



# Closing the gap between acceptable and ideal in catheterisation for paediatric and congenital heart disease—A global view

## Editorial

**Cite this article:** Michel-Behnke I, Kumar RK, Justo R, Zabal C, Marshall AC, and Jacobs JP (2024) Closing the gap between acceptable and ideal in catheterisation for paediatric and congenital heart disease—A global view. *Cardiology in the Young* **34**: 937–944. doi: [10.1017/S1047951124000027](https://doi.org/10.1017/S1047951124000027)

Received: 28 November 2023  
Revised: 27 December 2023  
Accepted: 29 December 2023  
First published online: 3 May 2024

### Keywords:

CHD; congenital heart disease; paediatric heart disease; cardiac catheterisation; quality; safety

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## Abstract

In recent issues of the *Journal of the Society for Cardiovascular Angiography and Interventions* and the *Journal of the American College of Cardiology: Cardiovascular Interventions*, Holzer and colleagues presented an Expert Consensus Document titled: “PICS / AEPC / APPCS / CSANZ / SCAI / SOLACI: Expert consensus statement on cardiac catheterization for pediatric patients and adults with congenital heart disease.” This Expert Consensus Document is a massively important contribution to the community of paediatric and congenital cardiac care. This document was developed as an Expert Consensus Document by the Pediatric and Congenital Interventional Cardiovascular Society, the Association for European Paediatric and Congenital Cardiology, the Asia-Pacific Pediatric Cardiac Society, the Cardiac Society of Australia and New Zealand, the Society for Cardiovascular Angiography and Interventions, and the Latin American Society of Interventional Cardiology, as well as the Congenital Cardiac Anesthesia Society and the American Association of Physicists in Medicine.

As perfectly stated in the Preamble of this Expert Consensus Document, “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 catheterisation and transcatheter management of paediatric and adult patients with congenital heart disease, with added accommodations for resource-limited environments.” And, the fact that the authorship of this Expert Consensus Document includes global representation is notable, commendable, and important.

This Expert Consensus Document has the potential to fill an important gap for this patient population. National guideline documents for specific aspects of interventions in patients with paediatric heart disease, including training guidelines, do exist. However, this current Expert Consensus Document authored by Holzer and colleagues provides truly globally applicable standards on cardiac catheterisation for both paediatric patients and adults with congenital heart disease (CHD).

Our current Editorial provides different regional perspectives from senior physicians dedicated to paediatric and congenital cardiac care who are practicing in Europe, the Asia-Pacific region, Latin America, Australia/New Zealand, and North America. Establishing worldwide standards for cardiac catheterisation laboratories for children and adults with CHD is a significant stride towards improving the quality and consistency of care. These standards should not only reflect the current state of medical knowledge but should also be adaptable to future advancements, ultimately fostering better outcomes and enhancing the lives of individuals affected by CHD worldwide.

Ensuring that these standards are accessible and adaptable across different healthcare settings globally is a critical step. Given the variability in resources and infrastructure globally, the need exists for flexibility and tailoring to implement recommendations.

The potential impact of the Expert Consensus Document and its recommendations is likely significant, but heterogeneity of healthcare systems will pose continuing challenges on healthcare professionals. Indeed, this heterogeneity of healthcare systems will challenge healthcare professionals to finally close the gap between acceptable and ideal in the catheterisation of patients with paediatric and/or congenital heart disease.

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## Introduction

Ina Michel-Behnke

In recent issues of the *Journal of the Society for Cardiovascular Angiography and Interventions* and the *Journal of the American College of Cardiology: Cardiovascular Interventions*, Holzer and colleagues presented an “Expert consensus statement on cardiac catheterisation for paediatric patients and adults with congenital heart disease.”<sup>1,2</sup> This Expert Consensus Document<sup>1,2</sup> has the potential to fill an important gap for this patient population. National guideline documents for specific aspects of interventions in patients with congenital heart disease (CHD), including training guidelines, do exist. However, this current Expert Consensus Document<sup>1,2</sup> authored by Holzer and colleagues provides truly globally applicable standards on cardiac catheterisation for both paediatric patients and adults with CHD.

In 1991, 1998, and 2011, The American Heart Association published statements on cardiac catheterisation in paediatric patients.<sup>3,4,5</sup> The 2011 writing group for The American Heart Association scientific statement about “indications for cardiac catheterisation and intervention in paediatric cardiac disease” included representatives of The American Heart Association, and the publications were endorsed by The American Heart Association as well as the Society for Cardiovascular Angiography and Interventions and the American Academy of Pediatrics.<sup>5</sup> The objective of this 2011 scientific statement of The American Heart Association “was not only to provide the reader with an inventory of diagnostic catheterization and interventional treatment options but also to critically review the literature and formulate relative recommendations that are based on key opinion leader expertise and level of evidence. The writing group was charged with the task of performing an assessment of the evidence and giving a classification of recommendations and a level of evidence to each recommendation.”<sup>5</sup>

Meanwhile, the cohort of patients with CHD was not represented at all in the 2012 Society for Cardiovascular Angiography and Interventions/ACC Expert Consensus Document on Cardiac Catheterization Laboratory Standards<sup>6</sup>; in fact, patients with CHD were not represented in either the content of this document or the writing committee of this document. What makes this Expert Consensus Document<sup>1,2</sup> authored by Holzer and colleagues unique is its desired purpose to deliver truly globally applicable standards on cardiac catheterisation for both paediatric patients and adults with CHD.

In this Expert Consensus Document<sup>1,2</sup> authored by Holzer and colleagues, the focus on patients with paediatric and/or congenital heart disease is reflected in a writing committee that includes well-known individuals in the field of CHD, including representation from cardiac surgery, nursing, anaesthesia/critical care, and a physicist. The writing committee members practice in 15 different countries, and the document has been endorsed by 5 larger cardiac societies, representing North America (Society for Cardiovascular Angiography and Interventions), Europe (Association for European Paediatric and Congenital Cardiology), Asia-Pacific (Asia-Pacific Pediatric Cardiac Society), Latin America (Latin American Society of Interventional Cardiology), and Australia/New Zealand (Cardiac Society of Australia and New Zealand). In addition, the document was also endorsed by the lead society (Pediatric and Congenital Interventional Cardiovascular Society), a global paediatric and congenital cardiac interventional society, as well as two affiliated societies (Congenital Cardiac Anesthesia Society and American Association of Physicists in Medicine).

Because higher-level evidence for many congenital cardiac interventions is lacking, the format of an Expert Consensus Document was chosen. The creation of this Expert Consensus Document<sup>1,2</sup> by Holzer and colleagues included several rounds of reviews within the writing committee, input from 16 external reviewers, and ultimately review by each of the Societies.

The document with its 14 main sections provides recommendations on catheterisation laboratory standards, in terms of management and administration, and importantly addresses the special needs associated with caring for this fragile cohort of neonates, infants, children, and adults with CHD:

- Age-appropriate protocols
- Multidisciplinary collaboration
- Procedural training and certification
- Equipment and technology
- Surgical backup
- Circulatory support
- Data collection and reporting
- Patient-centred care
- Global accessibility

Importantly, each section has additional subsections for adults with CHD. Regional differences and resource-limited environments that require modification of the recommendations have been acknowledged by the writing committee.

The result of this work is a comprehensive document on cardiac catheterisation standards for patients with paediatric and/or congenital heart disease.

However, rather than providing a single point of view, this Editorial provides different regional perspectives from senior interventional cardiologists practising in Asia, Australia/New Zealand, Europe, Latin America, and North America. In addition, this Editorial provides a surgical viewpoint to contextualise this document with the recent publication of “Recommendations for centres performing paediatric heart surgery in the United States.”<sup>7</sup>

The expressed views in the following sections represent the views of the individual practising providers and are not considered official societal statements.

## Asian perspective

Raman Krishna Kumar

The Expert Consensus Document<sup>1,2</sup> that has been developed jointly by major leading international societies provides a comprehensive and practical framework for safe and effective cardiac catheterisation for paediatric patients and adults with CHD.<sup>1,2</sup> The statement also acknowledges the special circumstances in low-resource environments and outlines some of the specific adaptations that may be required in these contexts.<sup>1,2</sup>

While applying the recommendation to the Asian context, it is essential to recognise the extraordinary variations that exist regarding paediatric and congenital cardiac care across the Asian landscape. This tremendous variation is largely a reflection of extremely diverse human development, economic status, health systems, availability of trained paediatric cardiac specialists, and regulatory environments. However, it is reasonably accurate to state that the vast majority of children in the region either do not have any access to comprehensive paediatric cardiac care or are served by programmes that function under severe human and material resource constraints in largely unregulated healthcare

settings.<sup>8,9</sup> For these reasons, children may be at significant incremental risk of adverse events for cardiac catheterisation in many of these settings.

The Expert Consensus Document<sup>1,2</sup> promises to serve as a valuable resource for paediatric cardiac programmes across Asia. Although it is essential to contextually adapt the statement to individual settings while recognizing the specific prevailing challenges, several essential broad recommendations exist in the Expert Consensus Document<sup>1,2</sup> that can and must be applied to all situations where paediatric or congenital cardiac catheterisations are undertaken. These recommendations have the potential to greatly improve the overall safety and effectiveness of cardiac catheterisation in patients with paediatric and/or congenital heart disease. These recommendations can also improve the scope of catheter procedures by enabling “high-risk” catheter interventions. In general, recommendations relating to standardised sedation and monitoring protocols, preprocedural planning, and intraprocedural and post-procedural management, including, specifically, improved communication between team members before, during, and after the procedures, have tremendous scope for rapidly translating into substantially improved patient safety. These recommendations are applicable to all environments, cost very little, and should therefore be widely implemented.

An important area that was not addressed by the Expert Consensus Document<sup>1,2</sup> is the question regarding indications for interventional and diagnostic catheterisation, a question that has specific implications in the Asia-Pacific region because of differences in multiple domains<sup>10</sup>:

- the population of patients,
- cost of care versus affordability,
- variable availability of surgery, and
- differences in availability of devices.

Because of the common occurrence of late-presenting shunts with elevated pulmonary vascular resistance, an important need also exists to specifically address the procedural implications of pulmonary hypertension in greater detail.<sup>11,12</sup>

The Expert Consensus Document<sup>1,2</sup> has a section devoted to consumable supplies and stocking of inventory. New devices, innovations, improvisations, and refinements in catheter interventions have been developed in the Asia-Pacific region, and some of them have found applications in all parts of the world.<sup>13,14,15</sup> While some of the advancements have been systematically studied through multi-centre studies,<sup>16</sup> many innovations are not well documented. The Expert Consensus Document<sup>1,2</sup> does not address the process of how the safety and efficacy of new devices and innovations can be systematically tested and documented to enable wider acceptance. This may perhaps need to be considered in future revisions of the statement.

The Expert Consensus Document<sup>1,2</sup> provides a comprehensive framework for quality improvement covering all elements of paediatric and congenital cardiac catheterisation that can and must be adapted and integrated into local and regional Quality Improvement initiatives. Dedicated multi-institutional quality improvement collaboratives such as the International Quality Improvement Collaborative for Congenital Heart Disease (IQIC) have been developed to enable structured learning and systematic improvements in all the elements that constitute safe paediatric and congenital cardiac catheterisation in low-resource environments.<sup>17</sup> The Expert Consensus Document<sup>1,2</sup> outlines a number of essential recommendations that are also emphasised in the IQIC.

## Australasian perspective

### Robert Justo

The recently published Expert Consensus Document<sup>1,2</sup> on cardiac catheterisation for patients with CHD provides a comprehensive and coherent framework for service delivery, describing high-level performance aimed at ensuring excellent outcomes in children and adults. To achieve these outcomes, the statement emphasises the importance of service priorities such as collaborative teamwork, education, strategic innovation, and quality control. This document is not prescriptive and provides guidelines, which, if applied in either well-resourced or poorly-resourced health settings, will drive improved outcomes. Consequently, the recommendations of the Expert Consensus Document<sup>1,2</sup> are likely to be a valuable resource in Australasian congenital cardiac care.

Healthcare for children and adults with CHD in Australasia occurs predominantly in a government-funded healthcare setting. As the Australasian Adult Congenital Heart Disease population grows, subspecialty services for these patients continue to evolve, with a larger footprint in the private sector than seen in paediatrics. Our health services are well-resourced by world standards, and consequently, a reasonably uniform standard of care is seen throughout the region. All paediatric services are provided in freestanding children’s hospitals, some of which are co-located with an adult hospital with capabilities to care for adults with CHD. However, Australasia has a small population spread over a large geographic area. Tertiary congenital cardiac services are available in six cities and surgery for CHD is available in five cities, with some units providing services to relatively small State populations. Historically, Australasian interventional cardiologists have trained overseas where experience in large volume centres is available.

The congenital cardiac catheterisation laboratory is a unique environment where technically complex procedures are performed, sometimes in small numbers. The consensus statement establishes that the competency of both the operators and the institution to undertake these procedures is a complex dynamic, not simply determined by the number of cases performed. This is important in Australasia, where we have some geographically isolated catheter laboratories performing less than 150 catheterisations per year. It is important that elective, and when required, emergency procedures can be provided safely to the local population while maintaining competency. This has similar implications for the training of interventional cardiologists, with the statement discussing the context of regional training requirements and centre-specific volumes, which would allow larger Australasian programmes to develop training programmes, and remove the current need to spend time internationally. Importantly, it also identifies and defines the training, skills and resources required to deliver optimal care for adults with CHD.

Emphasis is placed on the importance of leadership and multidisciplinary collaboration in all environments to ensure systems are developed and maintained to ensure safety and best outcomes. Importantly, this collaboration should extend to all levels of health administration. The description of ideal and acceptable standards for training of staff, maintenance of skills, design of infrastructure, and standards of equipment, will support the leadership of the clinical team when planning and advocating in their local healthcare settings. This Expert Consensus Document<sup>1,2</sup> will be particularly valuable in resource-limited environments.

The Expert Consensus Document<sup>1,2</sup> mandates that evaluation of quality and safety is essential to ensure good patient outcomes. Measures utilised may be limited by resources but can include:

- evaluation of one's own practice,
- team evaluation of adverse events,
- evaluation of device-related events, and
- comparative reporting using registries.

The authors describe the existing registries, which are predominantly based in North America and have developed risk-adjusted outcomes, acknowledging that these outcomes may not be transferrable to other health settings. A methodology to assess new devices and innovations in other jurisdictions is not addressed by this document. Recognising the importance of benchmarking outcomes and the unique Australasian environment, a project to develop a registry for cardiac catheterisation (CCORANZ: Cardiac Catheter Outcome Registry for Australia and New Zealand) is well advanced with agreement between all regional centres, and data collection has commenced.

The Australasian community is small but very collaborative and is developing standards of care for childhood-onset heart disease to inform regional healthcare requirements. The strength of the cardiac catheterisation consensus statement is the extensive international collaborative authorship that has contributed to its development and writing. Consequently, its scope is broad, and it is relevant for paediatric and adult congenital cardiac services worldwide. It will complement and support Australasian endeavours aimed at improving health outcomes for this complex patient group.

## European perspective

*Ina Michel-Behnke*

Despite congenital heart defects being the commonest inborn malformations, they remain rare diseases, especially when compared to non-structural heart disease seen by adult cardiologists. With this in mind, specialised multidisciplinary centres were built within the European Union with infrastructure to provide centres of adequate expertise (i.e., European Reference Networks).<sup>18</sup>

Enormous diversity exists across Europe, regarding care for paediatric and adult patients with CHD. There are countries with more than 30 centres that provide the full spectrum of interventional catheterisation and surgical procedures and are represented by national paediatric cardiology societies with published guidelines for diagnosis and treatment of CHD. In contrast, in some countries, only one centre exists, and in some countries, catheterisation procedures are done on a monthly basis by international teams visiting the CHD units or with some patients crossing borders to different states for care.

Training of experts for catheterisation, especially those performing interventional procedures for patients with CHD, differs widely within Europe. Board certification for paediatric cardiology exists in about 20 countries, while 7 have substantial informal training, and less than a handful do not have any programme. An exit examination as part of a certificate exists in only 16 countries.<sup>19</sup> To reduce variation and achieve high-quality care across European countries, the Association of European Pediatric and Congenital Cardiology has made efforts to standardise training curricula.<sup>20</sup>

Furthermore, requirements for infrastructure to reach a given level of expertise and competence as a physician, and as a centre of excellence, on a national level and within Europe, have been published.<sup>21–24</sup> Finally, certification in paediatric and congenital cardiology training has been approved, which includes cardiac catheterisation procedures.

What the paper by Holzer and colleagues<sup>1,2</sup> adds, is the multi-societal, indeed global view on how to establish a level of expertise. This work should help to foster the quality of care for patients with CHD at any age, either adults or children. Those European countries, with limited resources and a lack of CHD cardiologists or even paediatric cardiologists, will be supported by these guidelines by enhanced recognition of the subspecialty of congenital cardiology and the special requirements for safe and effective catheterisation procedures.<sup>11</sup>

Few people would contest the fact that CHD facilities should have enough paediatric cardiologists, Adult Congenital Heart Disease physicians, and nursing staff to perform complex catheterisation procedures safely. The presence of established guidelines can help those facing reduction of resources and worsening of clinical services in several countries all over Europe. In particular, published standards will assist those starting a programme to ensure resources are optimally used to provide the best patient care.

All the evidence suggests that care for adults with CHD is improved when transition programmes are initiated at an early stage. Regarding catheterisation in adults with CHD, many will benefit from joint procedures performed by paediatric and adult congenital cardiologists. It must be the most experienced physician who takes the main responsibility for a procedure, with any patient's age restrictions. Interdisciplinary conversation and understanding are emphasised; and especially for adults with CHD, this interdisciplinary collaboration remains the key to success. Special equipment (like a biplane angiography machine) and configurations within the catheterisation laboratory environment are addressed and should allow the highest safety and quality of treatment.

Quality assessment and quality assurance are cornerstones of catheterisation procedures and are implemented in national healthcare regulations across most European countries. Data must be maintained at least in an internal database to track performance and outcomes. The Association for European Paediatric and Congenital Cardiology has recently launched an interventional module within a surgical database, *The European Congenital Heart Surgeons Association Congenital Database*, which allows analysis between European centres for catheter interventions, as well as comparison with surgical procedures.<sup>25,26</sup> Over time, it is envisaged that gathering and sharing data of this kind will improve the quality of paediatric and congenital cardiac care.

It is probably true that the ideal environment for hybrid procedures like stenting the arterial duct or closure of a ventricular septal defect is a hybrid catheterisation suite, but this should not preclude planning a hybrid strategy in a regular catheterisation laboratory or operating theatre.

In Europe, most paediatric CHD units are part of a children's hospital with paediatric-centred processes, while adults with CHD are mainly treated in cardiology units. Only very rarely, combined wards with personnel trained for all age groups are available. The big paediatric cardiology centres have their own catheterisation suites, while in the majority of centres, there are shared facilities with the cardiology units.

The consensus paper touches comprehensively on almost all aspects of organisational and periprocedural care in cardiac catheterisation of patients with CHD. Those discussed and the associated responsibilities and leadership reflect terms and conditions in the United States of America, which do not necessarily translate easily to all countries within Europe. Instead, it is a helpful adjunct to existing recommendations aiming to improve the outcomes of catheterisation procedures in paediatric

and adult patients with CHD. Being aware of limitations on a local or national level, the paper has the potential to decrease the gap between acceptable and ideal. Until this gap is bridged, international collaborations and exchange of knowledge should especially support those units in restricted environments, as these units strive to approach the ideal and develop a high standard of care in catheterisation for children and adults with CHD.

## Latin American perspective

### Carlos Zabal

This document outlines important standards and considerations for catheterisation laboratories, including staffing, equipment, and procedures, which can help ensure safe and effective patient care. It provides guidance on the roles and responsibilities of staff and leadership, as well as recommendations for equipment and facility requirements.

A dedicated catheterisation laboratory for congenital cardiac interventions plays a crucial role. Here are some key reasons why it is essential:

### Precision and expertise

Congenital cardiac conditions are complex and diverse. A dedicated catheterisation laboratory provides a controlled environment where specialised interventional cardiologists and nurses can perform intricate procedures with precision. These professionals have extensive experience in managing congenital heart defects, ensuring optimal outcomes for patients.

### Advanced imaging and visualisation

Catheterisation laboratories are equipped with state-of-the-art imaging technologies such as fluoroscopy, echocardiography, and angiography. These tools allow real-time visualisation of the heart's structures, blood flow, and abnormalities. Accurate imaging guides the placement of catheters, stents, and other devices during interventions.

### Minimally invasive procedures

Catheter-based interventions are less invasive than open-heart surgeries. Procedures like balloon valvuloplasty, closure of septal defects, and stent placement can be performed safely, even in low-weight premature babies. Minimally invasive approaches reduce recovery time, pain, and complications.

### Collaboration and multidisciplinary care

A dedicated catheterisation laboratory fosters collaboration among cardiologists, surgeons, anaesthesiologists, and other specialists. Multidisciplinary teams discuss cases, plan interventions, and provide comprehensive care. Regular meetings enhance decision-making and patient management.

### Emergency situations

Some congenital cardiac conditions require urgent intervention. Having a dedicated catheterisation laboratory ensures timely access to life-saving procedures during emergencies. Immediate catheter-based interventions, such as atrioseptostomy or ductal stenting, can stabilise patients and prevent complications.

A document with guidelines for congenital catheterisation laboratories, like the one presented here, is highly important for

Latin American countries. Guidelines provide a framework for consistent practices and quality assurance. In Latin America, where healthcare systems vary in each country, having standardised guidelines ensures that congenital cardiac interventions meet the highest standards. Guidelines help minimise risks during procedures. Proper protocols reduce complications, enhance patient safety, and improve outcomes. Latin American patients deserve the same level of care as those in other regions.

Guidelines also ensure optimisation of resource allocation, especially in countries or facilities with limited resources. In these situations, operators may have to utilise a single-plane laboratory due to a lack of availability of a biplane laboratory, and alternative strategies may be necessary to meet the supply demands for specific cases. Additionally, the document notes that re-sterilization may be required.

The Expert Consensus Document<sup>1,2</sup> also has some considerations about education and training for healthcare professionals. It helps cardiologists, nurses, and technicians stay updated on best practices. A well-trained staff contributes to successful interventions.

While global guidelines exist, local adaptations are crucial. Latin American guidelines can address region-specific challenges, cultural factors, and socio-economic realities.

In summary, this Expert Consensus Document<sup>1,2</sup> authored by Holzer and colleagues is a well-structured document with guidelines for congenital catheterisation laboratories that can significantly impact patient care, safety, and outcomes in Latin American countries.

## North American perspective

### Audrey Marshall

Despite the relative abundance of over 100 paediatric cardiac catheterisation practices concentrated in North America, many of which reside in academic medical centres, arriving at consensus around best practice in this tightly-connected field presents few material disagreements. Mutually-recognized best practices are shared by centres through commonly accessed publications, academic meetings, and more personally through mentorship and training. In fact, many current operators represent a diaspora of trainees from a handful of large North American centres, allowing rapid dissemination of specific procedural practices and models of care delivery.

The best catheterisation services pursue dual goals of innovation and quality. Standardisation, or simply reduction in variability, is an important tool through which high quality can be achieved and reproduced. Thus, the current effort to codify a broad set of global standards advances the efforts to improve and expand our field. Certain barriers exist, however to universal adoption of these practices even within the relatively homogeneous North American environment.

Most of the comments below will reflect the perspective of the populous and relatively well-resourced healthcare environments of the United States of America, Canada, and Mexico. It is a fact that some North American countries (for example, countries in the Caribbean) could be conventionally categorised as “resource limited,” and interventional catheterisation services are currently quite limited in these countries. As *Organisation for Economic Co-operation and Development* countries enjoy some of the highest Gross Domestic Products on the planet, one would expect that resource limitation should not present a major barrier to the

attainment of the “Ideal” rather than the “Acceptable” when it comes to procedural healthcare. The reality is that even in the United States of America, the country spending the highest percentage of its Gross Domestic Product on healthcare, financial constraints can necessitate compromise.<sup>27</sup> Even in wealthy countries, access to resources necessary to support a high-quality paediatric interventional cardiology service (for example, capital equipment, staffing, laboratory, and blood bank support) is subject to a variety of factors including competing institutional priorities, reimbursement rates, and state/provincial or federal budgets.

Non-financial factors may also present barriers to adoption of ideal standards. One example would be that of preparation and depth of the paediatric cardiac interventional workforce. As noted by the authors, determination of competency as a paediatric interventional cardiologist is largely based on completion of an unstandardised subspecialty fellowship. There is no single body governing certification in the speciality, and the conferral of procedural privileges is left to the discretion of an employer or institution. Once practising, maintenance of case volumes and procedural competency is largely self-monitored. In this context, the critical importance of quality consortiums or registries capable of providing benchmarked outcomes and standardised rates of adverse events is clear. Fortunately, several such enterprises are well-established in North America,<sup>28</sup> although participation remains voluntary. Beyond physician operators, there may be challenges in staffing other roles on the catheterisation laboratory team, where ideal circumstances like functional flexibility may be restricted by scope of practice regulations or union agreements.

Myriad state or provincial governmental regulations, as well as institutional policies, impact the degree to which some changes can be implemented. States within the United States of America and payors partner with the Joint Commission on Accreditation of Healthcare Organizations, which provides accreditation for hospitals and certification for certain services. Some best practices, such as adherence to National Patient Safety Standards (for example, two-factor patient identification, timely reporting of test results), are nearly universally observed.<sup>29</sup> And for the most part, these requirements will be well-aligned with the ideal standards for catheterisation laboratories. However, situations may arise where there is conflict. For example, some regulations on radiation safety and obligate disclosure may create periodic staffing challenges in meeting ideal catheterisation laboratory staffing standards. Work hour restrictions coupled with increased service demands on trainees require administrative vigilance to ensure consistent staffing for best practice. At the institutional level, policies mandating just-in-time procurement practices and reliance on periodic automated replenishment, can jeopardise the timely availability of essential equipment or devices.

Not coincidentally, this standards document arrives at a time when the maturity of the field and the finances of practice in North America are driving regionalisation of paediatric cardiac care. While the Canadian system has already largely regionalised paediatric cardiac procedural care, the United States of America is just beginning to tackle this issue. The proliferation of expert statements on the requirements for provision of care can be seen, in part, as an attempt to inform this rational regionalisation process.<sup>30</sup> In the best case, these recommendations are evidence-based, as with some pieces focusing on surgical care.<sup>7</sup> However, to date, relatively little evidence exists to support many of the recommendations described in these catheterisation standards. The distinction between minimal criteria (“acceptable”) and aspirational goals (“ideal”) is a consensus creation and may lead to

unintended consequences as regionalisation progresses. The concept of universal standards, particularly around issues of staffing and surgical backup, raises the spectre of penalising or marginalising those laboratories that may fail to meet them, even transiently, and may raise a barrier to entry for new or emerging programmes. If well-executed, with the goal of optimising access to care and patient outcomes, regionalisation promises to create both an efficient, and sufficient, network of high-quality centres. Having now articulated these catheterisation standards, the more rapidly we move on to refining them with evidence, the more credibly they will inform regionalisation to this laudable end.

## Surgical view

### Jeffrey Phillip Jacobs

The Expert Consensus Document<sup>1,2</sup> authored by Ralf J. Holzer, Lisa Bergersen, John Thomson, Ziyad M. Hijazi, and colleagues and titled: “*PICS / AEPC / APPCS / CSANZ / SCAI / SOLACI: EXPERT CONSENSUS STATEMENT ON CARDIAC CATHETERIZATION FOR PEDIATRIC PATIENTS AND ADULTS WITH CONGENITAL HEART DISEASE*” is a massively important contribution to the community of paediatric and congenital cardiac care. This document was developed as an Expert Consensus Document by the Pediatric and Congenital Interventional Cardiovascular Society, the Association for European Paediatric and Congenital Cardiology, the Asia-Pacific Pediatric Cardiac Society, the Cardiac Society of Australia and New Zealand, the Society for Cardiovascular Angiography and Interventions, and the Latin American Society of Interventional Cardiology, as well as the Congenital Cardiac Anesthesia Society and the American Association of Physicists in Medicine.

As perfectly stated in the Preamble of this Expert Consensus Document,<sup>1,2</sup> “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 catheterisation and transcatheter management of paediatric and adult patients with congenital heart disease, with added accommodations for resource-limited environments.” And, the fact that the authorship of this Expert Consensus Document<sup>1,2</sup> includes global representation is notable, commendable, and important.

It is a fact that the art and science of paediatric and congenital cardiac care continue to evolve. It is also a fact that the ongoing evolution of the art and science of paediatric and congenital cardiac care must span traditional geographic, temporal, and subspecialty boundaries.<sup>31,32</sup> This Expert Consensus Document<sup>1,2</sup> authored by Holzer and colleagues has successfully spanned traditional geographic boundaries and therefore is very powerful. Still, it is clear that a need exists for further advances in paediatric and congenital cardiac care that are derived from sources of data that span traditional subspecialty and temporal boundaries as well. Paediatric and congenital cardiac care is multidisciplinary and longitudinal, impacting the entire life of the patient. Thus, the creation and utilisation of sources of data about paediatric and congenital cardiac care that span these traditional geographic, temporal, and subspecialty boundaries are imperative.

Several ongoing collaborative efforts involving cardiologists and cardiac surgeons are notable and will help set the stage for the creation and utilisation of sources of data about paediatric and congenital cardiac care that span these traditional geographic, temporal, and subspecialty boundaries. Through the collaborative

efforts of multiple subspecialties, including interventional cardiologists and cardiac surgeons, the international nomenclature of paediatric and congenital cardiac care has been standardised with the creation of *The 2021 International Paediatric and Congenital Cardiac Code* and the *Eleventh Revision of the International Classification of Diseases*; this system of nomenclature for paediatric and congenital cardiac care has successfully unified the clinical and administrative nomenclatures of paediatric and congenital cardiac care.<sup>33–37</sup> Efforts have been made in the domain of paediatric and congenital cardiac care to create databases that capture *BOTH* interventional cardiology procedures and cardiac surgery procedures.<sup>25,26</sup> These efforts are exemplified by the recent collaborative efforts between The European Congenital Heart Surgeons Association and The Association for European Paediatric and Congenital Cardiology to create the new Association for European Paediatric and Congenital Cardiology Interventional Cardiology Part of The European Congenital Heart Surgeons Association Congenital Database.<sup>25,26</sup> This collaborative initiative allows centres to have access to robust surgical and transcatheter outcome data from their own centre, as well as robust national and international aggregate outcome data for benchmarking. The valuable synergies provided by the shared interventional and surgical analyses of the outcomes of patients will improve paediatric and congenital cardiac care. In the future, analyses of the outcomes of patients from the shared interventional cardiology and cardiac surgical data will inform the creation of Expert Opinions/White Papers, Expert Consensus Documents, and even Clinical Practice Guidelines.

## Conclusion

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Establishing worldwide standards for cardiac catheterisation laboratories for children and adults with CHD is a significant stride towards improving the quality and consistency of care. These standards should not only reflect the current state of medical knowledge but should also be adaptable to future advancements, ultimately fostering better outcomes and enhancing the lives of individuals affected by CHD worldwide.

Ensuring that these standards are accessible and adaptable across different healthcare settings globally is a critical step. Given the variability in resources and infrastructure globally, the need exists for flexibility and tailoring to implement recommendations.

The potential impact of the Expert Consensus Document<sup>1,2</sup> and its recommendations is likely significant, but heterogeneity of healthcare systems will pose continuing challenges on healthcare professionals to finally close the gap between acceptable and ideal in the catheterisation of patients with paediatric and/or congenital heart disease.

**Acknowledgements.** None.

**Financial support.** None.

**Competing interests.** None.

**Ethical standards.** The authors assert that all procedures contributing to this work comply with the ethical standards of the relevant national guidelines on human experimentation and with the Helsinki Declaration of 1975, as revised in 2008.

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