

## Core Curriculum

# Interventional Fellowship in Structural and Congenital Heart Disease for Adults

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Training for structural and adult congenital heart disease interventions remains undeveloped. With the advent of recent percutaneous interventions for the treatment of structural and valvular heart disease, such as transcatheter aortic and pulmonary valve implantation, mitral valve repair, and the expansion of shunt closure procedures, there is a clear need to define the training requirements for this category of procedures. The training needs to be aligned with the goals and priorities of a basic or advanced level and be categorized into acquired and congenital. This document will define the training needs and knowledge base for the developing field of structural heart disease intervention. © 2010 Wiley-Liss, Inc.

**Key words:** core curriculum; structural heart disease; training

## INTRODUCTION

The trends in cardiovascular disease diagnosis and therapeutics have rapidly evolved over the past 50 years and with this, educational programs have been developed to provide high quality training. Even though our current medical licenses stipulate that we are “physicians and surgeons,” the reality is that for more than half a century the vast majority of us are either one or the other; that has been the result of the training programs we entered. In the field of cardiovascular disease, the audacious work of several pioneers [1–8] has served to reconsider the concept of “physician and surgeon” once again, or certainly “proceduralist”. In today’s practice, we now have clinical cardiologists, vascular radiologists, vascular surgeons as well as cardiovascular surgeons performing transcatheter interventional procedures.

The American Board of Internal Medicine has long recognized the field of cardiovascular disease as a separate subspecialty and within the past 10 years, it has also developed an added qualification in interventional cardiology. This has focused on coronary and peripheral vascular interventions. Structural cardiovascular diseases are defined as those acquired or congenital cardiovascular pathologies that involve the major central cardiovascular

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structures outside of the acquired atherosclerotic coronary and peripheral vascular pathologies. Formal training for “structural and adult congenital heart disease interventions” remains relatively undeveloped. With the advent of recent percutaneous interventions for the treatment of structural and valvular heart disease, such as transcatheter aortic and pulmonary valve implantation, mitral valve repair, and the expansion of shunt closure procedures among many others, there is a clear need to define the basic training requirements for those physicians intending to perform such procedures.

Lifesaving advancements in the management of children with congenital heart disease have translated into an increasing number of adult patients with palliated congenital cardiovascular malformations [9]. Currently, there are more adults (over one million in the U.S. alone) than children with congenital heart disease [10], and it is estimated that the number of adults with repaired or palliated congenital cardiac defects will continue to rise. This fact has raised concern that the number of medical experts may be insufficient to manage the expanding population of adult patients with repaired and unrepaired congenital heart defects that require specialized care. Several institutions have developed dedicated clinical training programs in adult congenital heart disease. Nevertheless, when cardiovascular interventions are needed for such patients, most procedures are performed by pediatric interventional cardiologists who may be unfamiliar with the management of adults or by adult interventional cardiologists who are unfamiliar with the complexity of congenital cardiovascular diseases. The requirements for training cardiologists with the technical skills and knowledge to perform transcatheter interventions to palliate adult patients with uncorrected or corrected congenital cardiovascular malformations must now be developed and matured. The ACC/AHA 2008 guidelines for management of adults with congenital heart disease outlines the indications and types of treatment recommended for the most common congenital cardiovascular diseases affecting adults [11], but delineation of training requirements was outside the scope of the guidelines. The 32<sup>nd</sup> Bethesda Conference and the ACC/AHA ACHD Care Guidelines both recommended that care for adults with congenital heart disease be provided by clinicians specifically trained in the care of ACHD, and within centers of expert care for ACHD. Evaluations in the medical literature using administrative datasets from the National Inpatient Sample [12], Children’s Health Corporation of America database [13] and National Inpatient Sample [9] have all suggested that interventional (surgical and catheter-based) outcomes for ACHD are improved when procedures are performed by persons trained in congenital heart

disease and those who perform such procedures at considerable volume. Smaller single center studies have suggested similar findings regarding imaging of ACHD. These consensus statements have been supported by the American College of Cardiology, the American Heart Association, and supporting organizations such as the Society of Thoracic Surgeons, to name a few. To adequately understand the appropriate use of CHD interventional procedures requires a firm knowledge of CHD itself and this should be a prerequisite for training that leads to mastery of the necessary procedural skills. The commitments to ACHD interventional training, as well as the rewards of such, are both extensive and intense. During training, a skill set must be acquired that includes mastery of CHD anatomy and physiology, detailed principles and subtleties of past and current corrective procedures and potentials, CHD hemodynamic acquisition and interpretation, simple and complex shunts, refined localized angiography, principles and interpretation of extravascular and intravascular echocardiography, cardiac CT, and cardiac MRI, as well as causes for and management of pulmonary vascular disease and subpulmonary ventricular failure. Depending upon pathway of entry into ACHD interventional training, additional skills and pathway-specific curriculum should be outlined in detail to include development of expertise in basic internal medicine, adult cardiology, and general cath lab techniques. While this document suggests a potential for a minimum of 12-month training in SHD and ACHD intervention, the authors recognize that such a period is likely to under-represent the requisite time necessary for such training and skill mastery. Closure of an atrial septal defect may seem straightforward compared with interventions for the more complex forms of CHD described in the document, but to know the appropriate indications and perform the procedure safely requires expertise in the interpretation of noninvasive diagnostic imaging, shunt physiology, and pulmonary hypertension, so that the specialist can provide expert opinion regarding the need for trans-catheter closure. Likewise, other CHD lesions (e.g., pulmonic stenosis, valvular and sub-valvular left ventricular outflow tract obstruction, tetralogy of Fallot with abnormal pulmonary arterial anatomy, residual shunts, and complex aortic arch variants) demand comparable experience and judgment.

Additionally, development and assessment of standards for intervention, techniques of intervention, and follow-up after intervention, coordinated with metrics of quality, are as critical to the assessment of standards for ACHD interventional fellowship training as for training in other types of invasive medical or surgical procedures. Noncoronary cardiovascular pathology, excluding conduction and rhythm abnormalities, constitutes the majority of acquired

and congenital structural heart disease pathology affecting the adult population. Thus, ACHD interventional care must be delivered by people who are expert at ACHD catheterization and either are: (a) trained as CHD or ACHD caregivers, and are part of an ACHD care center (as recognized by existing guidelines and accreditation policies) where individual procedures are reviewed, discussed, and accomplished, or (b) trained only in ACHD catheterization (and not formally trained as CHD or ACHD caregivers) but are mandated to practice, and to have individual procedural review—discussion—and accomplishment, in coordinated fashion within an existing ACHD caregiving team in an ACHD care center (as recognized by existing guidelines and accreditation policies). It will therefore be crucial to begin to create clear and defined requirements for (a) training programs, (b) program directors, (c) curriculum, and (d) competencies and assessments, that take such requirements into account. The document must demonstrate how the objectives listed will be accomplished within 12 months accounting for various entry pathways and therefore skill sets.

In addition to congenital heart disease, there has been a great expansion in the application of interventional techniques for other cardiovascular conditions. Adult valvular heart disease is currently the subject of intense evolution with the introduction of novel percutaneous valve replacement or repair strategies. It is estimated that over 15,000 patients worldwide have received a percutaneous aortic valve replacement and two devices already have CE mark approval. Other conditions currently being treated include: catheter repair for mitral regurgitation, alcohol septal ablation for treatment of hypertrophic obstructive cardiomyopathy, postmyocardial infarction ventricular septal defects (VSD), closure of periprosthetic leaks, occlusion of the left atrial appendage for stroke prevention, and dilation and stenting of acquired systemic and pulmonary vessels.

It is clear that the knowledge base for intervening in such pathologies is very large and crosses several medical specialties (adult and pediatric cardiology, cardiovascular valvular, and congenital heart disease surgery). Therefore, to develop a comprehensive core curriculum, a panel of multi-disciplinary experts in those fields have been selected to develop a core curriculum for training in transcatheter interventions for adult structural and congenital cardiovascular pathologies.

### Rationale for Training and Educational Goals

One of the critical goals to be garnered from training is how to formulate and execute transcatheter interventions for the most common and also the extensive variety of complex structural heart disease. In developing these recommendations, one factor that is paramount is patient

safety. These are small volume procedures that should not be performed by all operators and centers and so expertise for these small volume procedures should be centralized. Agreed standards need to be developed for the institutions, the operating teams, their supporting infrastructure, and the workload of the centers and their results.

Ever since 1995 when the first guidelines for training in adult cardiovascular medicine were published [14], significant advances have occurred in the field of cardiovascular medicine. One of the areas within this field that perhaps had one of the fastest growth curves is interventional cardiology, and indeed this area has matured into a true subspecialty within cardiovascular medicine. Currently, the American Board of Internal Medicine, subspecialty board on cardiovascular disease requires a 3-year general cardiology fellowship training to qualify a candidate to sit for the certification and an additional year in adult interventional cardiology, typically focused on coronary interventions, to sit for the examination of added qualification in interventional cardiology.

However, over the past 2 decades, the field of noncoronary cardiovascular interventions has also significantly matured, to the point that it would be incorrect to believe that someone trained and certified in coronary interventions is qualified to perform the spectrum of complex peripheral interventions, carotid interventions, advanced valvular interventions, or interventions for complex congenital heart disease. Thus, additional and specialized training in these different arenas is required and in demand. Furthermore, there are some of these areas of expertise that are not the exclusive territory for those with the background of medicine and cardiovascular disease. For example, depending on the interests and training of the specific individual, a pediatric cardiologist trained in interventional procedures in children may be able to expand their expertise to adult patients. Similarly, many cardiovascular surgeons have already started to expand their expertise in the field of transcatheter techniques for valve interventions. Defining training requirements and program standards is a major challenge for structural heart disease interventions. Requirements for training centers are currently not defined, including procedural volume that those centers should maintain. At a minimum, a composite number of one hundred procedures a year should be required for eligibility to become a training center. Moreover, defining requirements for training and credentialing for the established practitioners may be an even greater hurdle. Not only are the procedures rapidly evolving, but also establishing training requirements poses some specific issues for structural interventions compared with coronary or peripheral vascular interventions. There needs to be an emphasis on developing a sensible and reliable system that we could track individual and institutional outcomes to ultimately be able to ensure the public of each practitioner

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and institution proficiency in this field, regardless of their background training.

The purpose of this consensus document is to outline the knowledge base and necessary skills to acquire proficiency in structural heart disease interventions. Furthermore, a career track in structural heart disease is outlined in detail and the importance of active participation in research activities is emphasized. Our educational goals for training are aligned with and modeled after the recommendations of the ACC/SCAI/AHA Task Force [15] on optimal adult interventional cardiology training programs as follows:

1. To understand the effectiveness and limitations of noncoronary cardiovascular interventional procedures to select patients and procedure types appropriately.
2. Define the cognitive knowledge base required for the field, i.e., the topics that comprise the core curriculum in structural cardiac interventions.
3. To achieve the appropriate cognitive knowledge and technical skills needed to perform interventional cardiovascular procedures with emphasis on procedural performance, patient selection, pre- and postadjunctive strategies, and complication management.
4. To foster an attitude of life-long learning and critical thinking skills needed to gain from experience and incorporate new developments.
5. To understand and commit to quality assessment and improvement in procedure performance.

All physicians and surgeons in training must be skilled clinicians and know the natural history of the different pathologies and their management. They must become well educated in the understanding of all different physiologies, their diagnosis including physical examination, hemodynamics (invasive and noninvasive), different and optimal imaging modalities to best define the pathology being considered, and also the therapeutic alternatives, medical, surgical and interventional, and decision making process for deciding which can serve best the well being of the patient. An integrated, multi-disciplinary teaching approach will be required, the existence of a specialized structural cardiac referral center with dedicated clinicians, imaging specialists, cardiac anesthesiologists, valvular surgeons and congenital heart surgeons. Furthermore, the physicians and surgeons in training will have to learn to act as a consultant for general cardiologist and cardiovascular surgeons relating to the interventional management of this kind of patient.

Guidelines for training in adult cardiovascular medicine have been heavily based on procedure volumes. The American College of Cardiology training standards statement [16,17] regarding structure for an optimal adult interventional training program requires a mini-

mum of 100 diagnostic catheterization procedures for a fellow in training, and additional 200 diagnostic procedures for a Level 2 certification, and 250 interventional procedures to define qualifications for independent interventional procedure performance. Further, there are numerous requirements for certifying the faculty and program for training. Faculty may supervise no more than an average of 1.5 trainees per faculty member and three key faculty members devoting at least 20 hr per week are required for minimum standards for a program. The program director is required to have several years experience after training and an aggregate experience of over 1,000 interventional procedures. Other key faculty are required to have an experience base of 500 coronary interventions and an activity level of 75 procedures per year. The faculty must achieve a minimum clinical activity level of 125 procedures per year.

While the use of procedure volume requirements is fairly straightforward in coronary interventions, structural cardiac interventions cannot be subjected to the same kind of volume requirements. In the coronary environment, there are many hundreds of thousands of procedures performed each year; in contrast, the structural heart disease environment includes highly complex and individualized procedures that are performed in much lower numbers. The ability to define training standards solely on procedure volumes is thus not applicable in the structural heart disease environment; instead the emphasis should be on basic technical skills commonly utilized in these procedures but more importantly on the outcomes.

In the absence of volume-based standards, what are the necessary elements for structural heart disease interventional training and certification? The basic attributes necessary for both experience and training include knowledge of the field, necessary equipment, a training experience, including variably proctoring and/or the use of simulators, the development of an independent experience, and ultimately some form of certification process and its maintenance that perhaps should be best based on outcomes. It is important to appreciate that training in SHD interventions is a life-long endeavor. New techniques and skills are constantly being introduced and certainly new technologies will impose new methodological challenges. However, an initial foundation for SHD interventions can be formed through traditional interventional training programs. For physicians' trainees, the first critical step in the process of training is to have acquired superb basic catheterization skills. Although many of these are developed over years and with experience, the ability to safely achieve standard and unusual types of vascular access, manipulate the different types of wires, catheters, balloons, devices, etc., and how to anticipate, recognize and deal with possible complications will be the main thrust of the training. Moreover, there is no better

enticement to trainees than the challenge and thrill of developing skills that ultimately translate into practice.

### Levels of Training

All trainees benefit from intense exposure to both experienced, engaged mentors and the tools employed for the different structural cardiovascular interventions. The body of knowledge necessary for structural interventional programs remains to be clearly defined. A core curriculum outlining the areas of knowledge and expertise that must be incorporated into both training programs and also into continuing education programs to prepare existing interventionalists for the certification process will be a first step towards this process. The concept of different levels of structural heart disease is currently confusing and ill defined. It is obvious that the cognitive knowledge and technical skill required to close a straightforward secundum atrial septal defect is far less complex than treating a patient with a Taussig-Bing anomaly who had a Rastelli operation and now suffers from a severely calcified RV-to-PA homograft. Specification of the training required of those who have accomplished what is currently considered “Level 2” training (i.e., additional training in one or more specialized areas that enables the cardiologist to perform and interpret specific procedures at an intermediate skill level or engage in rendering cardiovascular care in specialized areas), depends on the level of expertise sought in structural heart disease interventions. The training needs to be aligned with the goals and priorities of a “basic” or “advanced” level and be categorized into “acquired” and “congenital.”

## 1. Basic Interventions for Acquired Structural Cardiovascular Diseases

### a. Transseptal left heart catheterization

#### *i. Knowledge base*

1. Normal anatomy and different morpho-spatial pathologic variants (enlarged right atrium, enlarged left atrium, bi-atrial enlargement, dilated ascending aorta, dextrocardias, heterotaxias, etc).
2. Hemodynamic understanding of pressure waves.
3. Imaging (recognizing atrial septal structures by TTE, TEE, ICE as well as fluoroscopic landmarks).
4. Indications to intervene.

#### *ii. Interventional skills*

1. Percutaneous access for transseptal puncture.
2. Transseptal sheath, wires, needles, and other access devices such as RF.
3. Echo-guided selective puncture.
4. Acute and long-term postprocedural care.

### b. Adult aortic balloon valvuloplasty

#### *i. Knowledge base*

1. Natural history and etiology of aortic stenosis.
2. Hemodynamics of severe aortic stenosis with high and low gradients.
3. Imaging aortic valve and aorta (Echo, CT, MR, and cine-angiogram).
4. Guidelines.
5. Therapeutic options and outcomes.
6. Indications to intervene.

#### *ii. Interventional skills*

1. Interpreting hemodynamics of AS in the cath lab.
2. Optimal percutaneous access.
3. How to cross a stenotic aortic valve?
4. Sheaths, wires, and catheters to use.
5. Balloon catheters for valvuloplasty.
6. Fast RV pacing during intervention.
7. Closing devices.
8. Managing complications (vascular occlusion, dissections, thromboembolisms, hemodynamic collapse, retroperitoneal bleeds, cardiac perforations, arrhythmias/heart blocks, coronary occlusions, etc.).
9. Acute and long-term postprocedural care.

### c. Ventricular septal ablation (chemical)

#### *i. Knowledge base*

1. Natural history and etiologies of LVOT obstruction.
2. Hemodynamics of LVOT obstruction.
3. Imaging (Echo, MR, and cine-angiography).
4. Guidelines.
5. Therapeutic options.
6. Indications to intervene.

#### *ii. Interventional skills*

1. Interpreting hemodynamics of LVOT obstruction in the cath lab.
2. Optimal percutaneous access.
3. Sheaths, wires, and catheters to use.
4. Optimal coronary angiography for septal ablation.
5. RV pacing during intervention.
6. Ablative substances (ETOH, microspheres, etc.).
7. Echo-guidance of ablation.
8. Closing devices.
9. Managing complications (vascular occlusion, dissections, thromboembolisms, hemodynamic collapse, over-extended MI, formation of a postablative VSD,

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cardiac perforations, arrhythmias/heart blocks, coronary occlusions, etc.).

10. Acute and long-term postprocedural care.

## **2. Complex Interventions for Acquired Structural Cardiovascular Diseases**

### **a. Transapical ventricular access**

#### *i. Knowledge base*

1. Normal anatomy and different morpho-spatial pathologic variants.
2. Indications to intervene.

#### *ii. Interventional skills*

1. Micro-puncture access needles, wires, and sheaths.
2. CTA, Echo, and fluoroscopy guidance.
3. Types of occlusive devices.
4. Acute and long-term postprocedural care.

### **b. Transhepatic access**

#### *i. Knowledge base*

1. Normal anatomy and different morpho-spatial pathologic variants.
2. Indications to intervene.

#### *ii. Interventional skills*

1. Micro-puncture access needles, wires, and sheaths.
2. Ultrasound and fluoroscopy guidance.
3. Types of occlusive devices.
4. Acute and long-term postprocedural care.

### **c. Adult mitral or tricuspid balloon valvuloplasty**

#### *i. Knowledge base*

1. Natural history and etiology of mitral and tricuspid stenosis.
2. Hemodynamics of severe mitral and tricuspid stenosis.
3. Imaging mitral and tricuspid (Echo, MR, and cine-angiogram).
4. Guidelines.
5. Therapeutic options and outcomes.
6. Indications to intervene.

#### *ii. Interventional skills*

1. Interpreting hemodynamics of MS and TS in the cath lab.
2. Optimal percutaneous access.
3. Selective transeptal puncture.
4. How to cross a stenotic mitral and tricuspid valve?
5. Sheaths, wires, and catheters to use.
6. Balloon catheters for valvuloplasty.
7. Closing devices.
8. Managing complications (vascular occlusion, dissections, thromboembolisms, hemodynamic collapse, retroperitoneal bleeds, cardiac perforations/tamponade, arrhythmias/heart blocks, coronary occlusions, etc.).
9. Acute and long-term postprocedural care.

### **d. Balloon pericardiotomy**

#### *i. Knowledge base*

1. Natural history of malignant pericardial effusions.
2. Therapeutic option and outcomes.
3. Pericardial sac anatomy.
4. Indications to intervene.

#### *ii. Interventional skills*

1. Percutaneous access to pericardial sac techniques.
2. Echo-guided access.
3. Needles, wires, catheters, and balloon catheters.
4. Acute and long-term postprocedural care.

### **e. Exclusion of the left atrial appendage**

#### *i. Knowledge base*

1. Management and prevention of thromboembolism in atrial fibrillation with and without valvular disease.
2. Understanding the anatomical variations of the left atrial appendage.
3. Imaging left atrial appendage (Echo, CTA, MR, and cine-angiogram).
4. Guidelines.
5. Therapeutic options and outcomes.
6. Indications to intervene.

#### *ii. Interventional skills*

1. Interpreting images of LAA.
2. Optimal percutaneous access.
3. Selective transeptal puncture.
4. How to safely access the LAA?
5. Sheaths, wires, and catheters to use.

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6. Occlusive devices.
7. Managing complications (vascular occlusion, dissections, thromboembolisms, hemodynamic collapse, retroperitoneal bleeds, cardiac perforations/tamponade, arrhythmias/heart blocks, coronary occlusions, etc.).
8. Acute and long-term postprocedural care.

**f. Closure of postinfarction ventricular septal defects*****i. Knowledge base***

1. Natural history of post-MI VSD (anterior vs. inferior).
2. Management of cardiogenic shock.
3. Hemodynamics of post-MI VSD.
4. Imaging (Echo, CTA, and cine-angiography).
5. Indications to intervene.

***ii. Interventional skills***

1. Interpreting hemodynamics of post-MI VSD in the cath lab.
2. Optimal percutaneous access (SVC, IVC, transseptal etc.).
3. Selective transeptal puncture.
4. How to cross a VSD?
5. Sheaths, wires, and catheters to use.
6. Balloon sizing catheters.
7. Occlusive devices.
8. Mechanical hemodynamic support systems.
9. Managing complications (vascular occlusion, dissections, thromboembolisms, hemodynamic collapse, retroperitoneal bleeds, cardiac perforations/tamponade, arrhythmias/heart blocks, coronary occlusions, etc.).
10. Acute and long-term postprocedural care.

**g. Closure of paravalvular leaks*****i. Knowledge base***

1. Natural history of paravalvular leaks.
2. Mechanical and biological heart valve.
3. Clinical management of mechanical hemolysis.
4. Clinical management of CHF.
5. Image interpretation to accurately localize the leak in relation to the prosthesis.
6. Indications to intervene.

***ii. Interventional skills***

1. Interpreting hemodynamics paravalvular leaks in the cath lab.

2. Optimal percutaneous access (retrograde, transseptal-antegrade, and transapical).
3. Selective transeptal puncture.
4. Selective transapical access
5. How to cross a paravalvular leak?
6. Sheaths, wires, and catheters to use.
7. Occlusive devices.
8. Managing complications (vascular occlusion, dissections, thromboembolisms, hemodynamic collapse, retroperitoneal bleeds, cardiac perforations/tamponade, arrhythmias/heart blocks, coronary occlusions, retrieval of embolized devices, etc.).
9. Acute and long-term postprocedural care.

**h. Closure of ventricular pseudoaneurysms*****i. Knowledge base***

1. Natural history of LV pseudoaneurysm.
2. Mechanical and biological heart valve.
3. Clinical management of mechanical hemolysis.
4. Clinical management of CHF.
5. Image interpretation to accurately localize and characterize the LV pseudoaneurysm.
6. Indications to intervene.

***ii. Interventional skills***

1. Optimal percutaneous access (retrograde, transseptal-antegrade, and transapical).
2. Selective transeptal puncture.
3. Selective transapical access.
4. How to enter a LV pseudoaneurysm?
5. Sheaths, wires, and catheters to use.
6. Occlusive devices.
7. Managing complications (vascular occlusion, dissections, thromboembolisms, hemodynamic collapse, retroperitoneal bleeds, cardiac perforations/tamponade, arrhythmias/heart blocks, coronary occlusions, retrieval of embolized devices, etc.).
8. Acute and long-term postprocedural care.

**i. Closure of endovascular endoleaks*****i. Knowledge base***

1. Natural history and the different types of endoleaks.
2. Types of endovascular graft-prosthesis.
3. Understanding the arterial branching and collaterals of the aorta.
4. Image interpretation of the endoleaks (CTA, MRA, cine-angiography, and ultrasound).
5. Indications to intervene.

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1. Optimal percutaneous access.
2. Selective direct access.
3. Sheaths, wires, and catheters to use.
4. Occlusive devices and chemical-materials.
5. Managing complications (vascular occlusion, dissections, thromboembolisms, hemodynamic collapse, retroperitoneal bleeds, cardiac perforations/tamponade, arrhythmias/heart blocks, coronary occlusions, retrieval of embolized devices, etc.).
6. Acute and long-term postprocedural care.

**j. Closure of aortic pseudoaneurysms****i. Knowledge base**

1. Natural history and etiology of aortic pseudoaneurysms.
2. Image interpretation (ultrasound, CTA, and cine-angiography).
3. Indications to intervene.

**ii. Interventional skills**

1. Optimal percutaneous access.
2. Sheaths, wires, and catheters to use.
3. Occlusive devices and chemical-materials.
4. Covered-stents and endoluminal prosthesis.
5. Managing complications (vascular occlusion, dissections, thromboembolisms, hemodynamic collapse, retroperitoneal bleeds, cardiac perforations/tamponade, arrhythmias/heart blocks, coronary occlusions, retrieval of embolized devices, etc.).
6. Acute and long-term postprocedural care.

**k. Transcatheter aortic valve implantation (TAVI)****i. Knowledge base**

1. Natural history and etiology of aortic stenosis.
2. Hemodynamics of severe aortic stenosis with high and low gradients.
3. Imaging aortic valve and aorta (Echo, CT, MR, and cine-angiogram).
4. Guidelines.
5. Therapeutic options and outcomes.
6. Indications to intervene.

**i. Interventional skills**

1. Interpreting hemodynamics of AS in the cath lab.
2. Optimal percutaneous access.
3. Transapical access (surgical and percutaneous).

4. How to cross a stenotic aortic valve?
5. Sheaths, wires, and catheters to use.
6. Balloon catheters for valvuloplasty.
7. Fast RV pacing during intervention.
8. Use of TAVI devices (balloon and self-expanding).
9. Closing devices.
10. Managing complications (vascular occlusion, dissections, thromboembolisms, hemodynamic collapse, retroperitoneal bleeds, cardiac perforations, arrhythmias/heart blocks, coronary occlusions, etc.).
11. Acute and long-term postprocedural care.

**l. Transcatheter mitral valve repair or implantation (TMVR)****i. Knowledge base**

1. Understanding the different types and etiologies of mitral regurgitation.
2. Medical management of severe mitral regurgitation and outcomes.
3. Surgical management of mitral regurgitation and outcomes.
4. Imaging of the mitral valve apparatus including the coronary sinus and coronary arterial and venous anatomy (Echo, CTA, and cine-angiography).
5. Understanding the anatomy of the mitral valve apparatus.
6. Indications to intervene.

**ii. Interventional skills**

1. Interpreting hemodynamics of MR in the cath lab.
2. Optimal percutaneous access.
3. Selective transeptal puncture.
4. How to access the coronary sinus and great cardiac vein?
5. How to access and image the sub-annular region?
6. Sheaths, wires, and catheters to use.
7. Use of specific mitral valve repair devices.
8. Closing devices.
9. Managing complications (vascular occlusion, dissections, thromboembolisms, hemodynamic collapse, retroperitoneal bleeds, cardiac perforations/tamponade, arrhythmias/heart blocks, coronary occlusions, etc.).
10. Acute and long-term postprocedural care.

**m. Stenting pulmonary veins following ablation for atrial fibrillation****i. Knowledge base**

1. Natural history of acquired pulmonary vein stenosis.

2. Selective imaging of the pulmonary veins.
3. Indications to intervene.

### *ii. Interventional skills*

1. Interpreting hemodynamics of pulmonary vein stenosis in the cath lab.
2. Optimal percutaneous access.
3. Selective transeptal puncture.
4. How to access and image the each of the four pulmonary veins?
5. Sheaths, wires, and catheters to use.
6. Use balloon catheters and stents.
7. Closing devices.
8. Managing complications (vascular occlusion, dissections, thromboembolisms, hemodynamic collapse, retroperitoneal bleeds, cardiac perforations/tamponade, arrhythmias/heart blocks, coronary occlusions, etc.).
9. Acute and long-term postprocedural care.

## **3. Basic Interventions for Adult Congenital Cardiovascular Diseases**

### **a. Closure of patent foramen ovale**

#### *i. Knowledge base*

1. Natural history of paradoxical thromboembolic events and right-to-left shunts through the PFO.
2. Medical management and guidelines.
3. Image interpretation (Echo, MR, and TCD).
4. Indications to intervene.

#### *ii. Interventional skills*

1. Crossing a PFO.
2. Sheaths, wires, and catheters to use.
3. Image guidance (echo and fluoroscopy).
4. Occlusive devices.
5. Retrieval of embolized devices.
6. Acute and long-term postprocedural care.

### **b. Closure of simple atrial septal defect**

#### *i. Knowledge base*

1. Natural history of hemodynamically significant secundum septal defects.
2. Indications to intervene.
3. Differentiating a simple from a complex ASD.

#### *ii. Interventional skills*

1. Sheaths, wires, and catheters to use.
2. Image guidance (TEE, ICE, and fluoroscopy).
3. When and how to use sizing balloons?
4. Occlusive devices.
5. Retrieval of embolized devices.
6. Acute and long-term postprocedural care.

### **c. Closure of patent ductus arteriosus**

#### *i. Knowledge base*

1. Natural history of hemodynamically significant PDA.
2. Anatomic types of PDA.
3. Simple vs Complex PDA (associated anomalies-pulmonary hypertension).
4. Indications to intervene and when not to.

#### *ii. Interventional skills*

1. Understanding hemodynamics of a PDA with and without pulmonary hypertension.
2. Imaging profile of the PDA (echo, CTA, MRA, and cine-angiography).
3. Crossing the PDA (antegrade and retrograde).
4. Occlusive devices.
5. Retrieval of embolized devices.
6. Acute and long-term postprocedural care.

### **d. Pulmonary valvuloplasty**

#### *i. Knowledge base*

1. Natural history of simple and complex pulmonic stenosis.
2. Types and etiology of pulmonic stenosis (syndromic).
3. Imaging the pulmonic valve (echo, CTA, MRA, and cine-angiography).

#### *ii. Interventional skills*

1. Interpreting hemodynamics of PS in the cath lab.
2. Optimal percutaneous access.
3. Optimal imaging of PS in the cath lab.
4. How to cross a stenotic pulmonary valve?
5. Sheaths, wires, and catheters to use.
6. Balloon catheters for valvuloplasty.
7. Managing complications (vascular occlusion, dissections, thromboembolisms, hemodynamic collapse, retroperitoneal bleeds, cardiac perforations, arrhythmias/heart blocks, coronary occlusions, etc.).
8. Acute and long-term postprocedural care.

#### 4. Complex Interventions for Adult Congenital Cardiovascular Diseases

##### a. Closure of complex atrial septal defects

###### i. Knowledge base

1. Natural history of hemodynamically significant secundum septal defects.
2. Imaging (echo) of ASD.
3. Indications to intervene.
4. Differentiating a simple from a complex ASD.

###### ii. Interventional skills

1. Sheaths, wires, and catheters to use.
2. Image guidance (TEE, ICE, and fluoroscopy).
3. When and how to use sizing balloons?
4. Occlusive devices.
5. Special maneuvers to deploy occlusive devices.
6. Retrieval of embolized devices.
7. Acute and long-term postprocedural care.

##### b. Closure of native, residual-patch, muscular or perimembranous ventricular septal defects

###### i. Knowledge base

1. Natural history, types, and anatomic location of simple and complex (associated lesions).
2. Hemodynamics of VSD.
3. VSD and pulmonary hyperstension.
4. Suitability for VSD closure.
5. Indications to intervene.
6. Therapeutic options and outcomes.
7. Guidelines.

###### ii. Interventional skills

1. Interpreting hemodynamics of congenital and postop VSD in the cath lab.
2. Angiographic profiling of different VSD.
3. Optimal percutaneous access (SVC, IVC, transseptal etc.).
4. Selective transeptal puncture.
5. How to cross a VSD?
6. Sheaths, wires, and catheters to use.
7. Balloon sizing catheters.
8. Occlusive devices.
9. Mechanical hemodynamic support systems.
10. Managing complications (vascular occlusion, dissections, thromboembolisms, hemodynamic collapse, retroperitoneal bleeds, cardiac perforations/

tamponade, arrhythmias/heart blocks, coronary occlusions, etc.).

11. Acute and long-term postprocedural care.

##### c. Closure of coronary fistulas, pulmonary vascular malformations and aorto-pulmonary collaterals

###### i. Knowledge base

1. Natural history of coronary, peripheral and pulmonary arterio-venous malformations and sequestrations.
2. Comprehensive knowledge of arterio-venous anatomy.
3. Image interpretation of AVM (US, CTA, MRA, and Cine-angiography).
4. Indications to intervene.

###### ii. Interventional skills

1. Angiographic profiling of different AVM and APC.
2. Optimal percutaneous access.
3. How to access feeder vessels (antegrade and retrograde)?
4. Sheaths, wires, and catheters to use.
5. Occlusive devices and chemical substances.
6. Managing complications (vascular occlusion, dissections, thromboembolisms, hemodynamic collapse, retroperitoneal bleeds, cardiac perforations/tamponade, arrhythmias/heart blocks, coronary occlusions, etc.).
7. Acute and long-term postprocedural care.

##### d. Angioplasty and stenting of pulmonary artery branch stenosis

###### i. Knowledge base

1. Natural history and types of acquired (postop, Behcet's, etc.) and congenital pulmonary branch stenosis (isolated or in complex CHD).
2. Imaging of pulmonary arteries (echo, CTA, MR, and cine-angiography, perfusion-scans, etc.).
3. Understanding single-ventricle physiology and pulmonary branch stenosis.
4. Indications to intervene.

###### ii. Interventional skills

1. Interpreting images of pulmonary arteries.
2. Profiling lesions by cine-angiography.
3. Optimal percutaneous access.
4. Sheaths, wires, and catheters to use.

5. Balloon dilatation catheters.
6. Use of large stents and stenting techniques.
7. Managing complications (acute reperfusion pulmonary edema, vascular occlusion, dissections, thromboembolisms, hemodynamic collapse, retroperitoneal bleeds, cardiac perforations/tamponade, arrhythmias/heart blocks, coronary occlusions, etc.).
8. Acute and long-term postprocedural care.

#### **e. Angioplasty and stenting for coarctation of the aorta**

##### *i. Knowledge base*

1. Natural history and management of native and postop COA.
2. Types of simple and complex COA.
3. Interpreting Images (Echo, CTA, MRA, and Cine-angiography).
4. Indications to intervene.

##### *ii. Interventional skills*

1. Interpreting images of COA.
2. Profiling lesion by cine-angiography.
3. Optimal percutaneous access.
4. Sheaths, wires, and catheters to use.
5. Balloon dilatation catheters.
6. Use of large stents, covered stents, and stenting techniques.
7. Managing complications (aneurysm formation, tear/partial rupture, vascular occlusion, dissections, thromboembolisms, hemodynamic collapse, retroperitoneal bleeds, cardiac perforations/tamponade, arrhythmias/heart blocks, coronary occlusions, etc.).
8. Acute and long-term postprocedural care.

#### **f. Angioplasty and stenting of pulmonary veins**

##### *i. Knowledge base*

1. Natural history of congenital and postop pulmonary vein stenosis.
2. Selective imaging of the pulmonary veins.
3. Indications to intervene.

##### *ii. Interventional skills*

1. Interpreting hemodynamics of pulmonary vein stenosis in the cath lab.
2. Optimal percutaneous access.
3. Selective transeptal puncture.
4. How to access and image the each of the four pulmonary veins?

5. Sheaths, wires, and catheters to use.
6. Use balloon catheters and stents.
7. Closing devices.
8. Managing complications (vascular occlusion, dissections, thromboembolisms, hemodynamic collapse, retroperitoneal bleeds, cardiac perforations/tamponade, arrhythmias/heart blocks, coronary occlusions, etc.).
9. Acute and long-term postprocedural care.

#### **g. Angioplasty and stenting of surgical conduits, baffles and homograft**

##### *i. Knowledge base*

1. Natural history of different types (fabric, biological, homograft, valveless and valved) conduits and intracardiac baffles.
2. Anatomic and physiologic knowledge of the different intracardiac and extracardiac surgical conduits and baffles.
3. Understanding the anatomy and hemodynamics of postsurgical repairs of complex CHD.
4. In-depth understanding of transposition anatomy and physiology with and without ventricular inversion and, with and without VSD.
5. In-depth understanding of anatomy and physiology in single-ventricles.
6. Understanding the effects of pressure and/or volume overload of systemic and pulmonary ventricle in patients with complex CHD and conduits or baffles.
7. Indications to intervene.

##### *ii. Interventional skills*

1. Interpreting hemodynamics of complex CHD in the cath lab.
2. Optimal percutaneous access.
3. Imaging guiding (Echo, cine-angiography, MRI, and CTA).
4. Sheath, wires, and catheters.
5. Balloon dilatation catheters.
6. Large stents and cover stents.
7. Stenting techniques.
8. Managing complications (vascular occlusion, conduit rupture, dissections, thromboembolisms, hemodynamic collapse, retroperitoneal bleeds, cardiac perforations/tamponade, arrhythmias/heart blocks, coronary occlusions, etc.).
9. Acute and long-term postprocedural care.

#### **h. Angioplasty and stenting of interatrial septum and Fontan fenestrations**

##### *i. Knowledge base*

1. Natural history and types of single-ventricles.

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2. Understanding hemodynamics of single-ventricle.
3. In-depth knowledge of managing irreversible pulmonary hypertension.
4. Indications to intervene.

**ii. Interventional skills**

1. Interpreting hemodynamics of single-ventricle physiology in the cath lab.
2. Interpreting hemodynamics of pulmonary hypertension in the cath lab.
3. Image interpretation of the interatrial septum (echo and cine-angiography).
4. Transseptal puncture techniques in complex congenital anatomies.
5. Sheath, wires, and catheters.
6. Balloon dilatation catheters.
7. Stent and covered stents.
8. Stenting techniques.
9. Managing complications (vascular occlusion, acute desaturation, dissections, thromboembolisms, hemodynamic collapse, retroperitoneal bleeds, cardiac perforations/tamponade, arrhythmias/heart blocks, coronary occlusions, etc.).
10. Acute and long-term postprocedural care.

**i. Transcatheter pulmonary valve implantation (TPVI)****i. Knowledge base**

1. Natural history of different types (fabric, biological, homograft, valveless and valved) conduits and intracardiac baffles.
2. Anatomic and physiologic knowledge of the different intracardiac and extracardiac surgical conduits and baffles.
3. Understanding the anatomy and hemodynamics of postsurgical repairs of complex CHD.
4. In-depth understanding of transposition anatomy and physiology with and without ventricular inversion.
5. Understanding the effects of pressure and/or volume overload of pulmonary ventricle in patients with complex CHD and conduits.
6. Indications to intervene.

**ii. Interventional skills**

1. Interpreting hemodynamics of complex CHD in the cath lab.
2. Optimal percutaneous access.
3. Imaging guiding (Echo, cine-angiography, MRI, and CTA).

4. Sheath, wires, and catheters.
5. Assessing coronary perfusion.
6. Balloon dilatation catheters.
7. Large stents and cover stents.
8. Stenting techniques.
9. Use of TPVI devices.
10. Managing complications (vascular occlusion, conduit rupture, dissections, acute coronary compression, thromboembolisms, hemodynamic collapse, retroperitoneal bleeds, cardiac perforations/tamponade, arrhythmias/heart blocks, coronary occlusions, etc.).
11. Acute and long-term postprocedural care.

It is vital to the excellence of a training program that dedicated faculty members, including faculty that come from a variety of the traditional departments (anesthesiology, critical care, medicine, pediatrics, surgery, radiology, and pathology among others) be available to supervise and critique indications, performance and interpretation of procedures. The fellowship program should develop formal didactic sessions which will include weekly medical-surgical SHD conferences, quality assurance (QA), and M&M monthly reviews, inpatient and outpatient consultation services, clinical follow-up, and have provisions and resources to pursue basic and/or clinical research. Furthermore, a core-lecture series in cardiovascular anatomy and physiology of SHD-CHD, pathophysiology (valves, shunts, etc.), pharmacology, imaging technologies (echocardiography, CTA, and MRI), radiation exposure and safety, clinical management, and devices would be consistent with the recommendations of the ACC/SCAI/AHA guidelines [15]. The number and type of interventional procedures will vary depending on the level of training sought. Training centers should provide a sufficient variety and volume of patients from each level of training being offered. Numbers of procedures needed to provide adequate training will vary according to the spectrum of procedures usually performed at individual centers. Pediatric and adult programs will usually perform different types of procedures. Specific volumes of specific procedures cannot realistically be defined. Fellowship training in structural intervention is a foundation for a lifetime of learning and maturation, and very few trainees will master more than either the basics of a very select number of complex procedures during a 1 or even 2-year program. The duration of the training should be a minimum of 1 year, depending on the educational background of the trainee. It can be as short as 1 year if the trainee had a solid basic training in invasive catheterization procedures. With the expansion of noncoronary transcatheter interventions, cardiovascular medicine departments are no longer in exclusive control

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of all the necessary equipment, experienced personnel, and expertise required to provide a comprehensive training program for this emerging cardiovascular subspecialty. Thus, new collaborative relationships must be forged to complete the training mission. The training program should be aimed at teaching adult interventional cardiologists, pediatric interventional cardiologists, and cardiovascular surgeons the necessary clinical, imaging, and catheterization skills to become proficient in structural heart disease interventions.

### Training Objectives

1. The ability to take a clear and concise history that is both organized and comprehensive and that follows from the leads produced by the presenting complaints of the patient. Understanding the natural history of untreated and previously treated structural abnormalities.
2. The ability to perform a physical examination that is organized and detailed as well as the ability to carry out a focused examination in certain settings which may preclude a comprehensive examination.
3. The acquisition of a knowledge base that is broad, current, and that includes the critical analytical skills to interpret studies; and the establishment of this learning process as a professional life-long process. This should encompass normal physiology and pathophysiology as well as a wide spectrum of diseases that include the common medical illnesses as well as common diseases involving other specialties, such as neurology, hematology, nephrology, psychiatry, cardiothoracic and vascular surgery, heart failure and cardiac transplantation, that the invasive cardiologist is likely to see in medical practice.
4. Detailed knowledge of the specific techniques and interpretation of the results of imaging.
5. The development of competency in dealing with specific groups of patients who share common problems and for whom specific expertise is required such as the geriatric population, women, and adolescents.
6. The enhancement of humanistic qualities in interactions with patients, emphasizing respect, compassion, and regard for their general sense of participation in the decisions affecting their care.
7. The development of communication skills that stress discussion of matters of importance to the patient in comprehensible terms. Utilization of the proper communication skills should include the capacity to transmit discouraging as well as favorable information to the patient, the former with appropriate sensitivity and understanding.
8. An understanding of the ethical basis of medical practice and the patient-physician relationship, and understanding of the appropriate boundaries of the relationship. The ethical considerations related to interpersonal and economic conflicts of interest should be appreciated.
9. The appropriate utilization of screening tests for preventive care in the adult patient.
10. The development of skills in working as a member of a team of health care professionals in a multidisciplinary approach to the care of the patient.
11. The development of the capacity to practice in a variety of venues including the cardiac catheterization laboratory, operating rooms, ambulatory care setting, the hospital inpatient setting, the emergency ward and the critical care and recovery units.
12. Complication management and adjunctive treatment.
13. Participation in regional or national registries for data entry, quality improvement, and evaluation of outcomes.

### Standards for Certification

There are currently no standards for certification in interventional cardiology for patients, pediatric or adult, with congenital heart disease. In addition, there are no clear guideline statements regarding structural cardiovascular interventions, although some touch on pertinent issues as exemplified by the recent congenital heart disease in adults guideline consensus article [18] that extensively addresses diagnosis and therapy, but not training curriculum, credentialing, or certification. Such a document for structural heart disease seems desirable.

### Training Centers and Program Resources

The creation of a structural cardiovascular interventional program would best be served in centers with an integrated structural heart center in conjunction or partnership with a center with expertise in care of adults with congenital heart disease (as defined in the 2008 ACC/AHA adult with congenital heart disease guidelines). An ideal training center should provide a combination of a well-structured, formal curriculum that facilitates acquisition of methodological and technical skills in mentored, but independent cases as well as through the use of simulators.

It is the opinion of the writing committee of the ACC and SCAI that a successful SHD program needs a multidisciplinary team with participation of adult and pediatric clinical cardiologists, cardiovascular surgeons, echocardiographers, radiologists, interventionalists, anesthesiologists, intensivists, etc., with extensive

training in their respective disciplines working together as a multidisciplinary team. Throughout the training period, it is critical for trainees to engage in a formal, continuous mentorship process, in part, to ensure that (a) trainees develop their own clinical excellence in care of adults with congenital heart disease, or, (b) trainees ensure that their future practice will incorporate a partnership in expertise with established centers of excellence in care of adults with congenital heart disease. A close, mutually supportive relationship between a group of mentors and the trainee is needed to understand the trainee's interests, learning, and style. An ongoing mentoring process not only allows a mentor to periodically evaluate and provide guidance, but also permits feedback about management of complex structural heart disease entities, technical skills, team building, academic ethics, and career development.

The image guidance used in interventions for SHD differs from that for coronary interventions, which relies on selective angiography. Interventions for SHD require different types of ultrasound (2-D and 3-D TEE, TTE, ICE) and frequently utilize CTA and MRA for preprocedure planning and postprocedure assessment. This solidifies the need for a multidisciplinary team involving experts in these imaging modalities and requires that the training program devote sufficient time to the development of knowledge and skills in image acquisition and interpretation.

This requires a substantial institutional commitment, not only to support the dedicated facilities and equipment necessary for these interventions such as hybrid procedure rooms, sophisticated imaging equipment, and a large inventory of fungible equipment but, even more important, an integrated team of experts including specialists of diverse background who are dedicated to teaching trainees how to perform procedures, and to embed a philosophy about the approach to patients. The full scope of institutional requirements is difficult to define, and will vary from institution to institution, since the composition and function of these partnerships are highly institutionally specific, depending on the individual expertise of available faculty. However, the ability to assemble an integrated multidisciplinary team is mandatory for training as well as to assure safety and favorable outcomes for patients with relatively rare disorders undergoing often-complex interventional procedures.

All of these issues highlight the challenges in defining the resources needed for a training program. A 2005 consensus document from the STS/AATS/ACC and SCAI [19] made recommendations for the clinical development of percutaneous heart valve technology in a position statement. The basic thrust of the statement was that these procedures should be developed only in

high-risk patients with limited options for surgical therapy and only in centers with clear expertise in both surgical and catheter interventions. The surgical guidelines make recommendations for minimum volume criteria for surgical programs, and if the surgical volumes must be present in conjunction with guideline-recommended minimum institutional requirements for catheter-based interventional programs, very few centers are likely to have the resources and procedure volumes to qualify as training program centers. Thus, guidelines suggesting simply combining program requirements from various specialties should be revised and developed jointly. Accordingly, few certified training centers will be needed in the United States.

Lastly, simulators have come to play a clear role in training for this spectrum of procedures. The simulation technology is advancing at a very fast pace, which at present allows users to gain rudimentary experience with many different devices and techniques. However, seeing the advanced simulation technology currently in use by the aeronautical industry makes it obvious that they will soon play a more important role in the training and evaluation of structural cardiovascular interventions, where total procedure volumes are low and the complexity and variety of procedures is great. The aim of this technology is to enhance "learning" and therefore, this costly technology will become more prominent in centers with training programs. Furthermore, simulators offer the opportunity to train not only the operator but nursing and paramedical personnel as well.

To stay abreast of new and evolving techniques, both annual conferences (i.e., The i2 Summit of the American College of Cardiology, Transcatheter Cardiovascular Therapeutics, EuroPCR, Pediatric and Adult Interventional Cardiac Symposium) and focused seminars are available avenues to advance knowledge and maintain currency in cardiovascular interventions in structural heart disease. By leveraging such training from the start of training and throughout one's career, SHD interventionalists are well positioned to launch and sustain their careers.

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lines on the management of adults with congenital heart disease) developed in collaboration with the American Society of Echocardiography, Heart Rhythm Society, International Society for Adult Congenital Heart Disease, Society for Cardiovascular Angiography and Interventions, and Society of Thoracic Surgeons. *J Am Coll Cardiol* 2008;52:e67.

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