex procedures are performed in patients with concurrent noncardiac comorbidities in addition to the physiologically vulnerable hemodynamic state related to their underlying CHD. Consequently, it is classified as a high-risk specialty.[32,69,95] Depending on risk factors such as patient age, acuity, and case type, the incidence of complications during a catheterization procedure can be as high as 1 in 4.[69] Some events can result in downstream patient harm, such as unplanned surgery, permanent disability, or death.

To record AE and categorize them by severity, many centers have adopted the International Pediatric and Congenital Cardiac Code (IPCCC)[96,97] definitions and classification. According to these definitions, AE are defined as any anticipated or unanticipated event, for which patient harm could have or did occur, potentially or definitely due to the catheterization procedure performed. Full capture of all events regardless of severity allows a program to recognize event patterns and identify opportunities for improvement. In addition, the most robust databases will include patient and procedural factors to understand the associated risk of the procedure and allow adjustment if comparisons are reported.

AE reporting should include a detailed narrative, providing opportunities for improvement and facilitating internal review and discussion among all members of the catheterization team. Narrative summaries should address the following to maximize their utility:

- What was the overall health status of the patient prior to, during, and after the event?
- When did the event occur?
- When and how was the event identified?
- What procedural actions/steps were being done/taken at the time of the event?
- What interventions were necessary?
- Were additional diagnostic studies required to assess or monitor the patient?
- What was the outcome of the event?
- Did the patient require unexpected or additional care?
- Was there any permanent patient injury?

12.2.2. Quality assurance, internal analysis, and learning opportunities

Interventional cardiologists should continuously evaluate their practices, monitor outcomes, and work with local multidisciplinary teams to establish rigorous strategies to ensure that the highest quality of patient care is provided. Establishing processes to analyze and display data will allow for close monitoring of progress. Some common methods of graphically displaying QA and QI data include histograms, run charts, control charts, and scatter diagrams. It may be helpful to review data by subgroups, such as by procedure type, patient volume, or operator experience wherein identification of potential outliers can reveal areas to target for improvement.

"Key Conferences," including M&M and Serious Safety Event Reviews, facilitate practice improvement, CME, and professional development. To be successful, "key conferences" should be regular, inclusive, nonpunitive, and focused on practice improvement. Ideally, these meetings should be multidisciplinary and serve as a tool to link current practices with best practices, fostering process improvement. They should be recognized for CME credit acquisition. Conferences may also be required by the ACGME if an institution operates a fellowship training program in the United States.

12.2.2.1. Morbidity and mortality conferences

Invasive cardiology/cath lab M&M conferences include an open review and evaluation of all cath lab complications and in-hospital events following any invasive cardiovascular procedure. Cath lab M&M conferences are essential to achieving meaningful practice improvement in the lab. This review is conducted between peers in a collegial setting with engagement from multiple key stakeholders (physicians, allied health professionals, and other disciplines). Focusing on opportunities for improvement at the systems level, as compared to focusing on individuals, allows these conferences to serve as a vehicle for process improvement via collaboration, feedback, and education. These educational opportunities are especially important

with new techniques and interventions and for newer team members or trainees.

To maximize the benefit of cath lab M&M conferences, it may be useful for a quality officer (physician, physician's assistant, or designated cath lab staff member) to compile all cases with AE that occurred during the review period. Case identification should be unbiased and comprehensive. At a minimum, all cases resulting in death within 30 days of the procedure should be reviewed. Additionally, all major AE require review. Other AE (or unexpected length of stay) may also be prospectively selected for review as aligned with specific process and QI initiatives or learning opportunities.

These meetings should occur at least quarterly with mandatory cath lab staff attendance. The meeting environment should be psychologically safe and transparent to allow for a critical review of events as a means for performance improvement. Consideration should be given to include other multidisciplinary staff such as noninterventional physicians, nurses, and/or other allied health personnel. This is especially warranted for events involving other departments such as, for example, anesthesia-related AE or ICU management challenges. The responsible attending physician for each presented case must be in attendance when the case is reviewed, and a sign-in sheet for participating staff is encouraged. A Case Review Form, which includes an action plan and/or response to the AE, should be tailored to each institution and should be completed during the cath lab M&M conference. Ideally, a database or spreadsheet should be created and maintained to track AE and to archive the completed Case Review Forms.

12.2.2.2. Special safety event reviews

Serious unexpected AE and rare events that resulted in permanent patient harm require additional review. These reviews involve a formal Root Cause Analysis of an AE, to understand the chain of events leading to the AE, and to document what has been learned to be applied to future procedures. Major AE reviews often involve external experts on patient safety and are often performed in an expedited manner in anticipation of requirements for reporting to and review by external regulatory bodies.

12.2.2.3. Device-related events

AE involving medical devices should be reported to the Manufacturer and User Facility Device Experience (MAUDE). These reports are submitted to the regulatory body by both mandatory and voluntary reporters, including manufacturers, importers, health care professionals, patients, and consumers.[98] The past 10 years of device reports are searchable, providing information about device-related AE. The database can be queried for a specific complication, which offers valuable insights. For example, researchers used the MAUDE database to search and summarize major complications related to ASD occluder devices. Their query of the MAUDE database suggested that device-related complications were more common than had been previously reported in the literature.[99]

12.3. Continuous quality improvement

CQI involves an iterative system of improvements in processes, safety, and patient care. An example of a common methodology for CQI is the IHI's Plan-Do-Study-Act cycle, which allows process changes to be made, studied, and refined over time.[100] CQI cannot occur without a culture of QI in the cardiac cath lab, based on engagement of all staff in the environment. Through a team-based approach, active members of the team empower others, focusing on methods of improvement rather than an emphasis on QA. Simply providing data relevant to current practice trends can be helpful to engage staff.

Improving quality in the system of care is a team effort and requires individuals offering differing perspectives on the delivery of care, such as technical staff, anesthesiologists, nursing, and cardiologists.[101]

12.4. External performance measurement, risk adjustment, and comparative reporting

Evaluating local results is essential, but it is equally important to compare outcomes against established benchmarks. This allows a program or operator to determine how institutional results compare to peers. In some countries, national registries can be a good source of reference information. However, many large-scale clinical databases are designed specifically to compare results of a specific treatment or condition or to provide data for ongoing and future research. Cardiac catheterization in CHD is characterized by complex heterogeneous procedures performed infrequently, making it difficult for individual care centers to achieve an appropriate sample size and generalizable methodology alone. To counter this problem, key variables have been created to group procedures according to similar risk, which provides for risk adjustment and meaningful assessment when comparing outcomes among individuals or centers.

Over the past decade, registry participation and/or comparative outcomes reporting has become common utilizing collaborative structures such as:

- The Congenital Cardiac Interventional Study Consortium (CCISC)
- C3PO
- The IMproving Pediatric and Adult Congenital Treatments Registry in the US
- The National Institute of Cardiovascular Outcomes Research central cardiac audit database in the UK

- The IQIC in low- and middle-income countries
- External organizations such as (for example) the United States News and World Report

These have enabled large-scale data collection and implementation of important multi-institutional efforts to develop risk prediction and adjustment methodology, as well as identifying best practices and areas requiring improvement.[69,102-104] In areas with centralized patient data repositories, such as Belgium and Quebec, Canada, data may be collected longitudinally without third-party registries.[105,106]

Risk-adjusted outcomes are imperative for QA as they allow for comparisons between centers and operators in the heterogeneous population of congenital cardiac catheterization. The role of outcome comparison in driving QI has been shown in the reduction of radiation use in congenital cardiac catheterization labs.[53] The IMproving Pediatric and Adult Congenital Treatments risk adjustment methodology and the standardized AE ratios from CHARM can both fulfill this requirement. CHARM was the first pediatric catheterization outcome metric recognized by the US-based National Quality Forum in the Core Quality Metric Collaborative endorsed measure set. However, these measures are based on experiences in the United States and may not necessarily apply to other countries and health care settings.

12.5. Quality improvement projects and resources

The IHI toolkit is available online and provides useful training, worksheets, and project planning documents for general QI projects.[107] SCAI website includes a Pediatric QI Toolkit, which provides a centralized resource with information on QI within the field of congenital cardiac catheterization.[108] Modules include Quality in Healthcare, Conferences, QI Tools, and QI Examples. These modules provide training, links, and resources for users seeking to expand their knowledge and skills related to QI. In addition, SCAI website houses a library of QI projects submitted as examples for adaptation by SCAI members in local QI initiatives. These frameworks and initiatives may also meet requirements by national boards relating to QI, such as those required by the American Board of Pediatrics when submitting a local QI project for credit consideration.

12.6. Regulatory requirements

QA and QI efforts are no longer just a desirable "surplus" activity but are mandated by many national regulatory bodies. As an example, in the United States, the Federal government has mandated adoption of the continuous QI process in the health care industry. Governmental and accreditation bodies, such as the National Integrated Accreditation for Healthcare Organizations (NIAHO), the Joint Commission on Accreditation of Healthcare Organizations, and the IAC, now require CQI programs as part of accreditation.[109,110] Risk-adjusted outcomes are required by the Joint Commission to assess operator performance for Ongoing Professional Performance Evaluations.

In addition, as per the ACGME, physicians in training in the United States are required to complete QI projects during residency. Similar requirements exist in other training authorities, such as the need to participate in a clinical audit for junior doctors during training in the UK. While required quality monitoring in the cardiac cath lab can vary between countries and even regionally in the United States, professional organizations, such as the ACC, the AHA, and SCAI have produced guidelines and expert consensus documents recommending CQI programs for enhancing cardiovascular care.[101,111]

12.7. Considerations for resource-limited environments

Many of the measures in larger registries such as The IMproving Pediatric and Adult Congenital Treatments are based on experiences in the United States. Further research and metric development must be conducted to validate the utility of these methodologies in other countries, particularly in low-resource settings. As such, after an initial pilot phase, the IQIC, dedicated to improving care in low- and middle-income countries, launched a free congenital cardiac catheterization registry in 2019 with streamlined variables focused on patient risk and procedure outcomes.[112,113]

13. PREPROCEDURAL MANAGEMENT

Optimal outcomes are dependent on appropriate preprocedural planning, intraprocedural decision-making and execution, and postcatheterization management.[114] This section focuses on the precatheterization planning phase and includes all processes that need to be in place up to the point of the patient entering the cardiac cath lab. These processes include patient selection, procedure-specific case preparation, informed consent, preprocedure huddle, as well as transportation of the patient to the cardiac cath lab.

13.1. Patient selection: Congenital case management discussions

All interventional procedures that are either complex, carry significant risks, have potential alternative treatment options, or where there are questions about the pre- or postprocedural management, or the most suitable operator(s) to perform the procedure, should be discussed at regularly occurring combined case management conferences. These ideally should include a congenital heart surgeon, a congenital echocardiography specialist, a

pediatric cardiologist, a congenital axial imaging specialist, and ideally also a pediatric electrophysiologist and a representative from pediatric cardiac anesthesia. In addition, and depending on the planned procedure type, additional presence of other involved services, such as for example PICU, NICU, and pulmonary hypertension may be required. These conferences are the appropriate forum to make transparent case management decisions, including the type of procedural specialist(s) that should be performing the procedure, and the type of backup that may be required. All cath lab staff should be encouraged to attend those meetings.

While there will be institutional variation in format and the extended personnel involved, the discussion needs to include a thorough review of the indications (and potential contraindications) for the cardiac catheterization procedure, the data to be obtained, and any interventions planned. The discussion also needs to include any potential impact a procedure may have for future surgical or catheterization procedures and evaluation of any potential alternative treatment strategies. The discussions should be as comprehensive as needed for each specific case but may be more limited for more straightforward cases. During these discussions, the multidisciplinary team should comment on additional requirements for specific vulnerable patients, such as those with high-risk coronary lesions, cardiomyopathies, and pulmonary hypertension, as additional preparation may be required to minimize complications and optimize results. Decisions about the urgency of a specific case are usually made at the time of the case management conference.

13.2. Procedure-specific case preparation

Pediatric cardiac catheterization involves performance of many complex procedures. Successful performance is highly dependent on a sophisticated organizational system and coordinated efforts of multiple individuals working as a team with a high level of technical proficiency.

Before a procedure begins, there are multiple key points-in-time to communicate about optimizing care, allocating resources, and anticipating potential risks. These points-in-time are in addition to the case management discussion and the mandated immediate preprocedure "time out," such as the week before the procedure, the day prior, or the team "huddle" the day of the case. Such advance planning and communication can improve capacity management, allow schedule balancing based on procedure risk and anticipated case duration, inventory anticipated equipment, and plan for potential surgical backup (Section 9), or vendor support. While usually not feasible for smaller centers with limited personnel, daily multidisciplinary meetings can provide opportunities to review emergency resources, allow technicians to prepare equipment, and for other providers such as anesthesiologists to plan for complex cases.

While case selection and some case-specific decisions are often initiated at the time of the case management discussion, many elements important for the specific planning of a procedure follow afterward and are usually coordinated and supervised by the interventional cardiologist and the extended team. Examples include risk assessment, determination of a sedation or anesthesia plan, need for laboratory testing and blood bank requirements, anticipated vascular access, need for additional imaging, anticipated supplies and devices, coordination of surgical backup, review of comorbidities that might require the involvement of other subspecialties, as well as the anticipated case duration and intended length of hospital stay.

13.2.1. Imaging and chart review

Interventional cardiologists need to be inherently familiar with all aspects of the patient's cardiac and past medical history, as well as comorbidities. Important considerations that might impact the procedural planning include baseline cardiac function, especially those with known cardiomyopathies, CAD or anomalous coronary connections, pulmonary hypertension, and a history of arrhythmias.

A detailed review of cardiovascular data should include a review of all previous surgical and cardiac catheterization reports, as well as review of previous cardiac catheterization imaging. It should also include review of the recent echocardiogram, ECG, and in some cases, a chest x-ray (CXR). Two-dimensional and 3D chest/cardiac imaging (CT or MRI) and 3D printed models should also be reviewed, ideally with the aid of an axial imaging specialist. Important missing reports should be obtained in advance of the procedure.

The preprocedural review of these data is crucial, in particular in patients with a complex past cardiac history, to fully understand the development of the vasculature, illustrate limitations to vascular access, and allow the operator to anticipate how previous interventions may impact current procedural plans. Reports of imaging studies and preferably the images themselves should be easily accessible during the cardiac catheterization for reference if needed.

13.2.1.1. Medications

Prior to the procedure, all medications should be thoroughly reviewed. Commonly encountered medications are cardiac medications, including those specific for systemic and pulmonary hypertension, arrhythmia, or heart failure. Common noncardiac drugs include steroids, insulin, anticoagulants, antiplatelet medication, and bronchodilators. The timing of administration of each

medication needs to be considered individually. In some instances, medications may need to be held. Adjustments of antiarrhythmic medications should be made in consultation with the electrophysiologists as well as the anesthesiologists. The same applies to pulmonary vasodilators, which should be discussed with the pulmonary hypertension specialist. If patients are at risk of a pulmonary hypertensive crisis, inhaled nitric oxide (iNO) or alternatively iloprost for inhalation should be readily available during the procedure.

Aspirin is usually not discontinued prior to a catheterization procedure (but may need to be stopped for hybrid procedures), and in some instances such as ASD closure, it may be initiated a few days before a procedure. Depending on the planned procedure, full oral anticoagulation such as coumadin may need to be withheld and some patients, in particular those with mechanical valves, may need to be transitioned to either intravenous heparinization or low molecular weight heparin. Heparin can usually be discontinued just before the procedure, and in some patients on circulatory support, it may need to be continued throughout the case. Published data on cardiac catheterization while on ECMO suggests that even with full anticoagulation, these procedures can be performed safely.[115]

13.2.2. Risk assessment

In the past decade, much work has been done on risk prediction and risk-adjustment models, which have provided a better understanding of procedural risks and complications.[102,116,117] Advancements in risk prediction include development of the CRISP score[102] by the CCISC in 2007, which included participation of many centers around the world.[73,118] This prediction tool provides a precatheterization risk scoring system that can be applied to individual pediatric patients to determine risk of an AE based on anticipated procedure type and patient characteristics. The CRISP calculator has been made freely available online and serves as an easily applicable and widely utilized tool to predict procedural risk.[117] It is also used by operators for patient counseling and consent.

The CHARM model has undergone improvements to anticipate potential risk including summarization of individual procedures performed into a single case type, incorporation of new interventions performed in the catheterization lab, and an updated hemodynamic vulnerability scoring system based on a better understanding of hemodynamic risk.[70] Regular incorporation of risk prediction tools into procedure communications can allow teams to anticipate and prepare for emergencies. This can be done through detailed review during the precath workup and the precase huddle and/or through a simple red-yellow-green coding for anticipated patient risk in the scheduling system. Case-specific risk prediction is also a helpful element to include in the informed consent.

13.2.3. Procedural timing

The specific planned procedure and procedural risk, the urgency and duration of the procedure, and the hemodynamic stability of the patient will dictate procedural timing.[102,116,119] When possible, young infants and children along with complex cases should be scheduled early in the day to reduce nil-by-mouth time and to allow for postprocedural recovery and disposition during regular operational hours. Equally, higher-risk patients should be scheduled early in the day, to avoid procedures continuing beyond regular hours when there is less staffing support. Comorbidities such as insulin-dependent diabetes may also impact patient scheduling.

13.2.4. Expected hospital stay

For every patient and procedure, the precatheterization review needs to include the anticipated hospital stay and the expected location following the procedure. Where feasible and where resources allow, the respective units should ideally be notified in advance and beds booked, so that there are no surprises on the day of the procedure. Support and nursing staff are crucial to ensure beds and staffing are available for the post-cath patient, whether it is an inpatient, a same-day discharge, overnight admission, or prolonged hospitalization for further management.

13.2.5. Additional preprocedural testing

13.2.5.1. Consults

The most common consults that may be required prior to cardiac catheterization include anesthesia and surgical consults. Other subspecialty consultations may be needed on a case-by-case basis to address specific patient comorbidities. This may include consults with gastroenterology/hepatology for single ventricle patients with impaired liver function, nephrology consults for those with abnormal renal function, or hepatology consultations for those with a hyper-or-hypercoagulable state. Assessment and evaluation for any dental issues should be performed in any patient with an anticipated device or stent implantation. This includes consideration for a referral for formal dental clearance on a case-by-case basis. In some patients, preadmission consultations by pediatric specialists (or internal medicine specialists for adults) may aid in identifying other significant comorbidities.

13.2.5.2. Preprocedural nonlaboratory testing

Some additional preprocedural imaging and testing may be needed for specific cases to support the indication to intervene in a patient (such as an abnormal stress test

response in coarctation of the aorta, or an abnormal perfusion scan when planning to intervene on a branch pulmonary artery), or to aid assessing the potential degree of symptoms prior to a procedure as a pre-intervention baseline (through for example exercise testing) to serve as a reference for postprocedural testing.[120-128] Examples of frequently used preprocedural testing include cardiopulmonary exercise testing (CPET), 6-minute walk test, pulmonary function testing, MRI with differential pulmonary flows, pulmonary perfusion scan, or Holter monitoring.[129,130] In patients who have undergone previous cardiac catheterization procedures, vascular ultrasound may be needed for the assessment of vascular patency for procedural access. The need for this additional preprocedural testing should be identified through the preprocedural case review performed by the interventional cardiologist. For cases of potential right ventricular outflow tract (RVOT) stenting, preprocedural exclusion of the need for electrophysiologic treatment should be considered.

13.2.5.3. Laboratory testing

Laboratory testing and review should be case- and patient-specific, and may include electrolytes, renal, thyroid, and hepatic function, complete blood count, and a coagulation profile. In otherwise healthy infants and young children undergoing routine procedures, this testing can usually be obtained on the day of the procedure after sedation or anesthesia is initiated to eliminate the discomfort and anxiety of a blood draw and to preserve vascular access sites for anesthesia. Some preprocedure testing is mandatory though and includes pregnancy testing in postmenarche (in most countries), as well as an international normalized ratio for patients who were taken off coumadin prior to the procedure. In the presence of comorbidities, specific tests to assess end-organ function or metabolic profiles should be performed prior to taking a patient to the cardiac cath lab. In children with suspected genetic syndromes, genetic screening should be performed prior to any potential need for blood transfusion. Preprocedural lab-draws should also be considered in older compliant patients, as it can avoid waiting during the procedure for crossmatch to be completed.

13.2.5.3.1. Blood bank requirements

Blood may need to be accessible quickly (either in the room or close by) for certain procedure types which might include among others:

- Balloon angioplasty and/or stenting
- Transcatheter valve replacement
- Some procedures in premature infants
- Hybrid procedures
- Valvuloplasty procedures in critical AS and critical pulmonary valve stenosis (PS)
- Some VSD closure procedures

In such cases, cross-matched blood should be made available in the room either at the start of the procedure or prior to performing the interventional component of the procedure. When to obtain blood samples for cross-matching depends on the expected laboratory turn-around times which varies between institutions and should influence decisions on whether to obtain the needed samples in advance of a case, or after sheaths have been placed.

Depending on institutional workflows and requirements, obtaining the sample after hemostatic sheaths are placed may allow cross-matching to be performed and blood to be available, often prior to the operator being ready for the interventional component of the procedure (depending on procedure type). This requires that a specific workflow be outlined in advance between the cath lab and the blood bank so that this process can be expedited. This may not be feasible in every institution.

While this avoids patient discomfort and preserves access sites, there will however be situations when antibodies are identified, such as in patients who have undergone multiple past surgeries with multiple blood transfusions. In those situations, cross-matching can last significantly longer. Such situations require either waiting until the crossmatch is completed while a patient is under anesthesia or using emergency (O-negative) blood for backup (for interventions where the perceived risk of requiring a transfusion is extremely low or the status of the patient is so unstable that waiting would add significant risk).

13.2.6. Equipment, supplies, and support

Review of needed equipment and supplies should be performed well in advance of each case and should include rarely used bailout equipment that may be needed if an AE were to occur. This is especially important for smaller facilities that may not stock large par numbers for individual items (Section 7.4). In low-volume centers or for uncommon procedures, special devices or equipment not routinely stocked may need to be acquired. Antiarrhythmic medications, temporary pacing systems, and cardioversion/defibrillators should be immediately available for all patients. Bailout equipment is discussed in Section 7.4.

The need and timing for involving other subspecialty services (such as TEE or electrophysiology) or consulting services during the case needs to be coordinated in advance. This also includes availability of industry support if needed for procedures such as for example

transcatheter pulmonary valve replacement or device implants. The need for a second interventional cardiologist, other subspecialty operators, and surgical backup should be assessed and coordinated.

13.2.7. Concomitant procedures

Complex patients with multisystem diseases sometimes may benefit from additional subspecialty evaluations (ie, pulmonology, ophthalmology, and urology) or additional procedures (including sedated echocardiograms, liver biopsies, or permanent central line placement) at the time of the cardiac catheterization procedure. Consideration should also be given to planning for adjuvant imaging when there is a high potential risk for potential AE, such as intraprocedural bronchoscopy when bronchial compression during left pulmonary artery stent placement is a concern in selected patients.[131]

If additional surgical procedures are considered, a decision on whether to perform these procedures before or after heparin administration should be discussed with the operators. It is important to avoid concomitant procedures that can be associated with temporary bacteremia, especially if device or stent implantation is being considered.

13.2.8. Patient-specific considerations

13.2.8.1. Patients with renal impairment

Angiography with exposure to contrast media is a risk factor for acute renal failure, although this is a rare occurrence in pediatric patients with normal renal function. Adult patients with baseline renal dysfunction (estimated glomerular filtration rate [GFR] <60 mL/min/1.73 m^2), diabetes mellitus, hypotension, and chronic heart failure are at increased risk of contrast-induced nephropathy.

Renal disease is a major risk factor for ACHD patients undergoing cardiac catheterization.[132-134] Renal dysfunction is particularly common in patients with ACHD with 50% of young adults (65% with cyanosis) having at least mild disease and an 18-fold to 35-fold higher incidence of significant renal dysfunction compared to the general population. In patients with renal dysfunction, preprocedural discussion with the nephrology service is essential.

In patients deemed at risk for contrast-associated acute kidney injury (AKI) smaller volumes of contrast relative to GFR, and prehydration can be considered. Multiple agents (N-acetylcysteine, ascorbic acid, etc.) have been used for additional prophylaxis with varying results with initiation or continued use of statins seeming to be most consistently beneficial,[135] although the data on the protective effect of these interventions is inconclusive.[92,136,137] In addition, it is recommended to withhold angiotensin converting enzyme inhibitor or angiotensin II receptor blocker if eGFR <60 mL/min/1.73 m^2. Judicious use of contrast is required in all these patients, which needs to be included in the preprocedural planning.[138-141]

13.2.8.2. Patients with allergies

The history of patient allergies should be discussed at the time of the consent. The most important consideration is an allergy to contrast, even though contrast reactions are rare, in particular in patients less than 5 years of age. In patients with a prior reaction to contrast media, protocols are available for oral pretreatment with steroids.[142] It is not necessary to use premedication in patients with an allergy to shellfish but not contrast. Likewise, a protocol for treating severe anaphylactic contrast reactions should be in place. Other allergies to consider include latex, betadine, chlorhexidine, and tape. Communication with the anesthesiologist and the cath staff for potential allergies can mitigate these complications with advanced planning and the use of alternative options.

13.2.8.3. Considerations for thyroid dysfunction

Although exposure to iodinated contrast agents may alter thyroid function, the limited data available suggest that, in young children who have been exposed to contrast agents, hypothyroidism is rare and usually transient.[143,144] Patients who require repeated cardiac interventions (particularly in the context of medications that may affect thyroid function) may be more at risk. In neonates and preterm infants, evaluation of preprocedural and postprocedural thyroid function should be considered case-by-case.

13.2.8.4. Considerations for pulmonary hypertension

Patients with severe pulmonary hypertension on vasodilator therapy, are at increased risk of procedure-related AE. This includes angiography-induced pulmonary hypertensive crisis, and potential risk related to prophylactic intubation, where subsequently needed extubation can induce a pulmonary hypertensive crisis. As such, performing procedures under sedation should be considered on a case-by-case basis in these patients (Section 10).

13.3. Informed consent

Informed consent is crucial and legally required prior to performing any procedure (except for life-saving emergency interventions). The consent should always be obtained by direct communication between the operator and the legal caregivers or the adult patient. While obtaining consent on the day of the procedure is acceptable practice, it is ideal practice for the operator to meet with family and caregivers prior to the procedure date. This allows for the family to be less distracted by concerns

of an imminently happening procedure, or an upset child who has not eaten for several hours.

It is recommended that a licensed medical interpreter be utilized if the discussion is not in the patient's or family's native language. A thorough discussion of the planned procedure, indications, alternative treatment options, likely benefits, and risks should occur. This may be supplemented with data from preprocedural risk calculators such as rCRISP. Potential major and minor AE should be outlined. This should include a review of specific cardiac catheterization-related AE such as death, infection, bleeding, arrhythmia/heart block, thromboembolic events including stroke, vascular injury or compromise, and cardiovascular injury requiring emergent procedures or surgical repair. Additional AE should be included depending on the specific intervention planned such as valvular regurgitation or residual stenosis in valve dilations, or potential device malposition/embolization requiring additional repositioning or (surgical/cath) retrieval.[145]

Patients and caregivers should be informed about the expected intermediate and long-term outcomes and the need for additional procedures that may be required, especially in growing children with complex heart disease.

The discussion and consent should be age-appropriate for children and adolescents. Ideally, information should be provided at a 6th-grade education level. Consent is usually taken from the legal caregiver in pediatric patients, which also applies to older patients if the patient does not have the capacity to understand a basic consent/assent discussion. All parental and patient concerns and questions should be fully addressed, recognizing there will be substantial variation in the breadth and depth of the necessary discussion. It is often helpful to have the parents and/or patient articulate what they understand to avoid any misunderstanding. The family should be given a clear understanding of the expectations for procedural success. Questions regarding the operator's experience and previously encountered complications should be answered openly and transparently.

Permission to transfuse blood products may need to be included in the consent (with specific accommodations for Jehovah's Witnesses patients).

13.4. Precase clinical review

All patients planned to undergo cardiac catheterization should be clinically evaluated with a full history and physical examination in advance of the procedure (ideally within 30 days), with a final check-up immediately preprocedure, to make sure there are no infectious or other clinical contraindications to proceed with the procedure. This should ideally be supplemented by a phone call a day or 2 before the procedure, to identify any new problems and avoid last-minute cancelations.

13.5. "Nil-by-mouth" guidelines

During the clinical precatheterization assessment, information on when to stop eating and drinking must be provided to avoid procedural cancelations or inadvertent pulmonary aspiration. Generally, the 2-4-6-8 hour rule for clear liquids, breast milk, formula, and solids, respectively is utilized but there may be institutional variations.[146] Clear communication as to what constitutes each of the liquids is essential to avoid confusion on the patient's/parent's part. Ideally, patients/caregivers should be provided with written instructions. In neonates and infants, commencing glucose infusion after the last oral food administration should be considered in selected cases.[147] In addition, volume depletion should be avoided in very cyanosed patients with high hemoglobin. Preprocedure administration of intravenous fluids should be considered in such cases.

13.6. When to cancel or postpone a case

Unfortunately, certain situations or a change in condition may warrant a case being postponed or canceled. Reasons for cancelation may vary in severity from an acute change in patient status for in-house patients or signs of a respiratory and/or other infection to less severe reasons such as unknown poor dental hygiene, not following pre-cath nil-by-mouth instructions, or arriving late to the hospital on the procedure day. A thorough discussion between the interventional cardiologist, anesthesiologist, primary cardiologist, and/or possibly ICU physicians should occur. This discussion should include the risks and benefits of moving forward with performing the procedure on the scheduled day vs postponing the procedure. Other items to take into consideration are the length of the procedure, availability of the cath lab and support staff, and bed availability, particularly if ICU or high-dependency unit care is required. Note that a high-dependency unit may only exist in a limited number of institutions. Patient safety should always be at the forefront of this discussion.

13.7. Transportation

Transportation to the cath lab from various inpatient units and holding areas as well as from the cath lab to the recovery room and ICU will be unique in every institution depending on the distance between these units. In general, transportation should be conducted efficiently with adequate staffing and resuscitation supplies and medications readily available during transportation. Potential AE during transportation of critically ill children and neonates should be discussed. It is recommended to develop a checklist to reduce AE during transportation.[148,149] Intravenous access should be reviewed prior to

transportation, especially for patients who are potentially unstable, or on continuous intravenous medications including inotropic agents and prostaglandins.

For children who are transported awake, an assessment should be made regarding their anxiety and fear of separation from their parents. Ideally, consideration should be given to allow parents to accompany the child to the cath lab. Pretransport (and preprocedure), sedation may be needed in some patients and premedication should be ordered accordingly. Each institution should have a clear protocol for such transportations.

Additional transportation considerations for premature infants are discussed in Section 16.2.1.

13.7.1. Intubated and ventilated patients

In patients with an endotracheal tube in situ, tube position should be verified and optimized via auscultation or radiograph prior to transportation. Endotracheal suctioning, if necessary, should occur prior to transport in selected patients. A transport monitor should be utilized, and, at a minimum, should be capable of displaying continuous ECG, pulse oximetry, capnography, and intermittent blood pressure measurement. The transport team should travel with the full complement of resuscitation medications and equipment to manage the airway. In some circumstances, it may be necessary to transport a patient with a dedicated ICU ventilator, which often requires additional careful planning for transportation.

13.7.2. Transporting patients on extracorporeal membrane oxygenation, ventricular assist device, or with high-frequency oscillatory ventilation

Pediatric cardiac patients requiring circulatory support such as ECMO or VAD include those with low cardiac output, unexpected cardiac arrest, failure to wean from cardiopulmonary bypass postoperatively, severe cyanosis, and refractory arrhythmias.[150] Indications for catheterization in this patient population include hemodynamic and anatomic assessment of a surgical repair (and treatment of pathology amenable to transcatheter intervention), left heart decompression in patients with left heart dysfunction, and others. Published data suggest these procedures can be carried out safely and yield crucial information enabling therapeutic interventions or changes to the medical management strategy.[150]

These patients require additional preparation prior to going to the cardiac cath lab. A pretransportation huddle should be performed by all team members involved in the transport of the patient, essential for optimal planning and smooth transportation all the way to the table in the cardiac cath lab.

Because tubing for oscillation ventilators, ECMO, and VAD is significantly stiffer than routine ventilator tubing, extra precautions are required to avoid accidental separation. Nevertheless, transportation on HFOV has been shown to be safe with good planning.[151,152] It is not uncommon for transportation of these mechanically supported patients to be performed by 6 or more staff members. The route between the ICU and the PCCL should be well planned to include how to cross entry and exit doorways, how to enter elevators, and pre-emptive removal of movable impediments along the way to the PCCL. Important details include consideration of whether the head or the foot of the bed should enter the lab first, and on which side of the table the bed should be positioned to facilitate transfer of the patient.

Positioning of the patient may have additional challenges depending on the purpose of the cardiac catheterization. Use of the lateral camera or specific angulation for angiography or intervention may not be possible due to space constraints. It should be recognized that additional TEE imaging may be needed at the time of the catheterization, adding additional ergonomic challenges. Every cath lab has a unique space configuration; thus, careful consideration should be made in advance regarding how to transport the patient into the lab as well as placement of the patient onto the table safely.

13.8. Preprocedural team huddle

In addition to the immediate preprocedure timeout, or "safety briefing" as mandated by the World Health Organization, a team huddle adds additional (ideal) safety elements to a procedure.[153] However, this may not be practical in many institutions. The team huddle should ideally be performed with all team members in attendance and prior to the patient being transported to the cardiac cath lab (which is different from the preprocedure time out). This facilitates all team members being nondistracted by other commitments or patient needs. Checklists are recommended to complement those team huddles, and meant to improve periprocedural management and communication.[27] In fact, the use of a team huddle and World Health Organization-derived safe procedure checklists in the cardiac cath lab (before cases, immediately prior to access, and after cases) has led to decreased radiation exposure, fewer procedural complications, faster turnover time between cases, and improved staff experience.[154]

With the team present, a brief discussion of all relevant clinical information is provided which includes but is not limited to the following: diagnosis and previous procedures/treatments, planned procedure and indication, comorbidities, cardiac/renal/pulmonary function, recent laboratory testing (including pregnancy testing), baseline oxygen saturation, current medications and allergies, in situ lines and devices, laboratory and imaging results, previous access difficulties and planned access sites, type of sedation or anesthesia, potential medications to be

administered (heparin and potential alternative anticoagulation, antibiotics), expected amount of oxygen to be used, need for nitric oxide or inotropic support, potential need for blood, potential AE and their mitigation, known arrhythmias, and need for pacing pads and defibrillation.

If an ICU bed has been requested for postprocedure care, availability should be confirmed at this stage. Some patients, particularly from the adult congenital group, may occasionally have documented advance directives about resuscitation, and if so, this must be clearly noted.

13.9. Preparation for adverse events

The preprocedure team huddle is the ideal environment to discuss the potential AE of a specific procedure. A detailed discussion needs to focus on most likely and important periprocedural risks, potentially needed bailout procedures and equipment, as well as emergency backup activation (extra staff support, code teams, surgical backup, ECMO [Section 9]). Delineation of key roles for personnel during resuscitation and emergencies should be agreed prior to starting a case.

Beyond case-specific preparations, possible AE should also be discussed in team training and/or simulation settings to allow an opportunity for staff to practice protocols and review and discuss any prior events. This includes AE that have significant potential implications, such as cardiac perforation, vessel tear/rupture, stent or device embolization or migration, as well as hemodynamic complications. Preparation for the occurrence of AE and their mitigation may include checklists of equipment that will be rapidly required. All staff members and physicians involved in cardiac catheterization procedures should have formal training in pediatric and preferably adult resuscitation.

13.10. Considerations for ACHD patients

As is the case for pediatric patients, all ACHD interventional procedures should be discussed at regular case management conferences. In addition to the pediatric team as outlined in Section 13.1, it requires participation of ACHD specialists, and depending on the planned procedure type, additional presence of adult cardiologists specializing in structural heart disease or percutaneous coronary interventions. Support from the ACHD team is essential for optimal outcomes in ACHD interventional procedures.

13.10.1. Adult comorbidities and ACHD-specific considerations

A variety of conditions are seen more frequently in ACHD patients and are listed below. However, the same considerations equally apply to affected pediatric patients:

13.10.1.1. Arrhythmia

Adult patients with native and postoperative CHD are at increased risk of both tachyarrhythmias and bradyarrhythmias, which constitutes significant M&M in ACHD patients.[155-158] The ACHD interventional team should have a clear understanding of the potential arrhythmias each patient may have. ACHD patients with arrhythmias should be referred to an electrophysiologist for consultation prior to or at the time of catheterization for appropriate therapeutic strategies. For patients with atrial tachyarrhythmias, consideration of catheter ablation prior to device closure of an ASD is especially important, as access to the left atrium may be more difficult after closure. Appropriate antithrombotic therapy is necessary prior to catheterization and may continue after the procedure.

13.10.1.2. Failing Fontan (single ventricle) physiology

Patients with poor Fontan circulation often rely on a state of high adrenergic tone to maintain adequate cardiovascular hemodynamics. Thus, it is not unusual for these patients to become hemodynamically unstable with minimal sedation and especially inhaled anesthetic agents. Therefore, intravascular volume depletion needs to be avoided, in particular any diuretic overtreatment. However, the highest risk is related to inadequate positive pressure ventilation during the procedure, and mean airway pressure above 7 to 9 cmH2O needs to be avoided. Low-frequency ventilation with as low a positive end-expiratory pressure as possible for passive lung perfusion is important. A sedation/anesthetic regimen to minimize this occurrence and appropriate resuscitation strategies should be well thought out and put in place prior to starting the case.

13.10.1.3. Plastic bronchitis

Hyaline casts produced with plastic bronchitis can cause significant airway obstruction. Even if the patient has minimal respiratory symptoms, airway manipulation including intubation can mobilize casts producing respiratory distress. Consultation with adult bronchoscopy specialists should occur prior to the procedure to discuss the potential need for and timing of bronchoscopy with potential cast removal. These services should also be available throughout the catheterization.

13.10.1.4. Diabetes mellitus

Studies suggest that there is an increased risk of diabetes mellitus in ACHD patients with nearly 40% having impaired glucose tolerance and prediabetes.[159] Strategies to maintain proper blood sugar levels throughout the admission for cardiac catheterization for patients with diabetes should be created in consultation with adult

endocrinologists. Diabetes mellitus predisposes to early vascular and renal disease and patients with diabetes mellitus are at increased risk for contrast-mediated AKI. At least basic strategies for AKI prophylaxis should be instituted during ACHD catheterizations.

13.10.1.5. Chronic lung disease

CLD including restrictive lung disease and chronic obstructive pulmonary disease occurs frequently in patients with ACHD with as many as 45% having abnormal spirometry.[160,161] Abnormal spirometry should be followed by confirmatory formal pulmonary function testing. CLD poses significant risk during complex cardiac catheterizations.[162] A clear respiratory/ventilatory strategy should be created in advance of the procedure and participation by adult anesthesiologists is strongly encouraged. CLD may also potentiate the risk of pulmonary artery hypertension. In patients with severe CLD, intubation during the procedure may lead to prolonged mechanical ventilation postprocedure; hence, maintaining a natural airway with spontaneous respiration, when possible, may be advantageous. Adult pulmonology/critical care should be involved in the patient's postprocedure care.

13.10.1.6. Hypertension

There may be an increased risk of systemic hypertension in patients with ACHD compared with the general population. ACHD patients with renal abnormalities, cyanosis, heart failure, and coarctation of the aorta (unrepaired or repaired) are a particularly at-risk population.[163] Strategies to control blood pressure throughout the admission for cardiac catheterization need to be individualized and should be created with input from the appropriate internal medicine consultant. Systemic hypertension can lead to early vascular and renal disease, thus patients with hypertension are at increased risk for contrast-mediated AKI. At least basic strategies for AKI prophylaxis should be instituted during ACHD catheterizations.

13.10.1.7. Hypercoagulability and anticoagulation

Thrombosis is a common complication in adults with CHD; however, there are limited data on its prevalence. Cyanotic forms of ACHD are a particular risk. Patients with Eisenmenger syndrome and Fontan physiology have up to 33% occurrence of thrombosis; asymptomatic thrombosis is common.[163-166] Management of antithrombotic agents in patients referred for cardiac catheterization needs to be individualized based on patient-specific thrombosis risk and the risks of the planned procedure. In some instances, initiation or continuation of antiplatelet agents will suffice while in the highest risk situations (mechanical valve prosthesis, Fontan physiology, Eisenmenger syndrome, history of thrombosis, etc.), patients may require admission for heparin bridge after discontinuation of oral anticoagulants. Hemorrhage/bleeding occurrences constitute a relatively frequent intraprocedural and postprocedural major complication in CAD and SHD interventions. Thus, there needs to be meticulous attention to clinical and laboratory assessment of bleeding and/or thrombotic complications postprocedure as the patient is returned to an outpatient medical regimen.

13.11. Considerations for resource-limited environments

- Preprocedural planning will usually require detailed case-specific staffing, equipment, and supply arrangements, given that standard resources available often may be insufficient to support a specific planned procedure.
- Such planning also will need to include a detailed discussion with families about the costs of devices and whether in some cases, surgical options may be more affordable.

14. INTRAPROCEDURAL MANAGEMENT

14.1. Time out

As in other procedural settings, a formal "time out" or safety briefing as mandated by the World Health Organization should be performed at the start of the procedure.[153] It should include reconfirmation of the patient's identity, procedural plan, and confirmation of valid consent. This is different from the preprocedural huddle (Section 13.8), and in fact, occurs with the patient being in the cath lab. The preprocedural time out is also a useful opportunity to reconfirm the names and roles of all personnel present. The operator should reiterate any unusual procedural aspects, specific equipment requirements, and other important aspects relating to the procedure. The patient's weight and any existing allergies should also be confirmed.

14.2. Infection prevention

Infectious complications from cardiac catheterization are rare; however, careful sterile technique should be routine.[34] The access site should be appropriately cleaned with an antiseptic solution and sterile draping undertaken. In older patients, the skin may require depilation with clippers or a razor prior to application of antiseptic solution. Operators should undertake careful handwashing and don a sterile gown and gloves. A generally sterile environment should be maintained throughout the procedure with particular attention paid to maintenance of a sterile field for equipment. For hybrid or valve implant procedures, in particular, air quality and sterility are important. As such, special attention should be given to

operator and procedural preparation with a full surgical scrub technique per institutional policy. Wedding rings should be removed for any open chest hybrid procedure. Observers inside the cath lab should be limited in cases with biological implants and a potentially higher risk of infection.

Systemic antibiotics are not administered routinely but reserved for procedures where stents, coils, valves, or other foreign material is implanted, with the most common protocol being cefazolin in 2 divided doses, except in patients who have demonstrated allergy/sensitivity to penicillin/cephalosporin type agents.[167] However, the specific antibiotic administered may vary by institution. Transcatheter valve replacement warrants caution, and considerations should be given to providing 24 hours of antibiotic cover for this group of patients.

Hats, masks, and eye protection protect the operator and assistants from contact with blood splashes and should be worn in the interest of infection control. Care should be taken with equipment to minimize the risk of blood-borne infection. Protocols should be available for testing patients and staff and appropriate follow-up in the event of inadvertent needle stick injury or relevant body fluid exposure. Disposal of all equipment, particularly any equipment exposed to blood/body fluids, should follow local infection control and safety guidelines.

14.3. Hemodynamic calibration

General patient monitoring is discussed in Section 10.3. Hemodynamic data for pediatric patients requires accurate calibration of the transducer; inaccurate calibration can make the difference between a patient being considered a good vs a high-risk candidate for procedures such as Fontan completion. There are multiple methods to assure that the zero level is measured appropriately for each patient, which vary between institutions. It is important to emphasize that repeat calibrations may need to be performed at different times during a procedure, and when any of the obtained parameters are unexpected or do not make sense in the context of a patient's anatomy and physiology.

14.4. Patient positioning

Patient positioning at the commencement of the procedure is important, recognizing vulnerabilities relating to pressure areas, safety, risk of hyperextension (particularly at the shoulders), the need to maintain a sterile field, and preservation of patient body temperature. High-risk pressure areas such as sacrum/coccyx, head, heels, and shoulder blades may require additional protective padding. Intravenous lines and other patient monitoring equipment that will not be easily visible after draping should be carefully checked and secured.

If the patient is under GA, then risks of corneal exposure need to be minimized (for example through eyelid taping), and the risk of nerve compromise or compression due to pressure or position recognized and minimized. While a supine position with arms above the head is the most common positioning of patients in the PCCL, one must be mindful of the risk of brachial plexus injury. Thus regular (every 30-45 min) repositioning and resting of the arms is a worthwhile consideration, in particular in larger adult-sized patients. Arm abduction to ≥90°, particularly when also extended, and concurrent contralateral head rotation and abduction should be avoided.[168] Procedure length and the use of GA are established risk factors for these positional complications.[169]

14.5. Vascular access

A minimum of 1 working peripheral intravenous cannula should be in place at the start of the procedure for administration of fluids and medication as required. Procedural vascular access, particularly in smaller patients and those requiring repeated intervention, can be very challenging. Occasionally, offering a side port of a venous sheath for use by anesthesia providers can be helpful when intravenous access is limited. Where feasible, the use of ultrasound to facilitate access is encouraged and is considered the ideal standard of practice. Local anesthesia when indicated should be administered cautiously through a small needle to minimize vascular distortion.[170] All operators should develop and maintain competency in obtaining vascular access.

Procedural planning should consider minimizing sheath size wherever feasible. Arterial access may be required for monitoring, hemodynamics, or intervention but risks of arterial thrombosis in smaller vessels can be significant. On occasion, vascular access other than femoral should be considered.[30,171-173] Alternative routes such as access via the axillary artery or vein, radial artery, carotid artery, jugular veins, or transhepatic access are frequently needed in patients with CHD. While procedural constraints may necessitate a femoral arterial approach in adult congenital patients, there is evidence supporting the benefit of a radial arterial approach in reducing bleeding and vascular complications in older patients; thus, this approach should be considered where feasible and indicated.[174-177] For some less frequently used forms of vascular access, expertise from interventional radiologists, adult cardiologists, or anesthesiologists may be beneficial.

Many congenital patients have had prior procedures or monitoring via a femoral approach, thus the possibility of vascular occlusion should be kept in mind when considering vascular access. A vascular sheath should be used to minimize vascular trauma in all patients. Coated sheaths,

such as those used to achieve radial access in adult practice, may be valuable in selected cases.[178]

As a general principle, appropriate positioning is crucial to success in vascular access. Tailored approaches to patient positioning may be needed, particularly with nonfemoral access (such as flipping neonates and small infants in the table when neck access is utilized).[29] For femoral access it helps to elevate the pelvis and hips of the child with a small roll and mildly abduct the hips. Having suitable supplies assembled and close at hand is also crucial including suitable wires known to pass through the access needle.[178] A close fit between dilator and sheath is important to minimize vascular trauma.

14.6. Intraprocedural documentation

Formal documentation of the procedure by anesthesia, nursing, medical, and technical staff is mandatory via a written or computerized record (or a combination thereof). All medications administered should be clearly prescribed and signed off by an appropriately qualified prescriber. Documentation will follow local procedural norms but should be sufficiently detailed to accurately describe the hemodynamic condition of the patient throughout the procedure, steps undertaken to perform the procedure, equipment utilized, personnel present, hemodynamic and angiographic findings, and outcome of any intervention performed. Any AE must be clearly documented. Documentation including the formal report of the procedure should be in a format to promote easy access to procedural notes for all relevant health care professionals during the patient's admission and be easily accessible for later review (Section 15.5).[179]

14.7. Image acquisition and retention

The use of radiation is discussed in Section 11. The key images obtained must be available for prompt review and durably stored both for diagnostic purposes and to sufficiently document the procedure. Images must be available postprocedure for review by other professionals involved in the patient's ongoing care and for audit purposes. Long-term storage is important for congenital patients, who may be treated decades later by different providers or facilities, who then may need access to previous cardiac catheterization data. Storage requirements vary between health care settings, but the ideal standard is for images to be stored and available to access for the lifetime of a patient.

14.8. Intraprocedural adverse events

General preparation for AE is discussed in Section 13.9 and the availability of bailout equipment is discussed in Section 7.4. When AE occur, the priority in the management of any AE should be an assessment of patient stability which will dictate what additional resources may be needed. While it is beyond the scope of this document to discuss the technical details of the management of all possible AE, some recommendations can be made:

- Prevention of stroke: The overall risk of stroke (thrombotic or occasionally hemorrhagic) during left heart catheterization/percutaneous coronary intervention in adults is very low (0.2%-0.4%) and in pediatric catheterization, it is even rarer (0.09%-0.16%).[102,180-184] The most important measures to minimize stroke risk and thromboembolism include heparinization (Section 14.10), and the avoidance of air embolism.
- Airway bleeding: With pulmonary artery interventions, the possibility of acute airway compromise that may result from pulmonary artery hemorrhage or high-flow pulmonary edema, necessitating airway evacuation, techniques for hemostasis, thrombolysis, and selective bronchial intubation. Urgent consultation may be needed with interventional pulmonologists and/or otolaryngologists for the comanagement of airway compromise in acute settings.
- Vascular hemorrhage: Congenital interventions frequently involve expanding stenotic vessels and surgical grafts to adult size (coarctation dilation/stent, pulmonary artery dilation/stent, conduit stent placement, etc.). Rarely these procedures may result in vascular injury with extravasation of blood, which can be devastating, and survival may depend on temporary balloon occlusion followed by rapid implantation of covered stent/grafts to control the hemorrhage.

14.9. Intraprocedural drug administration

All solutions on the table should be labeled and drawn up in standard and agreed concentrations. Preprinted labels for common medications are useful in drape kits.

- Contrast agents: AE related to contrast administration (such as allergic reaction, fever, contrast-induced nephropathy or seizures, thyroid dysfunction) are well documented in adults although the use of newer, more soluble iodinated contrast agents has greatly reduced their incidence. Congenital catheter intervention may however require multiple angiograms. Contrast load per kilogram of patient weight can rise quickly, particularly in infants and small children. Larger contrast doses are however usually administered over longer procedure times. A review study found that, even with doses greater or equal to 6 ml/kg, AE related to contrast administration were extremely rare.[141]
- Local anesthetic agents: Local anesthetic agents are frequently used to decrease pain at vascular puncture sites. The agent most frequently used has been lidocaine/lignocaine but on occasion, other agents are used such as lidocaine-prilocaine cream, bupivacaine, or

prilocaine.[185,186] The risk of inadvertent intravenous or intra-arterial injection should be recognized and dose limits adhered to in order to avoid inadvertent toxicity.[187] In selected patients, consideration should be given to use of long lasting local anesthetics in the groin after the procedure.

- Heparin: Marked reduction in the incidence of thrombosis and thromboembolism can be achieved with heparinization which should be standard practice during almost all cardiac catheterization.[178] It is usual to commence pediatric procedures with a 50 to 100 U/kg bolus although solid data are limited to determine the exact effects of different dosing regimens for unfractionated heparin in this setting.[188-191] Hemodilution with fluid administration and premedication with aspirin may reduce the ACT achieved.[192] For procedures that are anticipated to be brief, particularly those confined to the right side or subpulmonic circulation, this dose may be reduced or not necessary. The risk of arterial thrombosis is increased in small children and infants, with use of larger or longer sheaths and prolonged procedure times.[193] Heparin dosing should be carefully monitored via ACT, the target ACT usually being 200 to 250 but determined more specifically with knowledge of the procedure planned (in left heart catheterization in adults usual target ACT is >250, but vascular closure devices are much more frequently used in adult patients). In situations of heparin-induced thrombocytopenia, there are limited data that can guide substitution with bivalirudin or argatroban.[194-197]
- Antibiotics: See Section 14.2.
- Dobutamine testing: Reference protocols are available which outline standard indications for dobutamine testing which may include assessment for possible ischemia and evaluation of contractile reserve. A common use of dobutamine testing in the pediatric population also includes the assessment of aortic valve or aortic arch gradients in patients under anesthesia, in whom baseline hemodynamic measurements do not support transcatheter intervention. Monitoring of cardiac rate, rhythm, and hemodynamic stability should be continuous, with staff present able to respond promptly and appropriately to any concerns as they arise.[198,199]
- Fluid challenge: Fluid challenge is most commonly undertaken in the setting of pulmonary hypertension or heart failure evaluation to assess the degree of diastolic dysfunction. In adults, the most common protocol is the rapid infusion of 500 ml of isotonic solution (0.9% saline).[200]
- Pulmonary vasodilator testing: Pulmonary vasodilator testing may be undertaken in the setting of pulmonary arterial hypertension meeting the standard definition, ie, mean PAP >20 mm Hg or pulmonary vascular resistance >3 Wood Units*m^2, confirmed at invasive catheterization[201] or on occasions in the setting of single ventricle complex CHD. The risks associated with catheterization should be recognized particularly in the pediatric setting where sedation/GA is likely to be required. Risk factors for AE include GA and patients in higher functional class.[77,202] Inhaled nitric oxide at 10 to 80 ppm is the preferred agent, even though intravenous sildenafil has been used in some settings.[203] The Sitbon criteria for positive acute response are defined by a decrease in mean pulmonary artery pressure by at least 10 mm Hg to a value of <40 mm Hg with maintained or increased cardiac output.[204] However, PAP should always be interpreted in relation to the corresponding systemic blood pressure.

14.10. Vascular hemostasis

In pediatric practice, it is common to obtain hemostasis by direct pressure once sheaths are removed at the end of the procedure. In larger patients, with larger sheaths, closure devices or a "figure-of-8" suture may be considered, although the need for repeated access to the vessel and size of the vessel may limit their use in smaller pediatric patients. With larger sheaths, careful consideration should be given to the reversal of heparin with protamine. In adult practice, studies generally show that the use of closure devices is noninferior with respect to access site complications. The infection rate may be higher but time to hemostasis and earlier ambulation may offer advantages.[205]

14.11. Considerations for ACHD patients

Vascular access and hemostasis in ACHD patients are often complicated by a greater risk of vascular calcification and arterial vascular occlusion, which will need to be taken into consideration for preprocedural planning as well as decisions about postprocedural hemostasis.

15. POSTPROCEDURAL MANAGEMENT

The removal of vascular sheaths may represent the conclusion of the cardiac catheterization procedure, but additional care pathways are necessary to ensure a safe transition to full patient recovery. Different recovery pathways postprocedure are necessary for patients who receive procedural sedation as compared to GA. The 2001 joint ACC/SCAI Expert Consensus Document on cardiac cath lab standards as well as the 2012 update are sparse in their recommendations for the congenital cath lab and do not address postprocedural issues.[1,111] While the 2021 SCAI expert consensus update on best practices in the cardiac cath lab does not contain specific recommendations regarding congenital cardiac catheterization,

postprocedural best practices are discussed which are generalizable to the congenital cath lab.[2]

15.1. Patient destination

After sedation/analgesia, patients should be observed and monitored in an appropriately staffed and equipped recovery unit until they are near their baseline level of consciousness.[74] The exact patient destination site postcatheterization will vary from 1 cardiac center to another depending on the location of the catheterization suite relative to the primary recovery area. Generally, in the pediatric hospital, the recovery area is specialized for the care of pediatric patients although at some centers, shared resource utilization may result in a more general recovery area for patients of all ages. Some catheterization laboratories may have a dedicated and staffed recovery area while others may rely on transfer to a common PACU. Phase 1 postanesthesia recovery allows for close monitoring as the patient fully recovers from anesthesia and vital signs return to baseline. The catheterization vascular access sites require monitoring for rebleeding and assessment of distal perfusion.

After all phase 1 priorities are met, phase 2 recovery proceeds during which preparations are made for hospital discharge or transfer to an inpatient unit. Any inpatient units accepting postcatheterization patients should ideally have cardiac telemetry capabilities. If a patient is transferred to an ICU after the procedure, this is usually done directly without PACU recovery, although in some settings the anesthesiologist may prefer to undertake phase 1 recovery closer to the procedural area prior to transfer to the ICU.

Direct transfer from the catheterization suite to an intensive care setting may occur if the procedure time and exposure to anesthesia are prolonged, large volumes of blood products are given during the procedure, vascular injury/disruption/hemoptysis is encountered, significant arrhythmia occurs during the procedure, or if it is felt that delayed extubation would be in the patient's best interest.

Infants with systemic to pulmonary shunts or ductal stents are ideally best served with postcatheterization recovery in the ICU, even if the cardiac catheterization procedure was completely uneventful. The same applies to patients with a higher hemodynamic vulnerability score, coronary abnormalities, or specific underlying higher-risk genetic conditions such as Williams-Beuren syndrome. If there is uncertainty as to the proper area for postcatheterization recovery, it would be prudent to select the care area which allows a higher level of care should escalation be required. A list of those patients and procedures that should be considered for overnight observation is listed in **Table 15**.

15.2. Patient handoffs/transfer of care

Communication to the next care team following a catheterization procedure should be clear, distraction-free, consistent, and comprehensive. Such communication should summarize the patient's diagnosis/history and details of the procedure, including complications and potential issues that may occur in the recovery period. Communication should be 2-way with all involved in the handoff expected to contribute openly and actively.

The benefits of a structured patient handoff/transfer of care process from the procedural suite to the next care area have proven to be significant. EMR-based, checklist, electronic, and family-assisted methods have been described with improved communication and patient safety results delivered. Processes such as I-PASS, Six Sigma, and "Situation-Background-Assessment-Recommendation" have been developed to standardize the patient handoff process.[206-209] Ideally those physically present at the initial patient handoff from the catheterization suite should include the proceduralist, anesthesiologist or nonanesthesiologist responsible for overseeing procedural sedation, procedural nursing staff, respiratory support staff, and receiving physicians and nurses. Inclusion of trainees in this process is encouraged to develop these habits for patient safety. A written/EMR-based brief procedure summary to direct immediate postprocedure care should be created prior to transfer to the initial recovery area. Information should include the vascular access sites used, procedures performed, a brief summary of findings/interventions, complications encountered, necessary postprocedure imaging or blood tests, anticoagulation plan following the procedure, new indwelling lines placed to be used postprocedure, and any new medications to be started. Also included should be information regarding difficulties encountered during endotracheal intubation or with maintaining a patent airway during sedation. A full accounting of all anesthesia/sedation drugs should be given with emphasis placed on the potential for residual effects such as prolonged sedation or residual neuromuscular blockade. If prophylactic treatment for nausea/vomiting was administered, these medications should be reported to the receiving team.

15.3. Postprocedural monitoring

Patients with CHD who require cardiac catheterization generally have higher Anesthesiologists Physical Status which may influence their risk both intraprocedurally as well as during procedural recovery. Young age and preexisting pulmonary hypertension are among those risk factors for severe AE associated with cardiac catheterization.[69,77,208,210] In 2016, SCAI, the Congenital Cardiac Anesthesia Society, and the Society for Pediatric

TABLE 15 Procedure Types and Patient Characteristics That May Benefit From Overnight Admission and Monitoring Postprocedure

Procedure types	Patient characteristics
■ Angioplasty ■ Stent implantation ■ Valve implantation ■ Closure of atrial septal defect or ventricular septal defect ■ Vascular or valvar perforation procedure ■ Transseptal puncture ■ Hybrid procedures	■ Age <1 mo ■ Hemodynamic vulnerability score ≥2 ■ Catheterization risk score in pediatrics ≥5 ■ Patients with systemic to pulmonary shunts or ductal stents ■ Pulmonary atresia with intact ventricular septum with coronary anomalies ■ William-Beuren syndrome ■ Biventricular outflow tract obstruction ■ Patients on vasodilator therapy for pulmonary hypertension ■ AE that require monitoring

AE, adverse event(s); PA-IVS, pulmonary atresia with intact ventricular septum.

Anesthesia (SPA) published a joint expert consensus statement for anesthesia and sedation practice for patients undergoing congenital catheterization procedures, and several recommendations in this document are adapted from this.[27]

Postprocedural monitoring should include ECG, continuous pulse oximetry, and periodic blood pressure checks. The patient's respiratory status must be closely monitored during phase 1 recovery. The transition from positive pressure ventilation to spontaneous breathing in the sedated patient requires monitoring for subsequent airway obstruction or hypoventilation. There should be continuous monitoring of arterial oxygen saturation with pulse oximetry during phase 1 recovery. The baseline systemic saturation prior to the procedure should be known for those patients with cyanotic heart disease.

Large fluid shifts may be encountered in patients presenting with fluid deficits due to preprocedural nil-by-mouth status. In infants, attention should be paid to fluids administered as both infusions and catheter flushes. Infants undergoing vascular interventions within the peripheral pulmonary arterial and venous trees may experience hemorrhage into the airways. Blood returned during airway suctioning should merit vigilance, especially in an anticoagulated patient. Additionally, dilation of the pulmonary arterial vasculature may induce pulmonary reperfusion injury and pulmonary edema which may become apparent in the postcatheterization recovery period. Furthermore, certain medications used during sedation/anesthesia such as ketamine may increase oral secretions.

Vascular access sites used during the catheterization procedure should be monitored frequently during recovery regardless of the sizes of hemostatic sheaths used. Distal limb perfusion and vascular congestion should be monitored diligently and consistently. If elastic compression bandages are used, it may be more difficult to evaluate the access sites due to the opacity of the adhesive dressings. Ideally, deep compression of vessels for long lengths of time should be avoided to prevent thrombotic consequences of cessation of blood flow. Postcatheterization arterial thrombosis pathways should be developed to allow early detection and initiation of antithrombotic therapies. Organized postprocedure vascular thrombosis therapeutic pathways have proven to be successful at maintaining vascular patency.[211]

Access to vascular ultrasound can be helpful in selected cases to determine the presence of any acute intravascular thrombus and to determine the next steps should intravenous anticoagulation measures need to be initiated. However, caution needs to be applied in interpreting the ultrasound images of a vessel where recent manual hemostasis was applied, as findings are never completely normal immediately after a procedure. Equally important is to involve an imaging specialist experienced in interpreting pediatric vasculature after cardiac catheterization procedures, to avoid misinterpreting the images, which could result in unnecessary commitment to longer courses of anticoagulation. Even more important than vascular ultrasound is a clinical comparison of the limb perfusion and pulses between both sides. The possibility of compartmental or intraperitoneal hemorrhage must be considered if hypotension or instability occurs following cardiac catheterization. In adult patients, the use of vascular compression and closure devices is common. Regardless of age, if there is concern for distal limb perfusion (with a side difference on clinical examination) or pseudoaneurysm formation, vascular ultrasound can be helpful in diagnosis. If critical limb ischemia is encountered, vascular surgery or interventional radiology consultation should be considered.

Following particularly long cases, intentional evaluation for pressure injuries and brachial plexus injuries is important. For those patients receiving implantable occlusion devices or stents, a CXR prior to discharge may be considered to document device position, as it then allows a comparison when a patient receives a subsequent CXR at an outside institution without echo services (a saved fluoroscopy image in straight anterior-posterior [AP] and lateral position can serve a similar purpose). For those interventional procedures involving device placement and an overnight in-hospital stay, a predischarge echocardiogram should be performed to verify the appropriate device position.

Although less common than in adults, intravenous contrast exposure may lead to allergic reactions or acute renal injury. Monitoring renal function and instituting postprocedural hydration strategies may be needed for those patients who received larger doses of contrast. Administration of 6 mL/kg of contrast would be considered a large dose for short procedures, while larger doses of up to 10 mL/kg could be administered for long procedural durations. For these patients, a formal evaluation of renal function following the procedure may be needed.

Acute neurologic changes should be assessed frequently following a catheterization procedure. If encountered, this should result in quick escalation to determine the cause. While some findings may be related to residual effects of agents used to provide sedation or anesthesia, the possibility of an acute embolic event resulting in stroke should always be considered. Quick access to emergent CT scanning and MRI capabilities should be available. Ideally, availability of subspecialties in neurology, neuroradiology, neurosurgery, and intensive care should be organized to function as a formal "stroke team."

15.4. Bedrest guidelines

The medical literature is sparse with respect to ideal bedrest times, although previously held beliefs have been challenged suggesting that vascular rebleeding complications may not be increased with shorter bedrest times.[212] Recommendations for lie flat times post cardiac catheterization vary widely from institution to institution and can be as short as 2 to 3 hours, even though 6 hours is a more commonly used time adopted at many centers. Factors influencing bedrest guidelines include variable use of intraprocedural anticoagulants with a variety of therapeutic targets, intravascular sheath sizes used, as well as the expectation of unwanted physical activity in the recovery area depending on patient age or developmental disabilities. A wide variety of vascular closure devices have been developed to reduce postprocedural rebleeding events at sheath insertion sites and to accelerate the time to ambulation postprocedure to as little as 1 to 2 hours. Discussion of the merits and potential disadvantages of each device is beyond the scope of this section, but undoubtedly the use of these devices continues to gain favor, particularly for those procedures in larger patients using large bore sheaths such as aortic coarctation stenting and transcatheter pulmonary valve implantation. However, there may be situations such as with patients who cannot cooperate due to significant developmental disabilities or anxiety where prolonged sedation may be necessary to prevent access site rebleeding events.

15.5. Structured procedure reporting

With the emergence and establishment of the EMR as the major repository of patient medical information, a health policy statement for structured reporting in the cath lab was created as a cooperative effort of the ACC, AHA, SCAI, and a broad range of additional medical societies in 2014.[179] Ideally, the final catheterization report should be "clear, concise, organized, consistent, reproducible, understandable, and in a format that is flexible to accommodate evolutionary procedural changes and documentation requirements."[179] The wide breadth of procedures performed in the congenital cath lab makes information capture as discrete data elements rather than free text prose more difficult compared to reports generated for procedures such as coronary interventions.

There have been efforts to standardize the nomenclature into a controlled vocabulary to be used in CHD.[96,97] Fundamentally, the structured congenital catheterization report should reflect the indications for pursuing the procedure, the entire scope of the procedure performed from patient room entry to exit, the condition of the patient at the beginning and end of the procedure, the tools used to achieve completion of the procedure, salient interpretation of hemodynamic and angiographic findings, and include a record of specifics of implanted devices for tracking. Summary details should be provided so other health care providers can easily understand indications, outcomes, and complications encountered. The full procedure report should ideally be completed and verified within 24 hours of the procedure, although 48 hours can be considered an acceptable standard. In some EMR systems, embedded links can be created to access the final catheterization report as well as the radiographic images.

15.6. Procedure logs

It is important to maintain an up-to-date log of all cases occurring in the cardiac catheterization labs. Whether the data are maintained through written logbooks, electronically through hospital databases, as a component of the hemodynamic monitoring software system, or through internal and external registries, the activities of the cath lab, individual physician information, and documentation of AE (Section 12) should be registered.

15.7. Outpatient discharge planning and instructions

A significant proportion of patients undergoing congenital cardiac catheterization will be able to be discharged to home the same day, including some patients undergoing interventional procedures. The timing of outpatient discharge to home will vary depending on the procedure performed, level and type of anticoagulation at the conclusion of the procedure, the type of vascular access used, and any postprocedural tests that need to be performed prior to discharge. The patient should have completely recovered from sedation/anesthesia, have returned to baseline respiratory status including baseline oxygen saturation, and have been able to tolerate enteral

fluid intake. The vascular access sites should be free of expanding hematoma and the perfusion of those structures associated with the access sites should not be compromised. If there is any doubt as to the stability of the patient, inpatient overnight observation should be the default.

Patient and family education is a major component of the discharge process. Communication should be in the language of the patient's/family's preference and medical interpretation services should be readily available. Medication reconciliation should be performed, and any new medications prescribed should be thoroughly reviewed with the patient/family. Verbal and written instructions after catheterization should be provided. These should include age-appropriate instructions for vascular access site monitoring, expectations after GA/sedation, appropriate medications for pain control, specific instructions after implanted devices including registration cards, MRI-compatibility of implanted devices, and the need for subacute bacterial endocarditis antibiotic prophylaxis measures. Should concerns arise from the patient or family after discharge, instructions on how to alert the catheterization team should be provided along with follow-up instructions with the primary care provider and referring cardiologist. Communication with the referring cardiologist can be by direct communication, secure electronic methods, or preferably a combination of both. One should consider seeing most patients within 4 to 6 weeks of the procedure (in particular, larger patients who received a cumulative air kerma of >2 Gy), while some patients will require earlier follow-up after 1 to 2 weeks. This includes for example patients with large ASD devices, patients where large sheaths were used, or patients who had an AE in the cardiac cath lab or during postprocedural recovery that requires closer follow-up.

15.8. Considerations for ACHD patients

- For all ACHD patients undergoing cardiac catheterization, the ACHD team needs to be involved in the periprocedural care of the patient.
- Postprocedure consultation by internal medicine specialists regarding the management of any significant comorbidities should be considered.
- Predischarge cardiac imaging should be performed by ACHD imagers.
- Follow-up with ACHD team providers should be arranged.

16. PROCEDURES REQUIRING SPECIFIC PREPARATIONS AND SETUP

16.1. Hybrid procedures

16.1.1. Types of hybrid procedures

Hybrid procedures combine surgical and interventional techniques, specifically intraoperative stent placements,[213] perventricular VSD closure,[214,215] balloon valvuloplasty,[216,217] intraoperative placement of transcatheter valves,[218,219] and hybrid palliation of HLHS.[220-222] Broadly speaking, hybrid procedures can be classified as follows: (1) adjuncts to traditional surgical interventions, (2) alternative forms of vascular access to aid transcatheter interventions, and (3) true hybrid procedures that offer alternative treatment options to traditional surgical or catheter-based approaches.

Adjunct to surgical interventions

For some surgical procedures, adding a transcatheter intervention can simplify the surgical course. Examples include intraoperative stenting and/or balloon angioplasty/valvuloplasty during surgery to repair Tetralogy of Fallot.[223-225] Other examples include hybrid or "exit" angiography performed after any type of surgical repair followed (or not) by directed interventional therapy as needed, or intraoperative stent placement performed at the time of pulmonary valve replacement.

Alternative forms of vascular access

For some transcatheter interventions, vascular access with help from a surgeon can be advantageous due to patient size, anatomy, or lack of standard access points. Historically, this includes, for example, a direct carotid artery cutdown[226] and a limited sternotomy to directly access a cardiac structure or great vessel.[224,226] Interventions that can be performed using such forms of alternative vascular access include aortic valvuloplasty, coarctation stenting in neonates and infants, and PDA stenting through carotid cutdown,[171,227,228] as well as pulmonary valve perforation and/or pulmonary valvuloplasty, stenting of the RVOT, and VSD closure through direct (per)ventricular cardiac access.[224,229-232]

More recently, carotid cutdown has been less frequently used and some centers are now preferring direct percutaneous access of the carotid artery, which has been shown to have excellent success rates.[172] However, whether the risk of carotid artery thrombosis with potential thromboembolism and stroke is the same as surgical carotid cutdown and subsequent repair of the vessel is difficult to determine given the low incidence of stroke following cardiac catheterization. Many operators for this reason may still prefer carotid cutdown as opposed to direct puncture, or an axillary artery approach.

Unique hybrid treatments

These hybrid procedures change the management strategy of a patient by combining surgical and transcatheter techniques to achieve an outcome that would not be feasible using either technique alone. An example is the hybrid palliation for HLHS, which consists of bilateral

TABLE 16 Recommended Environments For Specific Hybrid Procedures

Procedure	Environment	
	Acceptable	Ideal
Adjunct to surgical intervention	OR	Hybrid OR
Alternative form of vascular access		
Carotid cutdown for BAV or PDA stent, coarctation stenting, VSD closure	Cath lab	Hybrid cath lab
Perventricular VSD closure	OR Hybrid Cath lab	Hybrid OR
Perventricular BPV/stenting of RVOT	Cath lab Hybrid OR	Hybrid cath lab
Unique hybrid treatments		
Hybrid stage I palliation	OR	Hybrid OR Hybrid cath lab
TPVI with PA plication	OR Hybrid Cath Lab	Hybrid OR
Intraoperative open placement of a balloon-expandable transcatheter valve	OR	Hybrid OR

BAV, balloon aortic valvuloplasty; BPV, balloon pulmonary valvuloplasty; PA, pulmonary artery; PDA, patent ductus arteriosus; OR, operating room; RVOT, right ventricular outflow tract; TPVI, transcatheter pulmonary valve implantation; VSD, ventricular septal defect.

pulmonary artery banding (or placement of flow restrictors) and ductal stenting through either direct access of the main pulmonary artery or percutaneously when flow restrictors are being used.[221,222,233] Another example is intraoperative implantation of a balloon expandable transcatheter valve in mitral position in small children,[218,219] as well as banding or plication of a dilated main pulmonary artery to facilitate catheter-based pulmonary valve implantation.[234-236]

16.1.2. Environments for hybrid procedures

Hybrid procedures can be performed in a variety of environments and settings. The choice of location depends on the type of hybrid procedure being performed, and the specific equipment and imaging demands of the interventional and surgical teams (Table 16). Decisions about location must be informed by the availability of staff, equipment, and optimal fluoroscopic imaging (single vs biplane). Regardless of location, careful planning is needed in advance for each hybrid procedure, to ascertain that all potentially needed equipment and staff is available.

Intensive care unit setting with the use of a portable C-arm

This is the least desirable location for hybrid procedures and should be reserved for truly emergent procedures without other alternative options. Limitations relate to the ability to use a C-arm without the interference of beds and other structures, the nonsterile ICU environment, and staff generally being unfamiliar with the performance of complex procedures. However, for some very unstable patients who require immediate treatments this setting may be the only viable option in which to perform a procedure, in particular when an ICU has a dedicated procedure room.

Standard surgical operating room

While this location is ideal for completion of the surgical components of a hybrid procedure, its utility is limited for procedures where fluoroscopy needs are anticipated. Room size is often limited, and surgical tables often interfere with portable C-arm positioning and are usually not radiolucent. In addition, circumnavigating the cardiopulmonary bypass circuit, anesthesia equipment, and surgical trays can be challenging. Nonetheless, for hybrid procedures that do not rely on fluoroscopy such as some forms of open intraoperative stent placement under direct vision or many perventricular VSD closure procedures, this location may be adequate.[226,229,235-238] However, even for these procedures, it is not ideal since there is no capacity for postintervention imaging (exit angiography), which has been shown to be an invaluable tool to immediately assess surgical repair to allow treatment of residual pathology in a hybrid fashion if needed.[239]

Standard congenital cardiac catheterization laboratory

A standard congenital cardiac cath lab does offer the advantage of biplane fluoroscopy. However, the space in many cardiac catheterization laboratories is extremely limited, often just a little over 400 square feet (37 square meters) for the procedure room itself. This severely limits the ability to accommodate a bypass circuit or additional surgical trays and teams. Gas supply for a bypass circuit may be limited, and the setup of monitors is often not adequate to allow operators at different sides of the table to see the fluoroscopic images. A standard cardiac catheterization table does not offer the same right/left tilt and head up/down positioning of a surgical table and is also often more difficult (if not impossible) to lock securely. Furthermore, a standard cardiac cath lab may not offer the same level of sterility and room gas exchanges that are provided in a surgical OR.

Hybrid operating room

A dedicated hybrid OR is generally a good location for performing hybrid procedures.[240,241] When compared to a hybrid cath lab, disadvantages are the single plane setup, as well as the lack of a dedicated monitoring room and hemodynamic monitoring system. Furthermore, the table in a hybrid OR is designed primarily to accommodate surgical procedures and often has less radiolucency in some areas than a dedicated cardiac catheterization table.

However, it does offer the advantage of easily facilitating conversion to a regular cardiothoracic surgical procedure in cases where the hybrid procedures fail (such as failed attempts at perventricular VSD closure), which would be more cumbersome in a hybrid cardiac cath lab. It is beyond the scope of this section to provide the specific requirements for a hybrid cardiothoracic OR.

Hybrid cardiac catheterization laboratory

A hybrid cardiac cath lab is the ideal environment for most hybrid procedures, except those where the hybrid procedure is an adjunct to a more complex surgical intervention (and where a standard or hybrid OR would be more suitable). It usually offers a monitoring room, a hemodynamic monitoring system, and biplane imaging. Although a biplane system is ideal, it is important to emphasize that many hybrid catheterization laboratories utilize a single-plane x-ray source with rotational angiography capabilities that facilitates tomographic reconstruction of acquired images. The exact specifications for a hybrid PCCL are further discussed in Section 7.1.4.

16.1.3. Staffing

Personnel for hybrid procedures should include all members of the surgical and catheterization teams necessary to perform their individual procedural tasks. Additional staff may be needed to obtain equipment during a procedure that is not available in the specific hybrid environment. In addition, staff should be trained on how to work in a confined space as part of a larger team. Simulations using all equipment and staff members are recommended to familiarize everyone with the location and positioning of equipment, and with anticipated movement patterns of staff.

Teamwork is of utmost importance. What may be obvious standard practice for a surgical team, such as direct cardiac defibrillation, may not be the case for the interventional team and vice versa. Consequently, planning for these procedures and “dry runs” or simulations are necessary to allow identification of areas where team assumptions may not be aligned with reality.

16.1.3.1. Hybrid palliation of hypoplastic left heart syndrome

Beyond the general requirements for hybrid procedures, additional considerations apply to programs planning to offer hybrid palliation for patients with HLHS and similar anomalies. While there exist many technical variations of this treatment paradigm (including a fully percutaneous approach[240]), the one element most of these approaches have in common is that the ultimate outcome is determined to a large extent by the management and outcome of the interstage period.[241] It is recommended that only larger tertiary centers that have sufficient preprocedure and postprocedure experience with Norwood and Sano-type palliations, should embark on starting such a hybrid program. Exceptions include high-risk patients for whom no other surgical option can be offered and patients where the hybrid palliation is considered a last resort or rescue procedure. Given the potential problems after hybrid Stage I palliation, such as retrograde arch obstruction, atrial level restrictions, and PDA in-stent stenosis, follow-up after hybrid Stage I palliation should ideally be limited to a few cardiologists with accumulated experience within a center.

16.1.4. Equipment and other requirements

Hybrid procedures utilize a variety of equipment in different environments. When a C-arm is utilized, staff needs to be trained in using the C-arm, including calibration options, playback, and image storage. Because other specialties may require use of a C-arm for their procedures, a clear workflow needs to be established to ensure availability of the C-arm for a scheduled hybrid procedure. When hybrid procedures are performed in the OR, contingencies for in-room storage of lead shields and aprons and frequently used basic catheter equipment must be made. Workflows to obtain equipment that is needed during a procedure, but not routinely kept in the hybrid environment, must be established.

Conversely, hybrid procedures performed in a cardiac cath lab environment will require storage of some basic surgical trays and other equipment in that location. To support procedures such as perventricular VSD closure, a variety of transesophageal echo probes should be available to be employed in patients of different sizes and ages. In addition, where applicable, echocardiography machines should be equipped with the transducers necessary to obtain epicardial imaging.

16.2. Procedures in premature infants

Premature infants, especially those in the VLBW category (<1500 g) represent some of the most fragile patients undergoing cardiac catheterization and intervention. Procedures include but are not limited to the following:

- Closure of a hemodynamically significant patent ductus arteriosus in premature neonates (accounting for more than 95% of cardiac catheterization procedures performed in this patient category)
- Balloon valvuloplasty or angioplasty for obstructive lesions such as critical AS or PS
- Critical coarctation of the aorta requiring palliative dilation due to severely depressed left ventricle (LV) function or patient size deemed too small for surgical repair
- Atrial septal interventions for heart lesions requiring unrestricted atrial level communication to promote mixing (transposition of the great arteries) or

decompression of the atrium (HLHS with a restrictive atrial septum)
- Ductal or RVOT stenting to augment pulmonary flow (such as in patients with Tetralogy of Fallot)
- Ductal stenting to augment systemic output for single ventricle lesions (such as hybrid palliation of HLHS)
- Vascular access for any medical condition when umbilical and other vascular access sites are unavailable
- Retrieval of broken and embolized central venous and other lines

16.2.1. Preprocedure considerations in premature infants

A thorough preprocedure discussion involving at a minimum the teams of anesthesia, neonatology, cath lab, and cardiology should be standard to review all the specific needs of the infant prior to going to the cardiac cath lab. To minimize the time in the cardiac cath lab, some programs arrange for endotracheal intubation and appropriate intravenous access to be obtained by the NICU staff prior to transportation to the cardiac cath lab. This also has the advantage of avoiding unnecessary fluctuations of the oxygen level secondary to preoxygenation prior to intubation, which often can significantly change the size of the duct at least temporarily, and can complicate procedures such as PDA closure or PDA stent placement. Equally important is to educate the neonatal team that right femoral venous access is preferred for many of these procedures in premature infants, and peripherally inserted central catheter lines that are needed should preferentially be placed on the left side (ideally upper limb). Elective preprocedural transfusion of packed cells may be considered for those determined to be anemic.

16.2.2. Transport and catheterization laboratory preparation for premature infants

Transportation of the VLBW infant is a complex undertaking due to their fragile physiologic state, particularly with regard to the ability to maintain core temperature.[242] Institutions performing catheterizations on premature infants should develop a protocol and checklist to ensure comprehensive pre-cath preparation and safe transportation to and from the cardiac cath lab.[243] Ideally, the neonatologist should accompany the infant during transportation (in addition to the anesthesia team) and help manage the respiratory system, especially for more fragile infants and those on high-frequency oscillatory ventilation. Furthermore, to optimize care inside the cardiac cath lab, some centers may ask for a neonatologist and neonatal nurse to be present throughout the case, in addition to the dedicated pediatric cardiac anesthesia team.

The transporting isolette should have warming features and a full power supply for roundtrip transportation. Additional backup warmers for transportation might include chemical warmers. The ambient temperature in the cardiac cath lab should be increased to at least 23-24 °C (75-76 °F). Forced air warmers, heat lamps, warmed blankets, and IV fluid warmers should all be utilized as the patient is settled onto the cardiac cath lab table. Plastic wraps can be used to cover the head and body of the infant to further maintain core temperature as well as to minimize insensible fluid losses. Plastic wraps also allow for continuous visual monitoring of the infant.

16.2.3. Intraprocedural consideration for premature infants

Diluting contrast with saline may help minimize nephrotoxicity for those with renal dysfunction, as well as reduce the risk of contrast-induced hypothyroidism, and the performance of PDA occlusion procedures with echocardiographic guidance only should be considered.[244,245] Heparin should be avoided in selected cases with higher risks of intracranial hemorrhage. Maintenance of homeostasis in this high-risk group requires detailed assessment and constant monitoring. A vigilant multidisciplinary approach utilizing a standard protocol and checklist can mitigate AE. Guidelines to prevent and manage complications in premature infants for selected procedures such as PDA occlusion have been published.[246-250]

16.3. Procedures done outside the congenital catheterization laboratory

When patients are too unstable to be transported to the PCCL, cardiac catheterizations and intravascular procedures may need to be performed by pediatric interventional cardiologists outside of the PCCL, most commonly in the pediatric and neonatal ICU. These procedures may include diagnostic cardiac catheterization including placement of a catheter for pulmonary artery pressure monitoring, aid with ECMO cannulation, and pericardiocentesis or pleurocentesis with or without drain placement. Other procedures include balloon atrial septostomy under echocardiography guidance,[247,251-254] as well as transcatheter PDA closure in selected premature infants.[244,245] Requirements vary greatly between cases and improvisation in these non-PCCL environments is usually needed. Ideally, procedures performed in these vulnerable patient populations using echo guidance should have immediate availability of a fluoroscopy unit in case of any complication arising.

Other procedures that occasionally require performance outside the congenital cardiac cath lab include procedures in interventional radiology, electrophysiology, or neuroradiology environment. Whenever cooperation with a discipline beyond interventional congenital cardiology is required, careful advance planning with all team members involved is needed, to decide the best

location for a procedure. These decisions and procedural planning need to consider the required imaging equipment, software applications, need for hemodynamic monitoring, and staff experience as well as the equipment that may be needed during the procedure. Most importantly, workflows for emergencies need to be defined in advance, so that all team members know how to get support if needed, and to ensure emergency bailout equipment is readily available when operating in a nonfamiliar environment.

16.4. Fetal interventional procedures

While fetal cardiac interventions were first reported in 1991,[255] it was not until the 2000s, due to work at Boston Children's Hospital and later at the Hospital for Sick Kids in Toronto and centers in Brazil, that this approach became more commonplace.[256-260] Currently, performed fetal cardiac interventions are:

- Balloon valvuloplasty of the aortic valve in severe AS
- Atrial septal stenting in HLHS with intact or highly restrictive atrial septum
- Less commonly, perforation and balloon valvuloplasty of the pulmonary valve in pulmonary atresia with intact ventricular septum

Because the mother is considered the primary patient, these procedures are typically performed in the obstetric suite or an OR. The procedure requires a dedicated multidisciplinary team including at a minimum a maternal-fetal-medicine specialist, an anesthesiologist to care for the mother (and the fetus), a fetal echocardiographer to guide the intervention, and a pediatric cardiac interventional cardiologist. In general, performance of fetal cardiac interventions is beyond the capabilities of most CHD programs. There are ongoing studies of medium- and long-term outcomes following these interventions and the field will continue to evolve as new data are generated.[261-263] It should be emphasized that the degree of technical difficulty and goals of the currently available fetal cardiac interventions vary greatly.

- The goal of fetal aortic valvuloplasty is to achieve a postnatal biventricular circulation (and to recompensate the LV in critical AS) recognizing that these children will require multiple additional surgeries and interventions over many years. This prenatal procedure is only the beginning of a long and often difficult pathway of prenatal and postnatal decision-making which requires the commitment of the cardiac surgical, critical care, and anesthesia teams to follow standardized postnatal management plans in order to truly reach clinical success in the long term.[264]
- For fetal atrial septal stenting, the goal is to decompress the pulmonary venous atrium and relieve pulmonary venous hypertension to optimize lung function prenatally with the intent to optimize survival following a postnatal Norwood operation. Technically, this is the most difficult among the fetal cardiac interventions due to the need for precise placement of a stent in a moving septum. Embolization of the stent can result in fetal death.[258,265]
- While the goal of fetal pulmonary valve perforation and valvuloplasty is also to achieve postnatal biventricular circulation, predicting a successful outcome is more challenging due to other factors including size of the tricuspid valve, presence of RV-dependent coronary circulation and the greater likelihood that a small RV can support the postnatal circulation as compared to a small LV.[266,267] Additional need for postnatal surgery as well as the option of one and a half ventricle repair add more complexity to the risk-benefit assessment for the procedure.[267] It is also the least performed among the fetal cardiac interventions and consequently outcome data are very limited.[268]

16.4.1. Starting a fetal program

While definitive requirements to start a fetal cardiac intervention program are lacking, published data suggest that large volume centers are in the best position to provide the environment to reach a high rate of technical success with reasonably acceptable risk to the fetus and low risk to the mother. However, not the institution per se, but rather the experience and skill of the entire team is the most important component for performing these procedures.

While a program's surgical volume alone is not the sole determinant for predicting the long-term success of these procedures, initiating such a program at a center with a low annual surgical volume can be fraught with risk; thus such practice should be discouraged.[264] This is particularly true if a low-volume center does not provide the full spectrum of surgical palliations that may be needed after delivery of the infant.

It is important to recognize that the learning curve for fetal interventions is steep. It is crucial that the team gain some experience with in vitro as well as animal models, visit other programs with established fetal cardiac intervention programs, and invite proctors to assist in their first few cases. In light of these factors, it is very important to keep in mind that fetal cardiac procedures carry a risk to the fetus and to the mother, albeit the latter being very small.

When a program has developed the infrastructure and made the long-term commitment to institute a fetal cardiac intervention program, it is further recommended that the team works out in advance the OR spatial considerations. This includes where to place the

echocardiography machine and table holding the interventional supplies along with where each member of the team is positioned around the OR table.

The technical details of these procedures including the best methods for fetal positioning are beyond the scope of this section. It is not uncommon though for 3 pairs of hands to be placed on a small area on the mother's abdomen. Hence, the setup for the echocardiography machine and monitor, surgical table, and interventional table will require advanced planning to avoid delays once the needle is in place. Maternal and fetal resuscitation medications and appropriate needles and syringes should be readily available. Emergent performance of pericardial drainage for fetal hemopericardium ± tamponade can effectively restore normal fetal hemodynamics.

17. CORONARY INTERVENTIONS IN PEDIATRIC PATIENTS

There are multiple, rare congenital CA lesions that may lead to myocardial insufficiency and perfusion abnormalities. These lesions include anomalous CA origins with interarterial or intramural course, hooded CA, an anomalous CA arising from the pulmonary artery, CA fistula, congenital CA ostial stenosis or atresia, etc. They may occur as isolated lesions; however, CA obstructive lesions may be frequently found with other congenital abnormalities (pulmonary atresia with intact ventricular septum, Williams-Beuren Syndrome, etc.). Surgical correction is required for some of these lesions.

CA stenoses in children may also develop from acquired forms of heart disease which includes Kawasaki disease associated with giant CA aneurysms and post-cardiac transplant CA vasculopathy. The latter entity typically involves small vessels and the microvasculature; however, occasionally larger CA may have discrete areas of stenosis. These acquired forms of coronary disease may be amenable to transcatheter intervention.[269-271]

Lastly, CA lesions may have iatrogenic etiologies resulting after surgical CA manipulation, acute injury during CA catheterization, or external compression with transcatheter interventions involving adjacent cardiac structures. While most postsurgical CA lesions involve the ostia with limited utility from transcatheter therapies, acute CA injury or compression may necessitate emergent transcatheter intervention.[272-276]

17.1. Coronary artery dilation/stent

Except for centers treating high rates of Kawasaki disease, the need to consider balloon dilation or stent implantation within the CA in children occurs only rarely. Thus, few pediatric cardiac catheterization laboratories will have anywhere near comparable training and experience with interventional treatment of CA obstructive lesions as do their adult CA interventional counterparts. The pediatric interventional cardiologist should maintain a high index of suspicion for CA obstructive lesions in patients referred for cardiac catheterization who are at risk, and CA adult interventional cardiologists should be consulted early prior to the procedure. Additional preprocedural assessment including tests and imaging should be determined. Preprocedural medical management including use of antiplatelet/anticoagulation agents should be considered and instituted where appropriate. A collaborative procedural strategy should be created including the potential use of adjunct CA assessments such as IVUS imaging and FFR functional assessment. Additionally, emergency and "bailout" measures should be in place.

Therefore, when catheter procedures for CAD are conducted in pediatric or congenital heart patients, it is strongly recommended that pediatric cardiologists collaborate with expert adult CA interventional cardiologists rather than performing the procedure alone. In addition, there are few catheter devices suitable for pediatric and congenital CAD; so it may be necessary to modify devices designed for adult ischemic heart disease.

Whether the procedure is to be performed in a pediatric or adult cath lab will depend on multiple factors including operator comfort level, availability of equipment, catheterization, and recovery staff qualifications and comfort level, as well as potential hospital age restrictions. The catheterization should be carried out collaboratively, where both pediatric and adult interventional cardiologists can perform to their strengths; the pediatric interventional cardiologist is responsible for overall care and catheterization while the adult interventional cardiologist is responsible for the CA intervention, thus optimally providing patient safety and procedural efficacy. Post-procedure care, follow-up testing, and imaging as well as location of recovery (potential hospital transfer) should be well planned with the appropriate providers. Though formal collaboration with adult interventional cardiologists is strongly recommended in controlled settings, their involvement in emergent settings of CA obstruction may not be immediately feasible. It is imperative that pediatric catheterization laboratories performing procedures that selectively engage or manipulate within the CA, as well as interventions with the potential for CA compression have immediate access to CA interventional wires, balloon catheters, and stents. It is also imperative that the pediatric interventional cardiologist be technically sufficiently competent with this equipment to successfully use it in acute CA obstruction.

17.2. Coronary artery fistula occlusion

The majority of significant CA fistulas are diagnosed in children; consequently, pediatric interventional cardiologists have built a wealth of experience and technical

TABLE 17 General Data Protection Regulation (GDPR) vs Health Insurance Portability and Accountability Act (HIPAA)

	HIPAA	GDPR
Scope	Patient health information	Any personal data
Data disclosure	Can disclose protected health information for treatment, payment, etc.	Identify all data processing activates including storage and movement of data
Local regulation	Privacy officer	Data protection officer
Subject access rights (copy of records)	30 d (admin cost)	30 d (free of charge)

expertise in treating CA fistulas by intravascular occlusion utilizing a plethora of different devices.[277,278] Though pediatric interventional cardiologists are often consulted to perform CA fistula occlusion found in adults, more adult interventional cardiologists are gaining experience with these procedures.[279] CA fistulas that meet indications for closure are rare and collaboration between pediatric and adult interventional cardiologists performing these procedures may aid in increasing their collective experience. Additionally, CA fistula occlusion carries a risk profile that includes thrombosis within the CA system especially in the presence of aneurysmal dilated CA segments. Collaboration of these interventional cardiologists may facilitate emergent therapy including CA thrombectomy and CA thrombolysis.

18. OTHER CONSIDERATIONS

18.1. Privacy, confidentiality, and data protection

Guidance regarding intraprocedural documentation and structured procedural reporting have been covered in Sections 14.6 and 15.5, respectively. Internationally agreed standards for protecting patient data do not exist. In the EU, the GDPR has been in place since 2018 and is perceived as the preeminent regulation around the world. In the US, data protection is covered by the Health Insurance Portability and Accountability Act which came into existence in 1996. The differences between these 2 privacy frameworks are covered in **Table 17**. It is worth noting that if the personal data of EU residents is used outside of the EU (including the US), GDPR compliance is still required.

The historical platform for the collection of health data has been guided by both the Council of Europe's 1981 Convention for the Protection of Individuals with Regard to the Automatic Processing of Data, which considered health data as "special," and the Organization for Economic Cooperation and Development 1989 Guidelines for the Protection of Privacy and Transborder Flows, that established the modern parameters for the principled regulation and security of medical data. The 8 Organization for Economic Cooperation and Development principles are: (1) collection limitation; (2) data quality; (3) purpose specification; (4) use limitation; (5) security safeguards; (6) openness; (7) individual participation; and (8) accountability.

It is noteworthy that the GDPR clearly allows health care professionals to use personal health data for medical diagnosis, provision of health care, management of health care, ensuring quality of health care, protecting someone's life where they cannot give consent and for public health purposes, provided that certain conditions are met. This should not be confused with Health Research Regulation which pertains to research and audit and not to normal clinical practice. Patients also have rights in relation to their own data and transparency, a key principle of the GDPR requiring that any information about the processing of a patient's personal data must be easily accessible and easy for them to understand.

Ultimately the legislation surrounding patient data is complex and not specific to the cath lab. Each health care institution under the umbrella of the national regulatory body will have guidelines for processing and protecting patient data. This should be overseen by a data protection officer who should have the appropriate skills, expert knowledge of data protection law, and due regard to the level of risk associated with processing activities that utilize patient data. However, the obligations of GDPR rest with the "data controller," which is the individual physician if in private practice or the hospital if employed by an organization. In the event of a data breach, the data controller should be informed.

Occasionally, it may be necessary to share patient data, particularly when seeking a second opinion or if the patient's care is being transferred to another institution. It is important there is clarity on:

- The purpose of the disclosure, which is of utmost importance as it determines the rules that apply.
- The legal basis for the disclosure.
- The patient's right to transparency.
- The duty of confidentiality to the patient

When seeking guidance from another physician or institution, data-sharing agreements may be in place but seeking permission from the patient and ensuring the patient's confidentiality are paramount.

18.2. Participation of industry

Interaction with representatives from industry, including clinical specialists, can facilitate an optimal patient experience and ultimately may improve patient outcomes. However, clear guidelines should exist in relation

to professional conduct. These vary by country and by individual hospitals and are usually developed by the regulatory body within the region. Participation from industry representatives may vary from ensuring necessary equipment is available, providing some guidance around the technical aspects of the equipment, and finally preparing the medical device for the implant. Conflicts of interest may happen where doctors, or their close family members, have financial interests with medical industries. Catheter laboratory staff should identify and try to avoid conflicts of interest that may affect clinical judgment. If a conflict of interest is unavoidable, it will require transparent and full disclosure to everyone, including the patient.

When clinical specialists are attending the hospital for the first time, it is important to ensure all the necessary required institutional documentation is completed. It is recommended to have a member of the catheter laboratory staff meet with the industry representative on arrival at the institution and subsequently introduce the industry representative to the team. Good communication lines are essential to ensure the necessary equipment is available for the intervention, often requiring preprocedural planning among the physician, the catheter laboratory manager, and the clinical specialist from industry. Occasionally and more recently, clinical support may be provided through virtual or remote communication. Ensuring patient confidentiality is not breached is paramount and forms of communication should be discussed with the data protection officer prior to engaging in this activity. This approach may be less suitable when technical skills are required for device preparation.

Introduction of new technologies or devices may also require proctoring by industry representatives and more experienced physicians. The scope of practice and case participation of a proctor is usually agreed between the industry representative, and the physician being trained, and local regulations for allowing proctor participation will need to be followed. The input and expectations of the proctor are often outlined in agreements between the proctor and the respective medical device company.

18.3. Taped cases and live cases

Live case transmissions (and the presentation of taped cases) for a technically focused specialty can provide a unique learning opportunity. However, there has been concern raised about the impact on patient care. For a detailed discussion on live case considerations, we like to refer to the "SCAI/ACCF/HRS/ESC/SOLACI/APSIC statement on the use of live case demonstrations at cardiology meetings: assessments of the past and standards for the future."[280]

ACKNOWLEDGMENTS

PICS Societal Staff Leadership

- Norm Linsky: Executive Director at The Pediatric and Congenital Interventional Cardiovascular Society

PEER REVIEW STATEMENT

Given his role as Associate Editor, Frank F. Ing had no involvement in the post-submission peer review of this article and has no access to information regarding its peer review; however, he did participate in the adjudication of pre-submission reviews provided by external reviewers as outlined in Appendix B.

DECLARATION OF COMPETING INTEREST

The following is a list of relationships with industry for the authors of this manuscript. Relationships include the following roles: consultant, speaker's bureau, research, expert witness, ownership/partnership/principal, institutional, organizational, or other financial benefit. Ralf J. Holzer: None. Lisa Bergersen: None. John Thomson: None. Jamil Aboulhosn: Edwards, Medtronic (significant financial interest). Varun Aggarwal: None. Teiji Akagi: None. Mazeni Alwi: None. Aimee K. Armstrong: Abbott, Renata Medical, Autus Valve Technologies, Siemens, Healthineers (no financial interest); Cook, Intersocietal Accreditation Commission (modest financial interest); Edwards, Medtronic (significant financial interest). Emile Bacha: None. Lee Benson: Medtronic, Carag, Abbott (modest financial interest). Regina Böekenkamp: Taewoong, Lifetech (no financial interest). Mario Carminati: Medtronic, Edwards, Abbott, Gore, Taewoong, Lifetech (modest financial interest). Bharat Dalvi: Medtronic, Meril (modest financial interest). James DiNardo: None. Thomas Fagan: None. Kenneth Fetterly: Siemens (modest financial interest). Frank F. Ing: Abbott (modest financial interest). Damien Kenny: Edwards, Medtronic, Occlutech, Venus Medtech (modest financial interest). Dennis Kim: Edwards, Medtronic (modest financial interest). Emily Kish: None. Michael O'Byrne: None. Clare O'Donnell: None. Xiangbin Pan: None. Joseph Paolillo: Medtronic (modest financial interest); Gore (significant financial interest). Carlos Pedra: Medtronic, Abbott, Edwards, Lifetech (modest financial interest). Alejandro Peirone: None. Harsimran S. Singh: None. Lars Søndergaard: None. Ziyad M. Hijazi: Venus Medtech (no financial interest); NuMED, Occlutech (modest financial interest).

FUNDING SOURCES

This research did not receive any specific grant from funding agencies in the public, commercial, or not-for-profit sectors.

REFERENCES

1. Bashore TM, Balter S, Barac A, et al. 2012 American College of Cardiology Foundation/Society for Cardiovascular Angiography and Interventions expert consensus document on cardiac catheterization laboratory standards update: A report of the American College of Cardiology Foundation Task Force on Expert Consensus Documents developed in collaboration with the Society of Thoracic Surgeons and Society for Vascular Medicine. *J Am Coll Cardiol*. 2012;59(24):2221–2305. https://doi.org/10.1016/j.jacc.2012.02.010

2. Naidu SS, Abbott JD, Bagai J, et al. SCAI expert consensus update on best practices in the cardiac catheterization laboratory: this statement was endorsed by the American College of Cardiology (ACC), the American Heart Association (AHA), and the Heart Rhythm Society (HRS) in April 2021. *Catheter Cardiovasc Interv*. 2021;98(2):255–276. https://doi.org/10.1002/ccd.29744

3. Erikssen G, Liestøl K, Seem E, et al. Achievements in congenital heart defect surgery: a prospective, 40-year study of 7038 patients. *Circulation*. 2015;131(4):337–346. https://doi.org/10.1161/CIRCULATIONAHA.114.012033

4. Raissadati A, Nieminen H, Jokinen E, Sairanen H. Progress in late results among pediatric cardiac surgery patients: a population-based 6-decade study with 98% follow-up. *Circulation*. 2015;131(4):347–353. https://doi.org/10.1161/CIRCULATIONAHA.114.011190. discussion 353.

5. Williams RG, Pearson GD, Barst RJ, et al. Report of the National Heart, Lung, and Blood Institute Working Group on research in adult congenital heart disease. *J Am Coll Cardiol*. 2006;47(4):701–707. https://doi.org/10.1016/j.jacc.2005.08.074

6. Wadia SK, Accavitti Jr MJ, Morgan GJ, et al. Transcatheter interventions in adults with congenital heart disease: surveys from the Society for Cardiovascular Angiography and Interventions to identify current patterns of care and perception on training requirements. *Catheter Cardiovasc Interv*. 2017;90(3):418–424. https://doi.org/10.1002/ccd.27151

7. Stout KK, Daniels CJ, Aboulhosn JA, et al. AHA/ACC guideline for the management of adults with congenital heart disease: executive summary: A report of the American College of Cardiology/American Heart Association Task Force on Clinical Practice guidelines. *J Am Coll Cardiol*. 2019;73(12):1494–1563. https://doi.org/10.1016/j.jacc.2018.08.1028

8. Aboulhosn JA, Hijazi ZM, Kavinsky CJ, et al. SCAI position statement on adult congenital cardiac interventional training, competencies and organizational recommendations. *Catheter Cardiovasc Interv*. 2020;96(3):643–650. https://doi.org/10.1002/ccd.28885

9. Armsby L, Beekman III RH, Benson L, et al. SCAI expert consensus statement for advanced training programs in pediatric and congenital interventional cardiac catheterization. *Catheter Cardiovasc Interv*. 2014;84(5):779–784. https://doi.org/10.1002/ccd.25550

10. Armsby LB, Vincent RN, Foerster SR, et al. Task force 3: Pediatric cardiology fellowship training in cardiac catheterization. *J Am Coll Cardiol*. 2015;66(6):699–705. https://doi.org/10.1016/j.jacc.2015.03.012

11. Butera G, Morgan GJ, Ovaert C, Anjos R, Spadoni I. Recommendations from the Association of European Paediatric Cardiology for training in diagnostic and interventional cardiac catheterisation. *Cardiol Young*. 2015;25(3):438–446. https://doi.org/10.1017/S1047951114001309

12. Chessa M, Baumgartner H, Michel-Behnke I, et al. ESC Working Group Position Paper: transcatheter adult congenital heart disease interventions: organization of care – recommendations from a Joint Working Group of the European Society of Cardiology (ESC), European Association of Pediatric and Congenital Cardiology (AEPC), and the European Association of Percutaneous Cardiac Intervention (EAPCI). *Eur Heart J*. 2019;40(13):1043–1048. https://doi.org/10.1093/eurheartj/ehy676

13. Ruiz CE, Feldman TE, Hijazi ZM, et al. Interventional fellowship in structural and congenital heart disease for adults. *J Am Coll Cardiol Intv*. 2010;3(9):e1–e15. https://doi.org/10.1016/j.jcin.2010.08.010

14. Hicks PJ, Englander R, Schumacher DJ, et al. Pediatrics milestone project: next steps toward meaningful outcomes assessment. *J Grad Med Educ*. 2010;2(4):577–584. https://doi.org/10.4300/JGME-D-10-00157.1

15. Mulder H, Ten Cate O, Daalder R, Berkvens J. Building a competency-based workplace curriculum around entrustable professional activities: the case of physician assistant training. *Med Teach*. 2010;32(10):e453–e459. https://doi.org/10.3109/0142159X.2010.513719

16. Royal College of Physicians and Surgeons of Canada. EPAs and CanMEDS milestones. Accessed November 15, 2022. https://royalcollege.ca/rcsite/cbd/implementation/cbd-milestones-epas-e

17. Tekian A, Hodges BD, Roberts TE, Schuwirth L, Norcini J. Assessing competencies using milestones along the way. *Med Teach*. 2015;37(4):399–402. https://doi.org/10.3109/0142159X.2014.993954

18. The American Board of Pediatrics. Entrustable professional activities for subspecialties. Accessed November 15, 2022. https://www.abp.org/content/entrustable-professional-activities-subspecialties

19. Carraccio C, Burke AE. Beyond competencies and milestones: adding meaning through context. *J Grad Med Educ*. 2010;2(3):419–422. https://doi.org/10.4300/JGME-D-10-00127.1

20. ten Cate O, Scheele F. Competency-based postgraduate training: can we bridge the gap between theory and clinical practice? *Acad Med*. 2007;82(6):542–547. https://doi.org/10.1097/ACM.0b013e31805559c7

21. Ruiz CE, Mullins CE, Rochini AP, et al. Core curriculum for the training of pediatric invasive/interventional cardiologists: report of the Society for Cardiac Angiography and Interventions Committee on Pediatric Cardiology Training Standards. *Cathet Cardiovasc Diagn*. 1996;37(4):409–424. https://doi.org/10.1002/(SICI)1097-0304(199604)37:4<409::AID-CCD10>3.0.CO;2-A

22. Writing Committee, Bass TA, Abbott JD, et al. 2023 ACC/AHA/SCAI Advanced Training Statement on Interventional Cardiology (coronary, peripheral vascular, and structural heart interventions): A report of the ACC competency management committee. *J Am Coll Cardiol*. 2023;81(14):1386–1438. https://doi.org/10.1016/j.jacc.2022.11.002

23. Organization of a pediatric/congenital catheterization laboratory. In: Mullins CE, ed. *Cardiac Catheterization in Congenital Heart Disease: Pediatric and Adult*. Wiley-Blackwell; 2006:1–24.

24. Tommaso CL, Bolman III RM, Feldman T, et al. Multisociety (aATs, ACCF, SCAI, and STS) expert consensus statement: operator and institutional requirements for transcatheter valve repair and replacement, Part 1: transcatheter aortic valve replacement. *J Am Coll Cardiol*. 2012;59(22):2028–2042. https://doi.org/10.1016/j.jacc.2012.02.016

25. Aboulhosn J. Rotational angiography and 3D overlay in transcatheter congenital interventions. *Interv Cardiol*. 2013;5(4):405–410. https://doi.org/10.2217/ica.13.30

26. O'Byrne ML, Kennedy KF, Steven JM, et al. Outcomes of operator-directed sedation and anesthesiologist care in the pediatric/congenital catheterization laboratory: A study utilizing data from the Impact registry. *J Am Coll Cardiol Intv*. 2021;14(4):401–413. https://doi.org/10.1016/j.jcin.2020.10.054

27. Odegard KC, Vincent R, Baijal R, et al. SCAI/CCAS/SPA expert consensus statement for anesthesia and sedation practice: recommendations for patients undergoing diagnostic and therapeutic procedures in the pediatric and congenital cardiac catheterization laboratory. *Catheter Cardiovasc Interv*. 2016;88(6):912–922. https://doi.org/10.1002/ccd.26692

28. Bauser-Heaton H, Qureshi AM, Goldstein BH, et al. Use of carotid and axillary artery approach for stenting the patent ductus arteriosus in infants with ductal-dependent pulmonary blood flow: A multicenter study from the congenital catheterization research collaborative. *Catheter Cardiovasc Interv*. 2020;95(4):726–733. https://doi.org/10.1002/ccd.28631

29. Bauser-Heaton H, Qureshi AM, Goldstein BH, Glatz AC, Petit CJ. Use of Novel "flip technique" Aids in percutaneous carotid artery approach in neonates. *J Am Coll Cardiol Intv*. 2019;12(16):1630–1631. https://doi.org/10.1016/j.jcin.2019.04.053

30. Breatnach CR, Aggarwal V, Al-Alawi K, et al. Percutaneous axillary artery approach for ductal stenting in critical right ventricular outflow tract lesions in the neonatal period. *Catheter Cardiovasc Interv*. 2019;93(7):1329–1335. https://doi.org/10.1002/ccd.28302

31. Dehmer GJ, Arani D, Noto T, et al. Lessons learned from the review of cardiac catheterization laboratories: a report from the Laboratory Survey Committee of the Society for Cardiac Angiography and Interventions. *Catheter Cardiovasc Interv*. 1999;46(1):24–31. https://doi.org/10.1002/(SICI)1522-726X(199901)46:1<24::AID-CCD7>3.0.CO;2-6

32. Bergersen L, Marshall A, Gauvreau K, et al. Adverse event rates in congenital cardiac catheterization – a multi-center experience. *Catheter Cardiovasc Interv*. 2010;75(3):389–400. https://doi.org/10.1002/ccd.22266

33. Pasquali SK, He X, Jacobs ML, et al. Hospital variation in postoperative infection and outcome after congenital heart surgery. *Ann Thorac Surg*. 2013;96(2):

657–663. https://doi.org/10.1016/j.athoracsur.2013.04.024

34. Chambers CE, Eisenhauer MD, McNicol LB, et al. Infection control guidelines for the cardiac catheterization laboratory: society guidelines revisited. *Catheter Cardiovasc Interv*. 2006;67(1):78–86. https://doi.org/10.1002/ccd.20589

35. Facilities Guideline Institute, Joint HVAC Task Force. *Joint Interim Guidance*. 2015. Accessed November 24, 2021. https://www.fgiguidelines.org/wp-content/uploads/2015/09/Interim-HVAC-Joint-Guidance-Statement.pdf

36. *ASHRAE Standing Standard Project Committee 170. ANSI/ASHRAE/ASHE Addendum a to ANSI/ASHRAE/ASHE Standard 170-2017*. 2020. Accessed November 24, 2021. https://www.ashrae.org/file%20library/technical%20resources/standards%20and%20guidelines/standards%20errata/standards/170_2017_a_20200901.pdf

37. Taylor KL, Laussen PC. Anaesthesia outside of the operating room: the paediatric cardiac catheterization laboratory. *Curr Opin Anaesthesiol*. 2015;28(4):453–457. https://doi.org/10.1097/ACO.0000000000000206

38. Hirsch R. The hybrid cardiac catheterization laboratory for congenital heart disease: from conception to completion. *Catheter Cardiovasc Interv*. 2008;71(3):418–428. https://doi.org/10.1002/ccd.21318

39. Krasemann T, Berger F, Liuba P, Thomson J. Recommendations for the configuration of a cardiac catheterisation laboratory for the treatment of children with CHD. *Cardiol Young*. 2018;28(6):791–794. https://doi.org/10.1017/S1047951118000112

40. Abu Hazeem AA, Dori Y, Whitehead KK, et al. X-ray magnetic resonance fusion modality may reduce radiation exposure and contrast dose in diagnostic cardiac catheterization of congenital heart disease. *Catheter Cardiovasc Interv*. 2014;84(5):795–800. https://doi.org/10.1002/ccd.25473

41. Dori Y, Sarmiento M, Glatz AC, et al. X-ray magnetic resonance fusion to internal markers and utility in congenital heart disease catheterization. *Circ Cardiovasc Imaging*. 2011;4(4):415–424. https://doi.org/10.1161/CIRCIMAGING.111.963868

42. Glatz AC, Zhu X, Gillespie MJ, Hanna BD, Rome JJ. Use of angiographic CT imaging in the cardiac catheterization laboratory for congenital heart disease. *J Am Coll Cardiol Img*. 2010;3(11):1149–1157. https://doi.org/10.1016/j.jcmg.2010.09.011

43. Grant EK, Kanter JP, Olivieri LJ, et al. X-ray fused with MRI guidance of pre-selected transcatheter congenital heart disease interventions. *Catheter Cardiovasc Interv*. 2019;94(3):399–408. https://doi.org/10.1002/ccd.28324

44. Kang SL, Armstrong A, Krings G, Benson L. Three-dimensional rotational angiography in congenital heart disease: present status and evolving future. *Congenit Heart Dis*. 2019;14(6):1046–1057. https://doi.org/10.1111/chd.12838

45. Malkin R, Teninty B. Medical Imaging in Global Public Health: Donation, Procurement, Installation, and Maintenance. In: Mollura DJ, Culp MP, Lungren MP, eds. *Radiology in Global Health: Strategies, Implementation, and Applications*. Springer; 2019:77–83.

46. Canadian Association of Radiologists. Lifecycle Guidance for Medical Imaging Equipment in Canada. 2013. Accessed September 27, 2022. https://car.ca/wp-content/uploads/car-lifecycleguidance-summary.pdf

47. European Society of Radiology (ESR). Renewal of radiological equipment. *Insights Imaging*. 2014;5(5):543–546. https://doi.org/10.1007/s13244-014-0345-1

48. Downing TE, McDonnell A, Zhu X, et al. Cumulative medical radiation exposure throughout staged palliation of single ventricle congenital heart disease. *Pediatr Cardiol*. 2015;36(1):190–195. https://doi.org/10.1007/s00246-014-0984-5

49. Glatz AC, Purrington KS, Klinger A, et al. Cumulative exposure to medical radiation for children requiring surgery for congenital heart disease. *J Pediatr*. 2014;164(4):789–794.e10 e710. https://doi.org/10.1016/j.jpeds.2013.10.074

50. Johnson JN, Hornik CP, Li JS, et al. Cumulative radiation exposure and cancer risk estimation in children with heart disease. *Circulation*. 2014;130(2):161–167. https://doi.org/10.1161/CIRCULATIONAHA.113.005425

51. Journy N, Dreuil S, Rage E, et al. Projected future cancer risks in children treated with fluoroscopy-guided cardiac catheterization procedures. *Circ Cardiovasc Interv*. 2018;11(11):e006765. https://doi.org/10.1161/CIRCINTERVENTIONS.118.006765

52. McDonnell A, Downing TE, Zhu X, Ryan R, Rossano JW, Glatz AC. Cumulative exposure to medical sources of ionizing radiation in the first year after pediatric heart transplantation. *J Heart Lung Transplant*. 2014;33(11):1126–1132. https://doi.org/10.1016/j.healun.2014.05.013

53. Quinn BP, Cevallos P, Armstrong A, et al. Longitudinal improvements in radiation exposure in cardiac catheterization for congenital heart disease: A prospective multicenter C3PO-QI study. *Circ Cardiovasc Interv*. 2020;13(5):e008172. https://doi.org/10.1161/CIRCINTERVENTIONS.119.008172

54. Reusz G, Csomos A. The role of ultrasound guidance for vascular access. *Curr Opin Anaesthesiol*. 2015;28(6):710–716. https://doi.org/10.1097/ACO.0000000000000245

55. Auerbach SR, Fenton MJ, Grutter G, et al. The complication rate of intravascular ultrasound (IVUS) in a multicenter pediatric heart transplant population: A study of the international pediatric IVUS consortium. *Clin Transplant*. 2020;34(9):e13981. https://doi.org/10.1111/ctr.13981

56. Mehra MR, Crespo-Leiro MG, Dipchand A, et al. International Society for Heart and Lung Transplantation working formulation of a standardized nomenclature for cardiac allograft vasculopathy-2010. *J Heart Lung Transplant*. 2010;29(7):717–727. https://doi.org/10.1016/j.healun.2010.05.017

57. Callahan R, Gauthier Z, Toba S, Sanders SP, Porras D, Vargas SO. Correlation of intravascular ultrasound with histology in pediatric pulmonary vein stenosis. *Children (Basel)*. 2021;8(3). https://doi.org/10.3390/children8030193

58. Callahan R, Jenkins KJ, Gauthier Z, Gauvreau K, Porras D. Preliminary findings on the use of intravascular ultrasound in the assessment of pediatric pulmonary vein stenosis. *Catheter Cardiovasc Interv*. 2021;97(3):E362–E370. https://doi.org/10.1002/ccd.29264

59. Nakanishi T, Tobita K, Sasaki M, et al. Intravascular ultrasound imaging before and after balloon angioplasty for pulmonary artery stenosis. *Catheter Cardiovasc Interv*. 1999;46(1):68–78. https://doi.org/10.1002/(SICI)1522-726X(199901)46:1<68::AID-CCD18>3.0.CO;2-0

60. Sohn S, Rothman A, Shiota T, et al. Acute and follow-up intravascular ultrasound findings after balloon dilation of coarctation of the aorta. *Circulation*. 1994;90(1):340–347. https://doi.org/10.1161/01.cir.90.1.340

61. Ringel RE, Gauvreau K, Moses H, Jenkins KJ. Coarctation of the Aorta Stent Trial (COAST): study design and rationale. *Am Heart J*. 2012;164(1):7–13. https://doi.org/10.1016/j.ahj.2012.04.008

62. Stang AS, Joshi A. The evolution of freestanding children's hospitals in Canada. *Paediatr Child Health*. 2006;11(8):501–506. https://doi.org/10.1093/pch/11.8.501

63. Novick WM, Molloy F, Bowtell K, et al. Pediatric cardiac service development programs for low- and middle-income countries in need of improving or initiating local services. *Front Pediatr*. 2019;7:359. https://doi.org/10.3389/fped.2019.00359

64. Lin CH, Hegde S, Marshall AC, et al. Incidence and management of life-threatening adverse events during cardiac catheterization for congenital heart disease. *Pediatr Cardiol*. 2014;35(1):140–148. https://doi.org/10.1007/s00246-013-0752-y

65. Allan CK, Thiagarajan RR, Armsby LR, del Nido PJ, Laussen PC. Emergent use of extracorporeal membrane oxygenation during pediatric cardiac catheterization. *Pediatr Crit Care Med*. 2006;7(3):212–219. https://doi.org/10.1097/01.PCC.0000200964.88206.B0

66. Holzer R, Batlivala SP, Boe B, et al. The need for surgery after vascular or cardiac trauma, or technical adverse events in the congenital Cardiac Catheterization Laboratory. *Pediatr Cardiol*. 2023;44(4):795–805. https://doi.org/10.1007/s00246-023-03126-9

67. Intersocietal Accreditation Commission. *The IAC Standards and Guidelines for Cardiovascular Catheterization Accreditation*. 2018. Accessed April 1, 2023. https://intersocietal.org/wp-content/uploads/2023/07/IACCardiovascularCatheterizationStandards2023B.pdf

68. Feltes TF, Bacha E, Beekman III RH, et al. Indications for cardiac catheterization and intervention in pediatric cardiac disease: a scientific statement from the American Heart Association. *Circulation*. 2011;123(22):2607–2652. https://doi.org/10.1161/CIR.0b013e31821b1f10

69. Bergersen L, Gauvreau K, Foerster SR, et al. Catheterization for congenital heart disease adjustment for risk method (CHARM). *J Am Coll Cardiol Intv*. 2011;4(9):1037–1046. https://doi.org/10.1016/j.jcin.2011.05.021

70. Quinn BP, Yeh M, Gauvreau K, et al. Procedural risk in congenital cardiac catheterization (PREDIC(3)T). *J Am Heart Assoc*. 2022;11(1):e022832. https://doi.org/10.1161/JAHA.121.022832

71. Benson L, Macpherson B. Operator-directed sedation in the pediatric Cardiac Catheterization Laboratory: "the wheel has come full circle.". *J Am Coll Cardiol Intv*. 2021;14(4):414–416. https://doi.org/10.1016/j.jcin.2020.11.023

72. Lin CH, Desai S, Nicolas R, et al. Sedation and anesthesia in pediatric and congenital cardiac catheterization: A prospective multicenter experience.

Pediatr Cardiol. 2015;36(7):1363–1375. https://doi.org/10.1007/s00246-015-1167-8

73. Odegard KC, Vincent R, Baijal RG, et al. SCAI/CCAS/SPA expert consensus statement for anesthesia and sedation practice: recommendations for patients undergoing diagnostic and therapeutic procedures in the pediatric and congenital Cardiac Catheterization Laboratory. *Anesth Analg*. 2016;123(5):1201–1209. https://doi.org/10.1213/ANE.0000000000001608

74. Practice guidelines for moderate procedural sedation and analgesia 2018: A report by the American society of anesthesiologists task force on moderate procedural sedation and analgesia, the American Association of Oral and Maxillofacial Surgeons, American College of Radiology, American Dental Association, American Society of Dentist Anesthesiologists, and Society of Interventional Radiology. *Anesthesiology*. 2018;128(3):437–479. https://doi.org/10.1097/ALN.0000000000002043

75. O'Byrne ML, Millenson ME, Steven JM, et al. Operator-directed procedural sedation in the congenital Cardiac Catheterization Laboratory. *J Am Coll Cardiol Intv*. 2019;12(9):835–843. https://doi.org/10.1016/j.jcin.2019.01.224

76. Tierney N, Kenny D, Greaney D. Anaesthesia for the paediatric patient in the cardiac catheterisation laboratory. *BJA Educ*. 2022;22(2):60–66. https://doi.org/10.1016/j.bjae.2021.09.003

77. Vaiyani D, Kelleman M, Downey LA, Kanaan U, Petit CJ, Bauser-Heaton H. Risk factors for adverse events in children with pulmonary hypertension undergoing cardiac catheterization. *Pediatr Cardiol*. 2021;42(4):736–742. https://doi.org/10.1007/s00246-020-02535-4

78. Hirshfeld Jr JW, Ferrari VA, Bengel FM, et al. ACC/HRS/NASCI/SCAI/SCCT Expert Consensus Document on Optimal Use of Ionizing Radiation in Cardiovascular Imaging-best practices for safety and effectiveness, Part 2: Radiological equipment operation, dose-sparing methodologies, patient and medical personnel protection: A report of the American College of Cardiology task force on expert consensus decision pathways. *J Am Coll Cardiol*. 2018;71(24):2829–2855. https://doi.org/10.1016/j.jacc.2018.02.018

79. Hill KD, Frush DP, Han BK, et al. Radiation safety in children with congenital and acquired heart disease: A scientific position statement on multimodality dose optimization from the image gently alliance. *J Am Coll Cardiol Img*. 2017;10(7):797–818. https://doi.org/10.1016/j.jcmg.2017.04.003

80. Balter S, Hopewell JW, Miller DL, Wagner LK, Zelefsky MJ. Fluoroscopically guided interventional procedures: a review of radiation effects on patients' skin and hair. *Radiology*. 2010;254(2):326–341. https://doi.org/10.1148/radiol.2542082312

81. Walsh MA, Noga M, Rutledge J. Cumulative radiation exposure in pediatric patients with congenital heart disease. *Pediatr Cardiol*. 2015;36(2):289–294. https://doi.org/10.1007/s00246-014-0999-y

82. Cohen S, Gurvitz MZ, Beauséjour-Ladouceur V, Lawler PR, Therrien J, Marelli AJ. Cancer risk in congenital heart disease-what is the evidence? *Can J Cardiol*. 2019;35(12):1750–1761. https://doi.org/10.1016/j.cjca.2019.09.023

83. Justino H. The ALARA concept in pediatric cardiac catheterization: techniques and tactics for managing radiation dose. *Pediatr Radiol*. 2006;36(suppl 2):146–153. https://doi.org/10.1007/s00247-006-0194-2

84. Justino H. Radiation safety in the Cardiac Catheterization Laboratory is our responsibility: A call to humility and action. *Circ Cardiovasc Interv*. 2020;13(5):e009236. https://doi.org/10.1161/CIRCINTERVENTIONS.120.009236

85. Goudeketting SR, Heinen SGH, Ünlü Ç, et al. Pros and cons of 3D image fusion in endovascular aortic repair: A systematic review and meta-analysis. *J Endovasc Ther*. 2017;24(4):595–603. https://doi.org/10.1177/1526602817708196

86. Ghelani SJ, Glatz AC, David S, et al. Radiation dose benchmarks during cardiac catheterization for congenital heart disease in the United States. *J Am Coll Cardiol Intv*. 2014;7(9):1060–1069. https://doi.org/10.1016/j.jcin.2014.04.013

87. Tao AT, Miller D, Hindal M, Fetterly KA. [technical note]. Technical Note: Assessment of scatter originating from the x-ray tube collimator assembly of modern angiography systems. *Med Phys*. 2019;46(10):4371–4380. https://doi.org/10.1002/mp.13720

88. Dauer LT, Miller DL, Schueler B, et al. Occupational radiation protection of pregnant or potentially pregnant workers in IR: a joint guideline of the Society of Interventional Radiology and the Cardiovascular and Interventional Radiological Society of Europe. *J Vasc Interv Radiol*. 2015;26(2):171–181. https://doi.org/10.1016/j.jvir.2014.11.026

89. López PO, Dauer LT, Loose R, et al. ICRP Publication 139: occupational radiological protection in interventional procedures. Ann ICRP. *ICRP Publication*. 2018;47(2):1–118. https://doi.org/10.1177/0146645317750356

90. King JN, Champlin AM, Kelsey CA, Tripp DA. Using a sterile disposable protective surgical drape for reduction of radiation exposure to interventionalists. *AJR Am J Roentgenol*. 2002;178(1):153–157. https://doi.org/10.2214/ajr.178.1.1780153

91. American College of Radiology (ACR) and the Society for Pediatric Radiology (SPR). ACR-SPR Practice Parameter For Imaging Pregnant or Potentially Pregnant Adolescents and Women With Ionizing Radiation. Accessed January 20, 2023. https://www.acr.org/-/media/ACR/Files/Practice-Parameters/Pregnant-Pts.pdf; 2018

92. Levine GN, Bates ER, Blankenship JC, et al. 2011 ACCF/AHA/SCAI Guideline for Percutaneous Coronary Intervention: a report of the American College of Cardiology Foundation/American Heart Association Task Force on Practice Guidelines and the Society for Cardiovascular Angiography and Interventions. *Circulation*. 2011;124(23):e574–e651. https://doi.org/10.1161/CIR.0b013e31823ba622

93. European Society of Radiology (ESR). Summary of the European Directive 2013/59/Euratom: essentials for health professionals in radiology. *Insights Imaging*. 2015;6(4):411–417. https://doi.org/10.1007/s13244-015-0410-4

94. Ali F, Rizvi A, Ahmad H, et al. Quality initiative to reduce cardiac CT angiography radiation exposure in patients with congenital heart disease. *Pediatr Qual Saf*. 2019;4(3):e168. https://doi.org/10.1097/pq9.0000000000000168

95. Martin GR, Anderson JB, Vincent RN. Impact registry and National pediatric cardiology quality improvement collaborative: contributions to quality in congenital heart disease. *World J Pediatr Congenit Heart Surg*. 2019;10(1):72–80. https://doi.org/10.1177/2150135118815059

96. Bergersen L, Everett AD, Giroud JM, et al. Report from the International Society for Nomenclature of Paediatric and Congenital Heart Disease: cardiovascular catheterisation for congenital and paediatric cardiac disease (Part 1 – Procedural nomenclature). *Cardiol Young*. 2011;21(3):252–259. https://doi.org/10.1017/S104795111000185X

97. Bergersen L, Giroud JM, Jacobs JP, et al. Report from the International Society for Nomenclature of Paediatric and Congenital Heart Disease: cardiovascular catheterisation for congenital and paediatric cardiac disease (Part 2 – Nomenclature of complications associated with interventional cardiology). *Cardiol Young*. 2011;21(3):260–265. https://doi.org/10.1017/S1047951110001861

98. United States Food and Drug Administration. MAUDE. Manufacturer and User Facility Device Experience. Accessed December 23, 2021. https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfmaude/search.cfm#fn1

99. Delaney JW, Li JS, Rhodes JF. Major complications associated with transcatheter atrial septal occluder implantation: a review of the medical literature and the manufacturer and user facility device experience (MAUDE) database. *Congenit Heart Dis*. 2007;2(4):256–264. https://doi.org/10.1111/j.1747-0803.2007.00107.x

100. Institute for Healthcare Improvement. *Changes for Improvement*. 2019. Accessed September 10, 2022 https://www.ihi.org/resources/Pages/Changes/default.aspx

101. Frey P, Connors A, Resnic FS. Quality measurement and improvement in the cardiac catheterization laboratory. *Circulation*. 2012;125(4):615–619. https://doi.org/10.1161/CIRCULATIONAHA.111.018234

102. Nykanen DG, Forbes TJ, Du W, et al. CRISP: catheterization RISk score for pediatrics: a report from the Congenital Cardiac Interventional Study Consortium (CCISC). *Catheter Cardiovasc Interv*. 2016;87(2):302–309. https://doi.org/10.1002/ccd.26300

103. Moore JW, Vincent RN, Beekman III RH, et al. Procedural results and safety of common interventional procedures in congenital heart disease: initial report from the National cardiovascular Data Registry. *J Am Coll Cardiol*. 2014;64(23):2439–2451. https://doi.org/10.1016/j.jacc.2014.09.045

104. Cevallos PC, Rose MJ, Armsby LB, et al. Implementation of methodology for quality improvement in pediatric cardiac catheterization: a multi-center initiative by the congenital cardiac catheterization project on outcomes-quality improvement (C3PO-QI). *Pediatr Cardiol*. 2016;37(8):1436–1445. https://doi.org/10.1007/s00246-016-1454-z

105. Canadian Institute for Healthcare Information. Discharge Abstract Database metadata. Accessed July 22, 2022. https://www.cihi.ca/en/discharge-abstract-database-metadata-dad

106. Ombelet F, Goossens E, Willems R, et al. Creating the Belgian COngenital heart disease database combining administrative and clinical data (BELCODAC): rationale, design and methodology. *Int J Cardiol*. 2020;316:72–78. https://doi.org/10.1016/j.ijcard.2020.05.059

107. Institute for Healthcare Improvement. Quality Improvement Essentials Toolkit. 2023. Accessed April 9, 2023. https://www.ihi.org/resources/Pages/Tools/Quality-Improvement-Essentials-Toolkit.aspx

108. Society for Cardiovascular Angiography & Interventions. Pediatric Quality Improvement Toolkit. 2023. Accessed April 9, 2023. https://scai.org/clinical-practice/quality-improvement/quality-improvement-tools/pediatric-scai-quality-improvement

109. Joint Commission International. *Joint Commission International Standards for Hospitals*. 3rd ed. Joint Commission Resources; 2007.

110. NIAHO ® DNV. NIAHO ® Accreditation Requirements, Interpretive Guidelines, and Surveyor Guidance. Accessed September 10, 2022. https://www.dnv.us/supplychain/healthcare/standards/niaho-ac-dl.html

111. Bashore TM, Bates ER, Berger PB, et al. American College of Cardiology/Society for Cardiac Angiography and Interventions Clinical Expert Consensus Document on cardiac catheterization laboratory standards. A report of the American College of Cardiology Task Force on Clinical Expert Consensus Documents. *J Am Coll Cardiol*. 2001;37(8):2170–2214. https://doi.org/10.1016/S0735-1097(01)01346-8

112. Ali F, Qasim Mehdi M, Akhtar S, et al. Impact of congenital cardiac catheterization project on outcomes-quality improvement (C3PO-QI) in LMICs. *Heart Asia*. 2019;11(1):e011105. https://doi.org/10.1136/heartasia-2018-011105

113. Barry OM, Ali F, Ronderos M, et al. Pilot phase experience of the International Quality Improvement Collaborative catheterization registry. *Catheter Cardiovasc Interv*. 2021;97(1):127–134. https://doi.org/10.1002/ccd.28908

114. Duignan S, Ryan A, Burns B, Kenny D, McMahon CJ. Complex decision making in the pediatric catheterization laboratory: Catheterizer, know thyself and the data. *Pediatr Cardiol*. 2018;39(7):1281–1289. https://doi.org/10.1007/s00246-018-1949-x

115. Booth KL, Roth SJ, Perry SB, del Nido PJ, Wessel DL, Laussen PC. Cardiac catheterization of patients supported by extracorporeal membrane oxygenation. *J Am Coll Cardiol*. 2002;40(9):1681–1686. https://doi.org/10.1016/s0735-1097(02)02343-4

116. Taggart NW, Du W, Forbes TJ, et al. A model for assessment of catheterization risk in adults with congenital heart disease. *Am J Cardiol*. 2019;123(9):1527–1531. https://doi.org/10.1016/j.amjcard.2019.01.042

117. Catheterization RISk Score for Pediatrics. Accessed February 19, 2023. https://www.evidencio.com/models/show/678

118. Hill KD, Du W, Fleming GA, et al. Validation and refinement of the catheterization RISk score for pediatrics (CRISP score): an analysis from the congenital cardiac interventional study consortium. *Catheter Cardiovasc Interv*. 2019;93(1):97–104. https://doi.org/10.1002/ccd.27837

119. Bergersen L, Gauvreau K, Marshall A, et al. Procedure-type risk categories for pediatric and congenital cardiac catheterization. *Circ Cardiovasc Interv*. 2011;4(2):188–194. https://doi.org/10.1161/CIRCINTERVENTIONS.110.959262

120. Arar Y, Reddy SRV, Kim H, et al. 3D advanced imaging overlay with rapid registration in CHD to reduce radiation and assist cardiac catheterisation interventions. *Cardiol Young*. 2020;30(5):656–662. https://doi.org/10.1017/S1047951120000712

121. Awori J, Friedman SD, Chan T, et al. 3D models improve understanding of congenital heart disease. *3D Print Med*. 2021;7(1):26. https://doi.org/10.1186/s41205-021-00115-7

122. Batteux C, Haidar MA, Bonnet D. 3D-printed models for surgical planning in complex congenital heart diseases: A systematic review. *Front Pediatr*. 2019;7:23. https://doi.org/10.3389/fped.2019.00023

123. Boyer PJ, Yell JA, Andrews JG, Seckeler MD. Anxiety reduction after pre-procedure meetings in patients with CHD. *Cardiol Young*. 2020;30(7):991–994. https://doi.org/10.1017/S1047951120001407

124. Ehret N, Alkassar M, Dittrich S, et al. A new approach of three-dimensional guidance in paediatric cath lab: segmented and tessellated heart models for cardiovascular interventions in CHD. *Cardiol Young*. 2018;28(5):661–667. https://doi.org/10.1017/S1047951117002840

125. Goreczny S, Dryzek P, Morgan GJ, Lukaszewski M, Moll JA, Moszura T. Novel three-dimensional image fusion software to facilitate guidance of complex cardiac catheterization: 3D image fusion for interventions in CHD. *Pediatr Cardiol*. 2017;38(6):1133–1142. https://doi.org/10.1007/s00246-017-1627-4

126. Illmann CF, Ghadiry-Tavi R, Hosking M, Harris KC. Utility of 3D printed cardiac models in congenital heart disease: a scoping review. *Heart*. 2020;106(21):1631–1637. https://doi.org/10.1136/heartjnl-2020-316943

127. Jelnin V, Co J, Muneer B, Swaminathan B, Toska S, Ruiz CE. Three dimensional CT angiography for patients with congenital heart disease: scanning protocol for pediatric patients. *Catheter Cardiovasc Interv*. 2006;67(1):120–126. https://doi.org/10.1002/ccd.20551

128. Valverde I, Gomez-Ciriza G, Hussain T, et al. Three-dimensional printed models for surgical planning of complex congenital heart defects: an international multicentre study. *Eur J Cardiothorac Surg*. 2017;52(6):1139–1148. https://doi.org/10.1093/ejcts/ezx208

129. Steele JM, Moore RA, Lang SM. Use of advanced cardiac imaging in congenital heart disease: growth, indications and innovations. *Curr Opin Pediatr*. 2021;33(5):495–502. https://doi.org/10.1097/MOP.0000000000001051

130. Writing G, Sachdeva R, Valente AM, Armstrong AK, et al. ACC/AHA/ASE/HRS/ISACHD/SCAI/SCCT/SCMR/SOPE 2020 appropriate use criteria for multimodality imaging during the follow-up care of patients with congenital heart disease: a report of the American College of Cardiology Solution Set Oversight Committee and Appropriate Use Criteria Task Force, American Heart Association, American Society of Echocardiography, Heart Rhythm Society, International Society for Adult Congenital Heart Disease, Society for Cardiovascular Angiography and Interventions, Society of Cardiovascular Computed Tomography, Society for Cardiovascular Magnetic Resonance, and Society of Pediatric Echocardiography. *J Am Soc Echocardiogr*. 2020;33(10):e1–e48. https://doi.org/10.1016/j.echo.2020.04.026

131. O'Byrne ML, Rome N, Santamaria RW, et al. Intraprocedural bronchoscopy to prevent bronchial compression during pulmonary artery stent angioplasty. *Pediatr Cardiol*. 2016;37(3):433–441. https://doi.org/10.1007/s00246-015-1296-0

132. Nagaraja V, Kapadia S. Implications of renal disease in patients undergoing structural interventions. *Interv Cardiol Clin*. 2020;9(3):357–367. https://doi.org/10.1016/j.iccl.2020.02.010

133. Stefanescu Schmidt AC, Armstrong A, Kennedy KF, Nykanen D, Aboulhosn J, Bhatt AB. Prediction of adverse events after catheter-based procedures in adolescents and adults with congenital heart disease in the Impact registry. *Eur Heart J*. 2017;38(26):2070–2077. https://doi.org/10.1093/eurheartj/ehx200

134. Dimopoulos K, Diller GP, Koltsida E, et al. Prevalence, predictors, and prognostic value of renal dysfunction in adults with congenital heart disease. *Circulation*. 2008;117(18):2320–2328. https://doi.org/10.1161/CIRCULATIONAHA.107.734921

135. Toso A, Leoncini M, Maioli M, Bellandi F. Pharmacologic prophylaxis of contrast-induced nephropathy. *Interv Cardiol Clin*. 2020;9(3):369–383. https://doi.org/10.1016/j.iccl.2020.02.006

136. Rear R, Bell RM, Hausenloy DJ. Contrast-induced nephropathy following angiography and cardiac interventions. *Heart*. 2016;102(8):638–648. https://doi.org/10.1136/heartjnl-2014-306962

137. Windpessl M, Kronbichler A. Contrast-associated acute kidney injury (CA-AKI) in children: special considerations. *Child Kidney Dis*. 2019;23(2):77–85. https://doi.org/10.3339/jkspn.2019.23.2.77

138. Cantais A, Hammouda Z, Mory O, et al. Incidence of contrast-induced acute kidney injury in a pediatric setting: a cohort study. *Pediatr Nephrol*. 2016;31(8):1355–1362. https://doi.org/10.1007/s00467-016-3313-9

139. Gellis L, Gauvreau K, Ferguson M, Bergersen L, Shafer K, Porras D. Contrast volume to estimated glomerular filtration rate ratio for prediction of contrast-induced acute kidney injury after cardiac catheterization in adults with congenital heart disease. *Catheter Cardiovasc Interv*. 2018;92(7):1301–1308. https://doi.org/10.1002/ccd.27798

140. Maloney E, Iyer RS, Phillips GS, Menon S, Lee JJ, Callahan MJ. Practical administration of intravenous contrast media in children: screening, prophylaxis, administration and treatment of adverse reactions. *Pediatr Radiol*. 2019;49(4):433–447. https://doi.org/10.1007/s00247-018-4306-6

141. Senthilnathan S, Gauvreau K, Marshall AC, Lock JE, Bergersen L. Contrast administration in pediatric cardiac catheterization: dose and adverse events. *Catheter Cardiovasc Interv*. 2009;73(6):814–820. https://doi.org/10.1002/ccd.21902

142. Bangalore S, Barsness GW, Dangas GD, et al. Evidence-based practices in the Cardiac Catheterization Laboratory: A scientific statement from the American Heart Association. *Circulation*. 2021;144(5):e107–e119. https://doi.org/10.1161/CIR.0000000000000996

143. Jick SS, Hedderson M, Xu F, Cheng Y, Palkowitsch P, Michel A. Iodinated contrast agents and risk of hypothyroidism in young children in the United States. *Invest Radiol*. 2019;54(5):296–301. https://doi.org/10.1097/RLI.0000000000000541

144. Kubicki R, Grohmann J, Kunz KG, Stiller B, Schwab KO, van der Werf-Grohmann N. Frequency of thyroid dysfunction in pediatric patients with congenital heart disease exposed to iodinated contrast media – a long-term observational study. *J Pediatr Endocrinol Metab*. 2020;33(11):1409–1415. https://doi.org/10.1515/jpem-2020-0032

145. Mehta R, Lee KJ, Chaturvedi R, Benson L. Complications of pediatric cardiac catheterization: a review in the current era. *Catheter Cardiovasc Interv*. 2008;72(2):278–285. https://doi.org/10.1002/ccd.21580

146. Practice guidelines for preoperative fasting and the use of pharmacologic agents to reduce the risk of pulmonary aspiration: application to healthy patients undergoing elective procedures: an updated report by the American society of anesthesiologists task force on preoperative fasting and the use of pharmacologic agents to reduce the risk of pulmonary aspiration. *Anesthesiology*. 2017;126(3):376–393. https://doi.org/10.1097/ALN.0000000000001452

147. Stevens B, Yamada J, Ohlsson A, Haliburton S, Shorkey A. Sucrose for analgesia in newborn infants undergoing painful procedures. *Cochrane Database Syst Rev*. 2016;7(7):CD001069. https://doi.org/10.1002/14651858.CD001069.pub5

148. Delacrétaz R, Fischer Fumeaux CJ, Stadelmann C, Rodriguez Trejo A, Destaillats A, Giannoni E. Adverse events and associated factors during intrahospital transport of newborn infants. *J Pediatr*. 2022;240:44–50. https://doi.org/10.1016/j.jpeds.2021.08.074

149. Haydar B, Baetzel A, Elliott A, MacEachern M, Kamal A, Christensen R. Adverse events during intrahospital transport of critically ill children: A systematic review. *Anesth Analg*. 2020;131(4):1135–1145. https://doi.org/10.1213/ANE.0000000000004585

150. Power A, Navaratnam M, Murray JM, et al. Adverse events associated with cardiac catheterization in children supported with ventricular assist devices. *ASAIO J*. 2022;68(9):1174–1181. https://doi.org/10.1097/MAT.0000000000001627

151. Honey G, Bleak T, Karp T, MacRitchie A, Null Jr D. Use of the Duotron transporter high frequency ventilator during neonatal transport. *Neonatal Netw*. 2007;26(3):167–174. https://doi.org/10.1891/0730-0832.26.3.167

152. Mainali ES, Greene C, Rozycki HJ, Gutcher GR. Safety and efficacy of high-frequency jet ventilation in neonatal transport. *J Perinatol*. 2007;27(10):609–613. https://doi.org/10.1038/sj.jp.7211799

153. World Health Organization. *Implementation Manual: WHO Surgical Safety Checklist*. Accessed September 20, 2022. 1st ed 2008. https://apps.who.int/iris/handle/10665/70046

154. Lindsay AC, Bishop J, Harron K, Davies S, Haxby E. Use of a safe procedure checklist in the cardiac catheterisation laboratory. *BMJ Open Qual*. 2018;7(3):e000074. https://doi.org/10.1136/bmjoq-2017-000074

155. Walsh EP, Cecchin F. Arrhythmias in adult patients with congenital heart disease. *Circulation*. 2007;115(4):534–545. https://doi.org/10.1161/CIRCULATIONAHA.105.592410

156. Moore JP, Khairy P. Adults with congenital heart disease and arrhythmia management. *Cardiol Clin*. 2020;38(3):417–434. https://doi.org/10.1016/j.ccl.2020.04.006

157. Kumar S, Tedrow UB, Triedman JK. Arrhythmias in adult congenital heart disease: diagnosis and management. *Cardiol Clin*. 2015;33(4):571–588. https://doi.org/10.1016/j.ccl.2015.07.007. viii.

158. Bessière F, Mondésert B, Chaix MA, Khairy P. Arrhythmias in adults with congenital heart disease and heart failure. *Heart Rhythm*. 2021;2(6Part B):744–753. https://doi.org/10.1016/j.hroo.2021.10.005

159. Ohuchi H, Miyamoto Y, Yamamoto M, et al. High prevalence of abnormal glucose metabolism in young adult patients with complex congenital heart disease. *Am Heart J*. 2009;158(1):30–39. https://doi.org/10.1016/j.ahj.2009.04.021

160. Ginde S, Bartz PJ, Hill GD, et al. Restrictive lung disease is an independent predictor of exercise intolerance in the adult with congenital heart disease. *Congenit Heart Dis*. 2013;8(3):246–254. https://doi.org/10.1111/chd.12010

161. Raissadati A, Haukka J, Pätilä T, Nieminen H, Jokinen E. Chronic disease burden after congenital heart surgery: A 47-year population-based study with 99% follow-up. *J Am Heart Assoc*. 2020;9(9):e015354. https://doi.org/10.1161/JAHA.119.015354

162. Mok M, Nombela-Franco L, Dumont E, et al. Chronic obstructive pulmonary disease in patients undergoing transcatheter aortic valve implantation: insights on clinical outcomes, prognostic markers, and functional status changes. *J Am Coll Cardiol Intv*. 2013;6(10):1072–1084. https://doi.org/10.1016/j.jcin.2013.06.008

163. Lui GK, Saidi A, Bhatt AB, et al. Diagnosis and management of noncardiac complications in adults with congenital heart disease: A scientific statement from the American Heart Association. *Circulation*. 2017;136(20):e348–e392. https://doi.org/10.1161/CIR.0000000000000535

164. Daliento L, Somerville J, Presbitero P, et al. Eisenmenger syndrome. Factors relating to deterioration and death. *Eur Heart J*. 1998;19(12):1845–1855. https://doi.org/10.1053/euhj.1998.1046

165. Jensen AS, Idorn L, Thomsen C, et al. Prevalence of cerebral and pulmonary thrombosis in patients with cyanotic congenital heart disease. *Heart*. 2015;101(19):1540–1546. https://doi.org/10.1136/heartjnl-2015-307657

166. Tomkiewicz-Pajak L, Hoffman P, Trojnarska O, Lipczyńska M, Podolec P, Undas A. Abnormalities in blood coagulation, fibrinolysis, and platelet activation in adult patients after the Fontan procedure. *J Thorac Cardiovasc Surg*. 2014;147(4):1284–1290. https://doi.org/10.1016/j.jtcvs.2013.06.011

167. Gillett CD, Morgan GJ. Prophylactic antibiotics in interventional paediatric cardiac catheterisation: old habits die hard? *Cardiol Young*. 2015;25(4):693–697. https://doi.org/10.1017/S1047951114000675

168. Kwaan JH, Rappaport I. Postoperative brachial plexus palsy. A study on the mechanism. *Arch Surg*. 1970;101(5):612–615. https://doi.org/10.1001/archsurg.1970.01340290068015

169. Papp AM, Justin GA, Vernau CT, et al. Perioperative corneal abrasions after nonocular surgery: A systematic review. *Cornea*. 2019;38(7):927–932. https://doi.org/10.1097/ICO.0000000000001972

170. Law MA, Borasino S, McMahon WS, Alten JA. Ultrasound- versus landmark-guided femoral catheterization in the pediatric catheterization laboratory: a randomized-controlled trial. *Pediatr Cardiol*. 2014;35(7):1246–1252. https://doi.org/10.1007/s00246-014-0923-5

171. Breatnach CR, Kenny D, Linnane N, et al. Transcarotid approach to ventricular septal defect closure in small infants. *Pediatr Cardiol*. 2021;42(7):1539–1545. https://doi.org/10.1007/s00246-021-02638-6

172. Justino H, Petit CJ. Percutaneous common carotid artery access for pediatric interventional cardiac catheterization. *Circ Cardiovasc Interv*. 2016;9(4):e003003. https://doi.org/10.1161/CIRCINTERVENTIONS.115.003003

173. Lichtenwalter C, Guleserian KJ, Holper EM. Carotid access for cardiac catheterization: revisiting the past for a complex intra-arterial approach. *Cardiovasc Revasc Med*. 2011;12(2):134.e1–134.e5. https://doi.org/10.1016/j.carrev.2010.10.001

174. Safirstein JG. Optimizing transradial access: radiation, contrast, access site crossover, and ergonomics. *Interv Cardiol Clin*. 2020;9(1):99–105. https://doi.org/10.1016/j.iccl.2019.08.001

175. Sattar Y, Majmundar M, Ullah W, et al. Outcomes of transradial versus transfemoral access of percutaneous coronary intervention in STEMI: systematic review and updated meta-analysis. *Expert Rev Cardiovasc Ther*. 2021;19(5):433–444. https://doi.org/10.1080/14779072.2021.1915768

176. Shroff AR, Gulati R, Drachman DE, et al. SCAI expert consensus statement update on best practices for transradial angiography and intervention. *Catheter Cardiovasc Interv*. 2020;95(2):245–252. https://doi.org/10.1002/ccd.28672

177. Virk HUH, Ullah W, Ahmed M, Chattarjee S, Witzke CF, Banka S. Transradial versus transfemoral artery catheterization: A comparative meta-analysis on cerebrovascular accidents. *Expert Rev Cardiovasc Ther*. 2021;19(2):103–105. https://doi.org/10.1080/14779072.2021.1860752

178. Qureshi SA, Kumar RK. Vascular access in pediatric interventions: science or skill? *Ann Pediatr Cardiol*. 2020;13(1):1–3. https://doi.org/10.4103/apc.APC_213_19

179. Sanborn TA, Tcheng JE, Anderson HV, et al. ACC/AHA/SCAI 2014 health policy statement on structured reporting for the cardiac catheterization laboratory: a report of the American College of Cardiology Clinical Quality Committee. *Circulation*. 2014;129(24):2578–2609. https://doi.org/10.1161/CIR.0000000000000043

180. Chung MG, Guilliams KP, Wilson JL, et al. Arterial ischemic stroke secondary to cardiac disease in neonates and children. *Pediatr Neurol*. 2019;100:35–41. https://doi.org/10.1016/j.pediatrneurol.2019.06.008

181. Hamon M, Baron JC, Viader F, Hamon M. Periprocedural stroke and cardiac catheterization. *Circulation*. 2008;118(6):678–683. https://doi.org/10.1161/CIRCULATIONAHA.108.784504

182. Harrar DB, Salussolia CL, Vittner P, et al. Stroke after cardiac catheterization in children. *Pediatr Neurol*. 2019;100:42–48. https://doi.org/10.1016/j.pediatrneurol.2019.07.005

183. Jayaram N, Spertus JA, Kennedy KF, et al. Modeling major adverse outcomes of pediatric and adult patients with congenital heart disease undergoing cardiac catheterization: observations from the NCDR Impact registry (National cardiovascular data

registry improving pediatric and adult congenital treatment). *Circulation*. 2017;136(21):2009–2019. https://doi.org/10.1161/CIRCULATIONAHA.117.027714

184. Kirton A, DeVeber G. Ischemic stroke complicating pediatric cardiovascular disease. *Nat Clin Pract Cardiovasc Med*. 2007;4(3):163–166. https://doi.org/10.1038/ncpcardio0825

185. Palma A, Viegas J, Manlhiot C, McCrindle B, Benson L. Use of local anesthetic (0.25% bupivacaine) for pain control after pediatric cardiac catheterization: A randomized controlled trial. *Catheter Cardiovasc Interv*. 2016;87(2):318–323. https://doi.org/10.1002/ccd.26284

186. Yamamoto M, Meguro K, Mouillet G, et al. Effect of local anesthetic management with conscious sedation in patients undergoing transcatheter aortic valve implantation. *Am J Cardiol*. 2013;111(1):94–99. https://doi.org/10.1016/j.amjcard.2012.08.053

187. Ryan CA, Robertson M, Coe JY. Seizures due to lidocaine toxicity in a child during cardiac catheterization. *Pediatr Cardiol*. 1993;14(2):116–118. https://doi.org/10.1007/BF00796991

188. Avila ML, Shah PS, Brandão LR. Different unfractionated heparin doses for preventing arterial thrombosis in children undergoing cardiac catheterization. *Cochrane Database Syst Rev*. 2020;2(2):CD010196. https://doi.org/10.1002/14651858.CD010196.pub3

189. Chen D, Långström S, Petäjä J, Heikinheimo M, Pihkala J. Thrombin formation and effect of unfractionated heparin during pediatric cardiac catheterization. *Catheter Cardiovasc Interv*. 2013;81(7):1174–1179. https://doi.org/10.1002/ccd.24621

190. Hanslik A, Kitzmüller E, Thom K, et al. Incidence of thrombotic and bleeding complications during cardiac catheterization in children: comparison of high-dose vs. low-dose heparin protocols. *J Thromb Haemost*. 2011;9(12):2353–2360. https://doi.org/10.1111/j.1538-7836.2011.04539.x

191. Moffett BS, Teruya J, Petit C. Heparin dosing in obese pediatric patients in the cardiac catheterization laboratory. *Ann Pharmacother*. 2011;45(7-8):876–880. https://doi.org/10.1345/aph.1Q090

192. Muster I, Haas T, Quandt D, Kretschmar O, Knirsch W. Factors influencing ACT after intravenous bolus administration of 100 IU/kg of unfractionated heparin during cardiac catheterization in children. *Clin Appl Thromb Hemost*. 2017;23(7):740–747. https://doi.org/10.1177/1076029616660761

193. Ding L, Pockett C, Moore J, El-Said H. Long sheath use in femoral artery catheterizations in infants <15 kg is associated with a higher thrombosis rate: proposed Protocol for Detection and Management. *Catheter Cardiovasc Interv*. 2016;88(7):1108–1112. https://doi.org/10.1002/ccd.26690

194. Argueta-Morales IR, Olsen MC, DeCampli WM, Munro HM, Felix DE. Alternative anticoagulation during cardiovascular procedures in pediatric patients with heparin-induced thrombocytopenia. *J Extra Corpor Technol*. 2012;44(2):69–74. https://doi.org/10.1051/ject/201244069

195. Cetta F, Graham LC, Wrona LL, Arruda MJ, Walenga JM. Argatroban use during pediatric interventional cardiac catheterization. *Catheter Cardiovasc Interv*. 2004;61(1):147–149. https://doi.org/10.1002/ccd.10720

196. Young G, Boshkov LK, Sullivan JE, et al. Argatroban therapy in pediatric patients requiring non-heparin anticoagulation: an open-label, safety, efficacy, and pharmacokinetic study. *Pediatr Blood Cancer*. 2011;56(7):1103–1109. https://doi.org/10.1002/pbc.22852

197. Zaleski KL, DiNardo JA, Nasr VG. Bivalirudin for pediatric procedural anticoagulation: A narrative review. *Anesth Analg*. 2019;128(1):43–55. https://doi.org/10.1213/ANE.0000000000002835

198. Douglas PS, Khandheria B, Stainback RF, et al. ACCF/ASE/ACEP/AHA/ASNC/SCAI/SCCT/SCMR 2008 appropriateness criteria for stress echocardiography: a report of the American College of Cardiology Foundation Appropriateness Criteria Task Force, American Society of Echocardiography, American College of Emergency Physicians, American Heart Association, American Society of Nuclear Cardiology, Society for Cardiovascular Angiography and Interventions, Society of Cardiovascular Computed Tomography, and Society for Cardiovascular Magnetic Resonance endorsed by the Heart Rhythm Society and the Society of Critical Care Medicine. *J Am Coll Cardiol*. 2008;51(11):1127–1147. https://doi.org/10.1016/j.jacc.2007.12.005

199. Sicari R, Nihoyannopoulos P, Evangelista A, et al. Stress echocardiography expert consensus statement—executive summary: European Association of Echocardiography (EAE) (a registered branch of the ESC). *Eur Heart J*. 2009;30(3):278–289. https://doi.org/10.1093/eurheartj/ehn492

200. Ewert R, Heine A, Müller-Heinrich A, et al. Exercise and fluid challenge during right heart catheterisation for evaluation of dyspnoea. *Pulm Circ*. 2020;10(3). https://doi.org/10.1177/2045894020917887

201. Simonneau G, Montani D, Celermajer DS, et al. Haemodynamic definitions and updated clinical classification of pulmonary hypertension. *Eur Respir J*. 2019;53(1). https://doi.org/10.1183/13993003.01913-2018

202. Beghetti M, Schulze-Neick I, Berger RM, et al. Haemodynamic characterisation and heart catheterisation complications in children with pulmonary hypertension: insights from the Global TOPP Registry (tracking outcomes and practice in paediatric pulmonary hypertension). *Int J Cardiol*. 2016;203:325–330. https://doi.org/10.1016/j.ijcard.2015.10.087

203. Kumar S, Memon D, Raj M, et al. Comparison of intravenous sildenafil with inhaled nitric oxide for acute vasodilator testing in pulmonary arterial hypertension. *Pulm Circ*. 2022;12(4):e12180. https://doi.org/10.1002/pul2.12180

204. Rosenzweig EB, Abman SH, Adatia I, et al. Paediatric pulmonary arterial hypertension: updates on definition, classification, diagnostics and management. *Eur Respir J*. 2019;53(1). https://doi.org/10.1183/13993003.01916-2018

205. Naidu SS, Aronow HD, Box LC, et al. SCAI expert consensus statement: 2016 best practices in the cardiac catheterization laboratory: (Endorsed by the Cardiological Society of India, and Sociedad Latino Americana de Cardiologia Intervencionista; Affirmation of value by the Canadian Association of interventional cardiology-Association Canadienne de cardiologie d'intervention). *Catheter Cardiovasc Interv*. 2016;88(3):407–423. https://doi.org/10.1002/ccd.26551

206. Blazin LJ, Sitthi-Amorn J, Hoffman JM, Burlison JD. Improving patient handoffs and transitions through adaptation and implementation of I-PASS across multiple handoff settings. *Pediatr Qual Saf*. 2020;5(4):e323. https://doi.org/10.1097/pq9.0000000000000323

207. Gleich SJ, Nemergut ME, Stans AA, et al. Improvement in patient transfer process from the operating room to the PICU using a lean and Six Sigma-based quality improvement project. *Hosp Pediatr*. 2016;6(8):483–489. https://doi.org/10.1542/hpeds.2015-0232

208. Odegard KC, Bergersen L, Thiagarajan R, et al. The frequency of cardiac arrests in patients with congenital heart disease undergoing cardiac catheterization. *Anesth Analg*. 2014;118(1):175–182. https://doi.org/10.1213/ANE.0b013e3182908bcb

209. Wheeler DS, Sheets AM, Ryckman FC. Improving transitions of care between the operating room and intensive care unit. *Transl Pediatr*. 2018;7(4):299–307. https://doi.org/10.21037/tp.2018.09.09

210. O'Byrne ML, Kennedy KF, Kanter JP, Berger JT, Glatz AC. Risk factors for major early adverse events related to cardiac catheterization in children and young adults with pulmonary hypertension: an analysis of data from the Impact (improving adult and congenital treatment) registry. *J Am Heart Assoc*. 2018;7(5). https://doi.org/10.1161/JAHA.117.008142

211. Glatz AC, Keashen R, Chang J, et al. Outcomes using a clinical practice pathway for the management of pulse loss following pediatric cardiac catheterization. *Catheter Cardiovasc Interv*. 2015;85(1):111–117. https://doi.org/10.1002/ccd.25686

212. Raic R, Steurer LM, Balakas K, Ercole PM. A randomized controlled trial comparing *Flat Times versus Standard* care in pediatric patients post cardiac catheterization. *J Cardiovasc Nurs*. 2020;35(3):307–313. https://doi.org/10.1097/JCN.0000000000000677

213. Hjortdal VE, Redington AN, de Leval MR, Tsang VT. Hybrid approaches to complex congenital cardiac surgery. *Eur J Cardiothorac Surg*. 2002;22(6):885–890. https://doi.org/10.1016/s1010-7940(02)00586-9

214. Bacha EA, Cao QL, Galantowicz ME, et al. Multicenter experience with perventricular device closure of muscular ventricular septal defects. *Pediatr Cardiol*. 2005;26(2: April):169–175. https://doi.org/10.1007/s00246-004-0956-2

215. Bacha EA, Cao QL, Starr JP, Waight D, Ebeid MR, Hijazi ZM. Perventricular device closure of muscular ventricular septal defects on the beating heart: technique and results. *J Thorac Cardiovasc Surg*. 2003;126(6):1718–1723. https://doi.org/10.1016/s0022-5223(03)01043-2

216. Li S, Chen W, Zhang Y, et al. Hybrid therapy for pulmonary atresia with intact ventricular septum. *Ann Thorac Surg*. 2011;91(5):1467–1471. https://doi.org/10.1016/j.athoracsur.2010.11.023

217. Ou-Yang WB, Li SJ, Xie YQ, et al. Hybrid balloon valvuloplasty for the treatment of severe congenital aortic valve stenosis in infants. *Ann Thorac Surg*. 2018;105(1):175–180. https://doi.org/10.1016/j.athoracsur.2017.05.069

218. Dranseika V, Pretre R, Kretschmar O, Dave H. Melody valve to replace the mitral valve in small children: lessons learned. *Ann Pediatr Cardiol*.

2021;14(1):35–41. https://doi.org/10.4103/apc.APC_74_20

219. Freud LR, Marx GR, Marshall AC, Tworetzky W, Emani SM. Assessment of the Melody valve in the mitral position in young children by echocardiography. *J Thorac Cardiovasc Surg*. 2017;153(1):153–160.e1 e151. https://doi.org/10.1016/j.jtcvs.2016.07.017

220. Galantowicz M, Cheatham JP. Fontan completion without surgery. *Semin Thorac Cardiovasc Surg Pediatr Card Surg Annu*. 2004;7:48–55. https://doi.org/10.1053/j.pcsu.2004.02.006

221. Galantowicz M, Cheatham JP. Lessons learned from the development of a new hybrid strategy for the management of hypoplastic left heart syndrome. *Pediatr Cardiol*. 2005;26(2: April):190–199. https://doi.org/10.1007/s00246-004-0962-4

222. Michel-Behnke I, Akintuerk H, Marquardt I, et al. Stenting of the ductus arteriosus and banding of the pulmonary arteries: basis for various surgical strategies in newborns with multiple left heart obstructive lesions. *Heart*. 2003;89(6):645–650. https://doi.org/10.1136/heart.89.6.645

223. Hofferberth SC, Nathan M, Marx GR, et al. Valve-sparing repair with intraoperative balloon dilation in tetralogy of Fallot: midterm results and therapeutic implications. *J Thorac Cardiovasc Surg*. 2018;155(3):1163–1173.e4. https://doi.org/10.1016/j.jtcvs.2017.08.147

224. Holzer RJ, Chisolm JL, Hill SL, et al. Hybrid" stent delivery in the pulmonary circulation. *J Invasive Cardiol*. 2008;20(11):592–598.

225. Meot M, Lefort B, El Arid JM, et al. Intraoperative stenting of pulmonary artery stenosis in children with congenital heart disease. *Ann Thorac Surg*. 2017;104(1):190–196. https://doi.org/10.1016/j.athoracsur.2016.12.012

226. Davenport JJ, Lam L, Whalen-Glass R, et al. The successful use of alternative routes of vascular access for performing pediatric interventional cardiac catheterization. *Catheter Cardiovasc Interv*. 2008;72(3):392–398. https://doi.org/10.1002/ccd.21621

227. Fischer DR, Ettedgui JA, Park SC, Siewers RD, del Nido PJ. Carotid artery approach for balloon dilation of aortic valve stenosis in the neonate: a preliminary report. *J Am Coll Cardiol*. 1990;15(7):1633–1636. https://doi.org/10.1016/0735-1097(90)92839-t

228. Sen S, Pradhan P, Jain S, Trivedi D, Kaushik P. Hybrid stenting of the arterial duct with carotid cut-down and flip technique: immediate and early results. *Cardiol Young*. 2021:1–7. https://doi.org/10.1017/S1047951121004017

229. Amin Z, Gu X, Berry JM, Titus JL, Gidding SS, Rocchini AP. Perventricular [correction of periventricular] closure of ventricular septal defects without cardiopulmonary bypass. *Ann Thorac Surg*. 1999;68(1):149–153. https://doi.org/10.1016/s0003-4975(99)00519-6. discussion 153-144.

230. Cools B, Boshoff D, Heying R, Rega F, Meyns B, Gewillig M. Transventricular balloon dilation and stenting of the RVOT in small infants with tetralogy of Fallot with pulmonary atresia. *Catheter Cardiovasc Interv*. 2013;82(2):260–265. https://doi.org/10.1002/ccd.24548

231. Lu W, Zhang F, Fan T, et al. Minimally invasive-perventricular-device-occlusion versus surgical-closure for treating perimembranous-ventricular-septal-defect: 3-year outcomes of a multicenter randomized clinical trial. *J Thorac Dis*. 2021;13(4):2106–2115. https://doi.org/10.21037/jtd-20-3298

232. Ou-Yang WB, Li SJ, Wang SZ, et al. Echocardiographic guided closure of perimembranous ventricular septal defects. *Ann Thorac Surg*. 2015;100(4):1398–1402. https://doi.org/10.1016/j.athoracsur.2015.05.036

233. Dave H, Rosser B, Knirsch W, Hübler M, Prêtre R, Kretschmar O. Hybrid approach for hypoplastic left heart syndrome and its variants: the fate of the pulmonary arteries. *Eur J Cardiothorac Surg*. 2014;46(1):14–19. https://doi.org/10.1093/ejcts/ezt604

234. Phillips AB, Nevin P, Shah A, Olshove V, Garg R, Zahn EM. Development of a novel hybrid strategy for transcatheter pulmonary valve placement in patients following transannular patch repair of tetralogy of Fallot. *Catheter Cardiovasc Interv*. 2016;87(3):403–410. https://doi.org/10.1002/ccd.26315

235. Sosnowski C, Matella T, Fogg L, et al. Hybrid pulmonary artery plication followed by transcatheter pulmonary valve replacement: comparison with surgical PVR. *Catheter Cardiovasc Interv*. 2016;88(5):804–810. https://doi.org/10.1002/ccd.26620

236. Travelli FC, Herrington CS, Ing FF. A novel hybrid technique for transcatheter pulmonary valve implantation within a dilated native right ventricular outflow tract. *J Thorac Cardiovasc Surg*. 2014;148(2):e145–e146. https://doi.org/10.1016/j.jtcvs.2014.04.046

237. Pedra CA, Pedra SR, Chaccur P, et al. Perventricular device closure of congenital muscular ventricular septal defects. *Expert Rev Cardiovasc Ther*. 2010;8(5):663–674. https://doi.org/10.1586/erc.10.31

238. Wang L, Xie L, Ruan W, Li T, Gan C, Lin K. Percutaneous-perventricular device closure of ventricular septal defect: mid-term follow-up. *BMC Surg*. 2020;20(1):208. https://doi.org/10.1186/s12893-020-00854-0

239. Holzer RJ, Sisk M, Chisolm JL, et al. Completion angiography after cardiac surgery for congenital heart disease: complementing the intraoperative imaging modalities. *Pediatr Cardiol*. 2009;30(8):1075–1082. https://doi.org/10.1007/s00246-009-9500-8

240. Bonatti J, Vassiliades T, Nifong W, et al. How to build a cath-lab operating room. *Heart Surg Forum*. 2007;10(4):E344–E348. https://doi.org/10.1532/HSF98.20070709

241. Kaneko T, Davidson MJ. Use of the hybrid operating room in cardiovascular medicine. *Circulation*. 2014;130(11):910–917. https://doi.org/10.1161/CIRCULATIONAHA.114.006510

242. Bull MJ, Engle WA. Committee on Injury, Violence, and Poison Prevention and Committee on Fetus and Newborn, American Academy of Pediatrics. Safe transportation of preterm and low birth weight infants at hospital discharge. *Pediatrics*. 2009;123(5):1424–1429. https://doi.org/10.1542/peds.2009-0559

243. Ing FF, Pelech A, Natale J, Anderson D, Null D, Lakshshminrushimba S. Transcatheter PDA occlusion in VLBW infants: development of an intra-procedural and transportation safety protocol For Homeostasis Development of an intra-procedural and transportation safety protocol for homeostasis. *Catheter Cardiovasc Interv*. 2020;95(S2):S5–S6.

244. Bentham J, Meur S, Hudsmith L, Archer N, Wilson N. Echocardiographically guided catheter closure of arterial ducts in small preterm infants on the neonatal intensive care unit. *Catheter Cardiovasc Interv*. 2011;77(3):409–415. https://doi.org/10.1002/ccd.22637

245. Pouldar TM, Wong R, Almeida-Jones M, Zahn E, Lubin L. Bedside transcatheter patent ductus arteriosus device occlusion in an extremely low birth weight neonate: A novel approach in a high-risk population. *Case Rep Anesthesiol*. 2021;2021:4716997. https://doi.org/10.1155/2021/4716997

246. Agrawal H, Waller III BR, Surendan S, Sathanandam S. New patent ductus arteriosus closure devices and techniques. *Interv Cardiol Clin*. 2019;8(1):23–32. https://doi.org/10.1016/j.iccl.2018.08.004

247. Cinteza E, Carminati M. Balloon atrial septostomy – almost half a century after. *Maedica (Bucur)*. 2013;8(3):280–284.

248. Eilers L, Qureshi AM. Advances in pediatric ductal intervention: an open or shut case? *Curr Cardiol Rep*. 2020;22(3):14. https://doi.org/10.1007/s11886-020-1266-x

249. Sathanandam S, Gutfinger D, Morray B, et al. Consensus guidelines for the prevention and management of periprocedural complications of transcatheter patent ductus arteriosus closure with the Amplatzer piccolo occluder in extremely low birth weight infants. *Pediatr Cardiol*. 2021;42(6):1258–1274. https://doi.org/10.1007/s00246-021-02665-3

250. Wang-Giuffre EW, Breinholt JP. Novel use of the Medtronic micro vascular plug for PDA closure in preterm infants. *Catheter Cardiovasc Interv*. 2017;89(6):1059–1065. https://doi.org/10.1002/ccd.26855

251. Gopalakrishnan A, Krishnamoorthy KM, Sivasubramonian S. Balloon atrial septostomy at the bedside versus the catheterisation laboratory. *Cardiol Young*. 2019;29(3):454. https://doi.org/10.1017/S1047951118002214

252. Martin AC, Rigby ML, Penny DJ, Redington AN. Bedside balloon atrial septostomy on neonatal units. *Arch Dis Child Fetal Neonatal Ed*. 2003;88(4):F339–F340. https://doi.org/10.1136/fn.88.4.f339

253. Savorgnan F, Zaban NB, Elhoff JJ, Ross MM, Breinholt JP. No difference found in safety or efficacy of balloon atrial septostomy performed at the bedside versus the catheterisation laboratory. *Cardiol Young*. 2018;28(12):1421–1425. https://doi.org/10.1017/S1047951118001439

254. Zellers TM, Dixon K, Moake L, Wright J, Ramaciotti C. Bedside balloon atrial septostomy is safe, efficacious, and cost-effective compared with septostomy performed in the cardiac catheterization laboratory. *Am J Cardiol*. 2002;89(5):613–615. https://doi.org/10.1016/s0002-9149(01)02309-8

255. Maxwell D, Allan L, Tynan MJ. Balloon dilatation of the aortic valve in the fetus: a report of two cases. *Br Heart J*. 1991;65(5):256–258. https://doi.org/10.1136/hrt.65.5.256

256. Freud LR, McElhinney DB, Marshall AC, et al. Fetal aortic valvuloplasty for evolving hypoplastic left heart

syndrome: postnatal outcomes of the first 100 patients. *Circulation*. 2014;130(8):638–645. https://doi.org/10.1161/CIRCULATIONAHA.114.009032

257. Jaeggi E, Renaud C, Ryan G, Chaturvedi R. Intrauterine therapy for structural congenital heart disease: contemporary results and Canadian experience. *Trends Cardiovasc Med*. 2016;26(7):639–646. https://doi.org/10.1016/j.tcm.2016.04.006

258. Kalish BT, Tworetzky W, Benson CB, et al. Technical challenges of atrial septal stent placement in fetuses with hypoplastic left heart syndrome and intact atrial septum. *Catheter Cardiovasc Interv*. 2014;84(1):77–85. https://doi.org/10.1002/ccd.25098

259. Tworetzky W, Wilkins-Haug L, Jennings RW, et al. Balloon dilation of severe aortic stenosis in the fetus: potential for prevention of hypoplastic left heart syndrome: candidate selection, technique, and results of successful intervention. *Circulation*. 2004;110(15):2125–2131. https://doi.org/10.1161/01.CIR.0000144357.29279.54

260. Pedra SR, Peralta CF, Crema L, Jatene IB, da Costa RN, Pedra CA. Fetal interventions for congenital heart disease in Brazil. *Pediatr Cardiol*. 2014;35(3):399–405. https://doi.org/10.1007/s00246-013-0792-3

261. Friedman KG, Sleeper LA, Freud LR, et al. Improved technical success, postnatal outcome and refined predictors of outcome for fetal aortic valvuloplasty. *Ultrasound Obstet Gynecol*. 2018;52(2):212–220. https://doi.org/10.1002/uog.17530

262. Kovacevic A, Öhman A, Tulzer G, et al. Fetal hemodynamic response to aortic valvuloplasty and postnatal outcome: a European multicenter study. *Ultrasound Obstet Gynecol*. 2018;52(2):221–229. https://doi.org/10.1002/uog.18913

263. Moon-Grady AJ, Baschat A, Cass D, et al. Fetal Treatment 2017: the evolution of fetal therapy centers – A joint opinion from the international fetal medicine and surgical society (IFMSS) and the North American fetal therapy network (NAFTNet). *Fetal Diagn Ther*. 2017;42(4):241–248. https://doi.org/10.1159/000475929

264. Kang SL, Jaeggi E, Ryan G, Chaturvedi RR. An overview of contemporary outcomes in fetal cardiac intervention: A case for high-volume superspecialization? *Pediatr Cardiol*. 2020;41(3):479–485. https://doi.org/10.1007/s00246-020-02294-2

265. Jantzen DW, Moon-Grady AJ, Morris SA, et al. Hypoplastic left heart syndrome with intact or restrictive atrial septum: A report from the international fetal cardiac intervention registry. *Circulation*. 2017;136(14):1346–1349. https://doi.org/10.1161/CIRCULATIONAHA.116.025873

266. Edwards LA, Justino H, Morris SA, et al. Controversy about a high-risk and innovative fetal cardiac intervention. *Pediatrics*. 2018;142(3). https://doi.org/10.1542/peds.2017-3595

267. Tworetzky W, McElhinney DB, Marx GR, et al. In utero valvuloplasty for pulmonary atresia with hypoplastic right ventricle: techniques and outcomes. *Pediatrics*. 2009;124(3):e510–e518. https://doi.org/10.1542/peds.2008-2014

268. Moon-Grady AJ, Morris SA, Belfort M, et al. International fetal cardiac intervention registry: A worldwide collaborative description and preliminary outcomes. *J Am Coll Cardiol*. 2015;66(4):388–399. https://doi.org/10.1016/j.jacc.2015.05.037

269. Akagi T. Catheter interventions for Kawasaki disease: current concepts and future directions. *Korean Circ J*. 2011;41(2):53–57. https://doi.org/10.4070/kcj.2011.41.2.53

270. Callahan R, Lock JE, Shah PB, Marshall AC. Transcatheter intervention of coronary obstructions in infants, children, and young adults. *Pediatr Cardiol*. 2018;39(7):1299–1307. https://doi.org/10.1007/s00246-018-1894-8

271. Jeewa A, Chin C, Pahl E, et al. Outcomes after percutaneous coronary artery revascularization procedures for cardiac allograft vasculopathy in pediatric heart transplant recipients: A multi-institutional study. *J Heart Lung Transplant*. 2015;34(9):1163–1168. https://doi.org/10.1016/j.healun.2014.11.011

272. Armstrong AK, Balzer DT, Cabalka AK, et al. One-year follow-up of the Melody transcatheter pulmonary valve multicenter post-approval study. *J Am Coll Cardiol Intv*. 2014;7(11):1254–1262. https://doi.org/10.1016/j.jcin.2014.08.002

273. Hamzeh RK, El-Said HG, Moore JW. Left main coronary artery compression from right pulmonary artery stenting. *Catheter Cardiovasc Interv*. 2009;73(2):197–202. https://doi.org/10.1002/ccd.21769

274. McElhinney DB, Hellenbrand WE, Zahn EM, et al. Short- and medium-term outcomes after transcatheter pulmonary valve placement in the expanded multicenter US melody valve trial. *Circulation*. 2010;122(5):507–516. https://doi.org/10.1161/CIRCULATIONAHA.109.921692

275. Morray BH, McElhinney DB, Cheatham JP, et al. Risk of coronary artery compression among patients referred for transcatheter pulmonary valve implantation: a multicenter experience. *Circ Cardiovasc Interv*. 2013;6(5):535–542. https://doi.org/10.1161/CIRCINTERVENTIONS.113.000202

276. Wittwer ED, Pulido JN, Gillespie SM, Cetta Jr F, Dearani JA. Left Main Coronary artery Compression following Melody Pulmonary Valve Implantation: use of Impella Support as Rescue Therapy and Perioperative Challenges with ECMO. *Case Rep Crit Care*. 2014;2014:959704. https://doi.org/10.1155/2014/959704

277. Thakkar B, Patel N, Poptani V, et al. Clinical and angiographic follow-up of coronary artery fistula interventions in children: techniques and classification revisited. *Cardiol Young*. 2015;25(4):670–680. https://doi.org/10.1017/S1047951114000614

278. Wu YH, Li TY, Lin YJ, et al. Midterm follow-up of transcatheter closure for coronary cameral fistula in pediatrics. *Acta Cardiol Sin*. 2021;37:58–64. https://doi.org/10.6515/ACS.202101_37(1).20200730B

279. Abdelfattah OM, Saad AM, Kassis N, et al. Utilization and outcomes of transcatheter coil embolization for various coronary artery lesions: single-center 12-year experience. *Catheter Cardiovasc Interv*. 2021;98(7):1317–1331. https://doi.org/10.1002/ccd.29381

280. Dehmer GJ, Douglas Jr JS, Abizaid A, et al. SCAI/ACCF/HRS/ESC/SOLACI/APSIC statement on the use of live case demonstrations at cardiology meetings: assessments of the past and standards for the future. *J Am Coll Cardiol*. 2010;56(15):1267–1282. https://doi.org/10.1016/j.jacc.2010.08.599

KEY WORDS adult congenital heart disease, cardiac catheterization, cardiac catheterization standards, congenital heart disease, quality and outcomes, resource limited environments

APPENDIX For the supplementary appendix files, please see the online version of this paper.

APPENDIX A Author Relationship With Industry and Other Entities, (Including Consultant, Speaker's Bureau, Research, Expert Witness, Ownership/Partnership/Principal, Institutional, Organizational, or Other Financial Benefit)

		Type of financial interest		
Committee member	**Hospital affiliation**	**None**	**Modest**	**Significant**
Ralf Holzer (Chair)	UC Davis Children's Hospital, Sacramento, California	None	None	None
Jamil Aboulhosn	UCLA Health, Los Angeles, California	None	None	Edwards, Medtronic
Varun Aggarwal	University of Minnesota Masonic Children's Hospital, Minneapolis, Minnesota	None	None	None
Teiji Akag	Okayama University Hospital, Okayama, Japan	None	None	None
Mazeni Alwi	Institute Jantung Negara, Kuala Lumpur, Malaysia	None	None	None
Aimee Armstrong	Nationwide Children's Hospital, Columbus, Ohio	Abbott, Renata Medical, Autus Valve Technologies, Siemens, Healthineers	Cook, Intersocietal Accreditation Commission	Edwards, Medtronic
Emile Bacha	NewYork-Presbyterian Hospital, New York, New York	None	None	None
Lee Benson	Hospital for Sick Children, Toronto, Ontario, Canada	None	Medtronic, Carag, Abbott	None
Lisa Bergersen	Boston Children's Hospital, Boston, Massachusetts	None	None	None
Regina Bökenkamp	Leiden University Medical Center, Leiden, the Netherlands	Taewoong, Lifetech	None	None
Mario Carminati	Policlinico San Donato Hospital, Milan, Italy	None	Medtronic, Edwards, Abbott, Gore, Taewoong, Lifetech	None
Bharat Dalvi	Glenmark Cardiac Center, Mumbai, India	None	Medtronic, Meril	None
James DiNardo	Boston Children's Hospital, Boston, Massachusetts	None	None	None
Thomas Fagan	Children's Hospital of Michigan, Detroit, Michigan	None	None	None
Ken Fetterly	Mayo Clinic, Rochester, Minnesota	None	Siemens	None
Frank Ing	UC Davis Children's Hospital, Sacramento, California	None	Abbott	None
Damien Kenny	Our Lady Children's Hospital, Dublin, Ireland	None	Edwards, Medtronic, Occlutech, Venus Medtech	None
Dennis Kim	Children's Healthcare of Atlanta, Atlanta, Georgia	None	Edwards, Medtronic	None
Emily Kish	Rainbow Babies Children's Hospital, Cleveland, Ohio	None	None	None
Michael O'Byrne	Children's Hospital of Philadelphia, Philadelphia, Pennsylvania	None	None	None
Clare O'Donnell	Starship Children's Hospital, Auckland, New Zealand	None	None	None
Xiangbin Pan	Cardiovascular Institute, Fu Wai, Beijing, China	None	None	None
Joseph Paolillo	Atrium Health Levine Children's, Charlotte, North Carolina	None	Medtronic	Gore
Carlos Pedra	Instituto Dante Pazzanes, São Paolo, Brazil	None	Medtronic, Abbott, Edwards, Lifetech	None
Alejandro Peirone	Children's Hospital of Cordoba, Cordoba, Argentina	None	None	None
Harsimran Singh	NewYork-Presbyterian Hospital, New York, New York	None	None	None
Lars Søndergaard	Rigshospitalet, Copenhagen, Denmark	None	None	None
John Thomson	Johns Hopkins Children's Center, Baltimore, Maryland Yorkshire Heart Center, Leeds, United Kingdom (at the initiation and first half of the project)	None	None	None
Ziyad Hijazi	Sidra Medicine, Doha, Qatar	Venus Medtech	NuMED, Occlutech	None

Adapted from Bashore et al.[1] This table delineates and relevant relationships of committee members with industry and other entities. The table does not necessarily reflect relationships with industry at the time of publication but reflects any relationships present within 12 months prior to submission to individual societies for societal approval. Definitions are taken from the previous cath lab standards document.[1] A person is deemed to have a significant interest in a business if the interest represents ownership of 5% or more of the voting stock or share of the business entity, or ownership of $10,000 of the fair market value of the business entity; or if funds received by the person from the business entity exceed 5% of the person's gross income for the previous year. Please refer to https://www.acc.org/guidelines/about-guidelines-and-clinical-documents/relationships-with-industry-policy. According to the ACCF, a person has a relevant relationship IF: (1) the relationship or interest relates to the same or similar subject matter, intellectual property, or asset, topic, or issue addressed in the document; or (2) the company/entity (with whom the relationship exists) makes a drug, drug class, or device addressed in the document, or makes a competing drug or device addressed in the document; or (3) the person or a member of the person's household, has a reasonable potential for financial, professional, or other personal gain or loss as a result of the issues/content addressed in the document. Any authors with a significant relationship with industry were recused from writing initial text and voting on document recommendations specific to the disclosed relevant relationships with industry in this document.

APPENDIX B External Reviewers

Peer reviewer	Institution
Balter, Steve	NewYork-Presbyterian Hospital, New York, New York
Bentham, Jamie	Leeds Children's Hospital, Leeds, United Kingdom
Boudjemline, Younes	Sidra Medicine, Doha, Qatar
Butera, Gianfranco	Cardiochirurgia, trapianto cardio-polmonare, Roma, Italy
Cheatham, Sharon	Nationwide Children's Hospital, Columbus, Ohio
Galantowicz, Mark	Nationwide Children's Hospital, Columbus, Ohio
Hassan, Babar	Sindh Institute of Urology and Transplantation (SIUT), Karachi, Pakistan
Kreutzer, Jacqueline	Pittsburgh Children's Hospital, Pittsburgh, Pennsylvania
Michel-Behnke, Ina	University Hospital Vienna, Austria
Naguib, Aymen	Nationwide Children's Hospital, Columbus, Ohio
Petit, Christopher	NewYork-Presbyterian Hospital, New York, New York
Raff, Gary	UC Davis Children's Hospital, Sacramento, California
Schranz, Dietmar	Pediatric Heart Centre, Giessen, Germany
Sivakumar, Kothandam	Madras Medical Mission, Chennai, India
Stapleton, Gary	Texas Children's Hospital, Houston, Texas
Zahn, Evan	Schmidt Heart Institute, Cedars Sinai, Los Angeles, California

The reviewers listed in this table provided comments on some or all sections of the document, which were considered in the revisions. However, reviewers were not asked to provide a formal agreement with the final version of the document.

APPENDIX C Abbreviations and Glossary

2D	two-dimensional
3D	three-dimensional
3DRA	three-dimensional rotational angiography
ACC	American College of Cardiology
ACE	angiotensin converting enzyme
ACGME	Accreditation Council for Graduate Medical Education
ACH	air changes per hour
ACHD	adult congenital heart disease
ACLS	advanced cardiac life support
ACR	American College of Radiology
ACT	activated clotting time
AE	adverse event
AEPC	Association for European Paediatric and Congenital Cardiology
AAPM	American Association of Physicists in Medicine
AHA	American Heart Association
AKI	acute kidney injury
ALARA	as low as reasonably achievable
ANSI	American National Standards Institute
AP	anterior-posterior
APPCS	Asia Pacific Pediatric Cardiac Society
AS	aortic valve stenosis

Continued on the next page

APPENDIX C Continued

ASA	American Society of Anesthesiology
ASD	atrial septal defect
ASHE	American Society for Healthcare Engineering
ASHRAE	American Society of Heating, Refrigerating, and Air-Conditioning
BAV	balloon aortic valvuloplasty
BPV	balloon pulmonary valvuloplasty
C3PO	Congenital Cardiac Catheterization Project on Outcomes
CA	coronary artery
CAD	coronary artery disease
Cath lab	catheterization laboratory
CBD	competence by design
CCAS	Congenital Cardiac Anesthesia Society
CCISC	Congenital Cardiac Interventional Study Consortium
CHARM	Congenital Heart Disease Adjustment for Risk Method
CHD	congenital heart disease
CLD	chronic lung disease
CO2	carbon dioxide
CME	continuing medical education
CP	cheatham-platinum
CPET	cardiopulmonary exercise testing
CPR	cardiopulmonary resuscitation
CQI	continuous quality improvement
CQMC	Core Quality Metric Collaborative
CRNA	certified registered nurse anesthetists
CRISP	Catheterization RISK Score for Pediatrics
CSANZ	Cardiac Society of Australia and New Zealand
CT	computerized tomography
CTO	chronic total occlusion
CTS	cardiothoracic surgery
CXR	chest X-Ray
DAP	dose area product
DSA	digital subtraction angiography
ECG	electrocardiogram
ECMO	extracorporeal membrane oxygenation
ECPR	extracorporeal cardiopulmonary resuscitation
ENT	ear nose throat
EMR	electronic medical record
EPA	entrustable professional activities
EU	European Union
FFR	fractional flow reserve
FiO_2	fraction of inspired oxygen
FOV	field of view
FPS	frames per second
FTE	full-time equivalent
GA	general anesthesia
GDPR	European Union General Data Protection Regulation
GFR	glomerular filtration rate

Continued on the next page

APPENDIX C Continued

Gy	gray
HDU	high dependency unit
HFOV	high frequency oscillatory ventilation
HIPAA	Health Insurance Portability and Accountability Act
HLHS	hypoplastic left heart syndrome
HVAC	heating, ventilation, and air conditioning
IAC	Intersocietal Accreditation Commission
ICE	intra-cardiac echocardiography
ICRP	International Commission on Radiological Protection
ICU	intensive care unit
IHI	Institute for Healthcare Improvement
IMPACT	IMproving Pediatric and Adult Congenital Treatments
iNO	inhaled nitric oxide
IPCCC	International Pediatric and Congenital Cardiac Code
IQIC	International Quality Improvement Collaborative
IVUS	intravascular ultrasound
JCAHO	Joint Commission on Accreditation of Healthcare Organizations
KAP	kerma area product
KeV	kilo-electron-volt
LV	left ventricle
MAUDE	Manufacturer and User Facility Device Experience
m-BTT	modified Blalock-Taussig-Thomas
M&M	morbidity and mortality
MERV	minimum efficiency reporting value rating
MFM	maternal fetal medicine
MPR	multiplanar reformation
MRI	magnetic resonance imaging
MRT	medical radiation technologists
NCRP	National Council on Radiation Protection and Measurements
NIAHO	National Integrated Accreditation for Healthcare Organizations
NICOR	National Institute of Cardiovascular Outcomes
NICU	neonatal intensive care unit
NIRS	near-infrared spectroscopy
NPO	nil by mouth
NQF	National Quality Forum
OECD	Organization for Economic Cooperation and Development
OMS	operator managed sedation
OPPE	ongoing professional performance evaluation
OR	operating room
PACU	post-anesthesia care unit
PAR	periodic automatic replenishment level
PCCL	pediatric and congenital cardiac catheterization laboratory
PDA	patent ductus arteriosus
PDSA	Plan-do-study-act
PFO	patent foramen ovale
PFT	pulmonary function test
PICC	peripherally inserted central catheter

Continued on the next page

APPENDIX C Continued

PICS	Pediatric and Congenital Interventional Cardiovascular Society
PICU	pediatric intensive care unit
PS	pulmonary valve stenosis
QA	quality assurance
QI	quality improvement
RCA	root cause analysis
RCIS	registered cardiovascular invasive specialist
RT	radiation technologist
RV	right ventricle
RVOT	right ventricular outflow tract
RVU	relative value unit
RWI	relationship with industry
SAER	standardized adverse events ratio
SBAR	situation-background-assessment-recommendation
SBE	subacute bacterial endocarditis
SCAI	Society for Cardiovascular Angiography & Interventions
SHD	structural heart disease
SOLACI	Latin American Society of Interventional Cardiology
SPA	Society for Pediatric Anesthesia
Sv	sievert
TAVI	transcatheter aortic valve implantation
TEE	trans-esophageal echocardiography
TPVR	transcatheter pulmonary valve replacement
TTE	transthoracic echocardiography
USS	ultrasound scan
U.S.	United States
USA	United States of America
USNWR	U.S. News & World Report
VAD	ventricular assist device
VLBW	very low birth weight
VO_2	oxygen consumption
VSD	ventricular septal defect
WC	writing committee