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EXPERT CONSENSUS DOCUMENT

SCAI/AATS/ACC/STS Operator and Institutional Requirements for Transcatheter Valve Repair and Replacement, Part III: Pulmonic Valve

Ziyad M. Hijazi, MD, MPH[1,*]
Carlos E. Ruiz, MD, PhD[2]
Evan Zahn, MD[3]
Richard Ringel, MD[4]
Gabriel S. Aldea, MD[5]
Emile A. Bacha, MD[6]
Joseph Bavaria, MD[7]
R. Morton Bolman III, MD[8]
Duke E. Cameron, MD[9]
Larry S. Dean, MD[10]
Ted Feldman, MD[11]
David Fullerton, MD[12]
Eric Horlick, MDCM[13]
Michael J. Mack, MD[14]
D. Craig Miller, MD[15]
Marc R. Moon, MD[16]
Debabrata Mukherjee, MD[17]
Alfredo Trento, MD[18]
Carl L. Tommaso, MD[19]

PREAMBLE

With the evolution of transcatheter valve replacement, an important opportunity has arisen for cardiologists and surgeons to collaborate in identifying the criteria for performing these procedures. Therefore, Additional Supporting Information may be found in the online version of this article. The Society for Cardiovascular Angiography and Interventions (SCAI), American Association for Thoracic Surgery (AATS), American College of Cardiology (ACC), and The Society of Thoracic Surgeons (STS) have partnered to provide recommendations for institutions to assess their potential for instituting and/or maintaining a transcatheter valve program. This article concerns transcatheter pulmonic valve replacement

[1]Sidra Cardiovascular Center of Excellence, Department of Pediatrics, Sidra Medical & Research Center, Doha, Qatar; [2]Lenox Hill Heart & Vascular Institute of New York, New York, New York; [3]Guerin Family Congenital Heart Program, Cedars-Sinai Heart Institute, Cedars-Sinai Medical Center, Los Angeles, California; [4]Pediatric Cardiac Catheterization Laboratory, The Johns Hopkins Hospital, Baltimore, Maryland; [5]Regional Heart Center, University of Washington Medical Center, Seattle, Washington; [6]Pediatric Cardiac Surgery, New York-Presbyterian/Columbia University Medical Center, Morgan Stanley Children's Hospital, New York, New York; [7]Division of Cardiothoracic Surgery, Hospital of the University of Pennsylvania, Philadelphia, Pennsylvania; [8]Division of Cardiac Surgery, Harvard Medical School, Boston, Massachusetts; [9]The Dana and Albert "Cubby" Broccoli Center for Aortic Diseases, The Johns Hopkins Hospital, Baltimore, Maryland; [10]University of Washington, School of Medicine, Seattle, Washington; [11]Cardiac Catheterization Laboratory, Evanston Hospital, Evanston, Illinois; [12]Cardiothoracic Surgery, University of Colorado Denver, Aurora, Colorado; [13]Peter Munk Cardiac Centre, Toronto General Hospital, Toronto, Ontario, Canada; [14]Cardiovascular Council Dallas, Heart Hospital Baylor, Plano, Texas; [15]Department of Cardiovascular Surgery, Stanford University School of Medicine, Stanford, California; [16]Division of Cardiothoracic Surgery, Washington University, St. Louis, Missouri; [17]Department of Internal Medicine, Cardiovascular Medicine, Texas Tech University, El Paso, Texas; [18]Division of Cardiothoracic Surgery, Cedars-Sinai Medical Center, Los Angeles, California; [19]Cardiac Catheterization Laboratory, Skokie Hospital, North Shore University Health System, Skokie, Illinois.

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*Correspondence to: Ziyad M. Hijazi, Sidra Cardiovascular Center of Excellence, Department of Pediatrics, Sidra Medical & Research Center, Doha, Qatar. E-mail: zhijazi@sidra.org.

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(tPVR). tPVR procedures are in their infancy with few reports available on which to base an expert consensus statement. Therefore, many of these recommendations are based on expert consensus and the few reports available. As the procedures evolve, technology advances, experience grows, and more data accumulate, there will certainly be a need to update this consensus statement. The writing committee and participating societies believe that the recommendations in this report serve as appropriate requisites. In some ways, these recommendations apply to institutions more than to individuals. There is a strong consensus that these new valve therapies are best performed using a Heart Team approach; thus, these credentialing criteria should be applied at the institutional level. Partnering societies used the ACC's policy on relationships with industry (RWI) and other entities to author this document (http://www.acc.org/guidelines/about-guidelines-and-clinical-documents). To avoid actual, potential, or perceived conflicts of interest due to industry relationships or personal interests, all members of the writing committee, as well as peer reviewers of the document, were asked to disclose all current healthcare-related relationships including those existing 12 months before the initiation of the writing effort. A committee of interventional cardiologists and surgeons was formed to include a majority of members with no relevant RWI and to be led by an interventional cardiology cochair and a surgical cochair with no relevant RWI. Authors with relevant RWI were not permitted to draft or vote on text or recommendations pertaining to their RWI. RWI were reviewed on all conference calls and updated as changes occurred. Author and peer reviewer RWI pertinent to this document are disclosed in Appendices AI and AIII, respectively. In addition, to ensure complete transparency, authors' comprehensive disclosure information (including RWI not pertinent to this document) is available in Appendix AII. The work of the writing committee was supported exclusively by the partnering societies without commercial support. SCAI, AATS, ACC, and STS believe that adherence to these recommendations will maximize the chances that these therapies will become a successful part of the armamentarium for treating valvular heart disease in the United States. In addition, these recommendations will hopefully facilitate optimum quality during the delivery of this therapy, which will be important to the development and successful implementation of future, less invasive approaches to structural heart disease.

INTRODUCTION

Enabled by the development of new technologies, treatment of valvular heart disease by transcatheter techniques has complemented standard surgical approaches, thus providing enhanced care for our patients. Transcatheter techniques offer a less invasive treatment for patients who were previously treatable only with open-heart surgery or, in many cases, who were not treatable at all. Recognition from the medical community of the applicability, effectiveness, and practicality of transcatheter valve therapies has further increased interest in these treatments. Training program content, standards, credentialing, and board certifications for cardiac surgical procedures and percutaneous coronary intervention are well developed, but no such structure exists in the field of percutaneous structural or valvular heart disease therapies. The purpose of this article is to outline criteria for operator and institutional requirements, to help enable institutions and providers to participate responsibly in this new and rapidly developing field.

The emergence of transcatheter pulmonic valve implantation as an alternative to traditional surgical therapy for valvular diseases has been facilitated by innovative devices, rapidly developing techniques, and careful patient selection. The combination of interventional skills, equipment, collaborative clinical management, surgical approaches, techniques, and decision making distinguishes the qualifications to participate in this field as unique, as does the complexity of the patients who require these therapies. Given both the high-risk nature of these catheter interventions and the availability of established alternative treatment options using traditional surgical approaches, several considerations are important for institutions and operators planning to implement these new technologies.

Defining operator and institutional requirements for these novel therapies is an important first step to ensure their optimal implementation. Part 1 of this series concerning transcatheter aortic valve replacement (TAVR) was previously published. The authors felt that the facilities and institutional requirements have remained unchanged; thus, those sections have not been repeated here and may be found in the previous report (1).

PULMONIC VALVE REPLACEMENT

Some congenital cardiac defects require surgical reconstruction of the right ventricular outflow tract (RVOT). This procedure may entail pulmonic valve replacement or placement of a pulmonic valve/conduit between the right ventricle (RV) and pulmonary artery.

Over time, these reconstructions often develop valve dysfunction, leading to pulmonary regurgitation and/or stenosis. Pulmonary stenosis and/or regurgitation may lead to right ventricular dysfunction associated with exercise intolerance, dysrhythmias, heart failure, and an increased risk of sudden cardiac death (2). Biological

valves are typically implanted in the pulmonary position, commonly in children and young adults. Given the limits of the durability of biological valves, these patients are likely to undergo serial open-heart surgical procedures over the course of their lifetimes.

Treatment of RVOT stenosis in patients following tetralogy of fallot (TOF) repair or for those with a conduit between the RV and the pulmonary artery with balloon dilatation has been used with limited and often short-lived success. RVOT conduit stenting has been shown to decrease RV pressure and to extend conduit lifespan (3,4). However, this treatment option usually produces free pulmonary regurgitation, which may be severe as the leaflets of the previously placed valve/conduit are rendered incompetent by the stent. Severe pulmonary regurgitation has significant long-term deleterious effects including progressive RV dilation and dysfunction, dysrhythmias, and sudden cardiac death (2). ACC/AHA 2014 focused guidelines for management of patients with valvular heart disease and ACC/AHA 2014 guidelines for the management of adults with congenital heart disease (5,6) provided the indications for pulmonary valve replacement for pulmonary regurgitation in postoperative patients with TOF: symptoms associated with severe pulmonary insufficiency or in the absence of symptoms, magnetic resonance imaging (MRI) criteria for severe pulmonary insufficiency including: RVEDV of >150 ml/m^2; pulmonary regur-gitant fraction >40% and RV ejection fraction <40%.

The operative risk is acceptably low (0.9-1.2%) for the first operation to implant a RV-pulmonary artery conduit (7,8). A recent report from Ong et al. (7) demonstrated that freedom from reoperation increased with successive interventions from 50% at 10 years following implantation of the first conduit to 74% and 86% at 10 years for the second and third conduit replacement, respectively. Pulmonary homograft replacement during the Ross procedure was associated with even greater durability with a reintervention incidence of 1 in 150 patient-years (9), and reoperative rates seem to be lower with larger conduits (10). Patients may require multiple operations over a lifetime, as the mean time to reoperation is about 10.3 years for xenografts and 16 years for homografts (11,12). Tweddell et al. (11) reported that at about 1-2 years after homograft replacement, 16% of patients had conduit dysfunction and at about 4-5 years, almost 50% of the homografts were dysfunctional. In that article, 25% of the patients had reoperations at about 4-5 years after conduit replacement. These reoperations are often complex and involve increasing morbidity (blood transfusions, medi-astinitis, etc.) and mortality over time (13). Currently, there is no established or validated operative risk calculator or score for pulmonary valve replacement. Thus, assessment of operative risk is highly limited to clinical judgment of the operator, which may be inaccurate due to bias.

The potential need for repeat surgery in this patient population makes transcatheter pulmonic valve replacement (tPVR) to replace an obstructed and/or regurgitant pulmonary bioprosthesis or conduit an attractive option. In 2000, Bonhoeffer et al. (14,15) reported the first experimental and clinical human application of a transcatheter valve in the pulmonary position in a 12-year-old patient with a previously implanted conduit for pulmonary atresia. In 2005, in a compassionate use case, a transcatheter pulmonary valve (Edwards SAPIEN valve; Edwards Lifesciences, Irvine, CA) was placed in a 16-year-old boy with congenital severe aortic stenosis who had undergone a Ross operation (16).

Since then, more than 6,000 patients have received percutaneously placed pulmonary valves (Ms. Jill Hen-nesen, Medtronic Inc., personal communication). Few reports from outside the United States have been published (17,18). In 2010, the Melody valve (Medtronic Corporation, Minneapolis, MN) was approved by the United States Food and Drug Administration (FDA) under Humanitarian Device Exemption (19,20). In January 2015, the Melody valve received full premarket approval (PMA). The SAPIEN valve is currently being used outside the United States (21) and is under clinical investigation in the United States for use in the RVOT (COMPASSION trial; Edwards Lifesciences) (22). Currently, there are no data published in the literature to indicate the total number of percutaneous pulmonary valves implanted in the United States. Furthermore, no data are published on the average number of procedures performed by various operators/institutions. Such data will be important to collect going forward. With current valve technology, pretreatment of the RVOT with bare metal stent implantation appears to offer several advantages including: creation of a landing zone for valve placement, elimination of conduit stenoses prior to the valve implant and a decrease in the incidence of stent/valve fracture that may lead to early valve failure (20,22). For detailed technical aspects of the procedure, the readers are referred to a chapter written by one of the authors of this document (23). The procedure in general is safe; however, there are potential complications that can be encountered during or after the procedure. The rate of serious complications in the US Melody trial (19,20) was reported at 6%, including death from coronary dissection (n = 1), conduit rupture (n = 1), unstable arrhythmia (n = 1), wire perforation in distal pulmonary artery (n = 2), and femoral vein thrombosis (n = 1). In the COMPASSION trial (22), the rate of serious complications was 21% (7 patients). Valve or stent migration occurred in four patients (three requiring surgical retrieval and one was deployed in the inferior vena cava), unstable arrhythmias in one patient, and self-limited wire

perforation in the distal pulmonary arteries in two patients. These complications can be divided into the following: procedural: pulmonary hemorrhage (secondary to guide wire); ventricular arrhythmias; stent embolization (prestenting); coronary artery compression (24); conduit rupture and valve embolization. Complications at follow-up: stent fracture and infective endocarditis (25). While these complications were initially reported to be as high as 12% in early smaller tPVR studies (17), more recent trials have shown a decrease of these adverse events to 5-6% (20). This decrease in procedural complications is most likely due to increased operator experience. In 2008, Bon-hoeffer's group published a study looking at the learning curve for tPVR since it was first used in 2001. They reported that after their initial 50 patients, the incidence of procedural complications fell to 2.9% (18). Institutions/operators that desire to embark on trans-catheter pulmonary valve implantation should meet certain requirements:

Institutional Requirements

Table 1 summarizes the institutional and operator requirements to embark on tPVR. These include but are not limited to the following:

1. Cardiac cases requirements

The institution should perform 150 congenital/structural catheterization procedures per year. Of those, 100 should be interventional in nature, including but not limited to stenting of branch pulmonary arteries and RVOT. The rationale for this number is the large number of various procedures performed in a congenital laboratory and the need for large number of inventory products. Furthermore, the institution should perform a minimum of a 100 open-heart surgical procedures in patients with congenital heart disease (if a Children's hospital) or an adult program associated with a Children's hospital. The adult program should perform a minimum of 25 adult-congenital surgical cases per year.

2. Staffing requirements

The institution should have a Heart Team (interventional cardiologists (pediatric trained or adult trained, as long as they have the expertise in this area), cardiac surgeons, noninvasive cardiologists, cardiac anesthesiologists, cardiovascular radiologists, and others) that is actively engaged in the treatment of congenital and/or structural heart disease. The Heart Team should have experience in the treatment of conditions of the pulmonary valve and the RVOT. Each case should be discussed among the Heart Team members (medical-surgical conference) and the best approach for each patient is determined.

Furthermore, the institution should have extracorporeal membrane oxygenation ECMO capabilities for the rare patient who may require such support.

3. Imaging requirements

a. Echocardiographic laboratory: transthoracic and transesophageal echocardiographic capabilities with sonographers and echocardiographers experienced in congenital heart disease.
b. Radiologic imaging: cardiac CT and cardiac MRI capabilities.
c. Cardiovascular catheterization laboratory or hybrid suite equipped with a fixed X-ray system with fluoroscopy offering high-resolution imaging, recording and archiving capability. A biplane unit is desirable.
d. Hemodynamic evaluation, recording and retrieval capabilities.
e. The institution should be a participant in a national registry (IMPACT) collecting data on all patients undergoing transcatheter pulmonary valve replacement, in a manner similar to sites performing TAVR. The professional societies will determine the exact registry that will collect data on patients undergoing tPVR to follow the outcomes of such patients and, hopefully, to compare these outcomes to

TABLE 1 Characteristic of tPVR Program

Institutional cath volume	150 congenital/structural heart disease caths/year
Interventionalist	100 diagnostic and therapeutic cases/year including 50 congenital/structural heart intervention cases/year
	Experience with stent implantation for branch pulmonary arteries and conduit stenosis Board certified/eligible or the equivalent in interventional cardiology, pediatric cardiology, or thoracic surgery
Device training	Suitable training on devices to be used
Surgical program	The program is or is associated with a congenital/structural open-heart program that performs >100 open surgical cases or the program is an adult-congenital cardiac program that performs 25 adult-congenital cardiac operations/year
	There should be ECMO capabilities in the institution for the rare case when needed
Data registry	All cases must be submitted to a national clinical database
Existing programs	Programs that have already performed 10 tPVR procedures may be considered established
New programs	New programs should have sufficient volume to perform 5 cases per year or 10 over the first 2 years
Outcomes	Patients should have 80% freedom from reintervention at 1 year

patients who undergo the traditional surgical approach.

f. ECMO: availability of ECMO support for the rare case when needed.

Operator Requirements

The individual operator interested in performing tPVR should meet the following criteria:

1. The operator performs congenital and/or structural heart interventions. In addition to experience with balloon valvuloplasty, experience in stenting of branch pulmonary arteries and RVOT is needed for the treatment of complex lesions. To minimize the risk of coronary artery compression, the operator should have full knowledge and experience assessing the location of the coronary arteries in relation to the RVOT. This assessment is crucial in every patient who undergoes percutaneous pulmonary valve implantation (24). The authors encourage collaboration with adult cardiologists when assessing the coronary arteries relation to the RVOT.
2. The operator should perform at least 100 diagnostic/interventional cases per year, 50 of which should be interventional (congenital/structural) cases per year. The rationale for demanding higher number than what we have published in the tAVR document is the fact that tPVR is a much more demanding procedure than tAVR or even percutaneous mitral valve repair. tPVR is a more challenging procedure with more potential serious complications, including stent embolization that requires certain skills in retrieving embolized foreign body, rupture of the branch pulmonary arteries that may lead to catastrophic consequences, and rupture of the RVOT that may lead to tamponade and death. Finally, compression of the coronary arteries induced by stenting the RVOT may occur and may lead to death. Based on this, the writing committee felt that the operator interested in performing tPVR should practice more cases on annual basis.
3. The operator should attend a peer-to-peer training course as recommended by the United States FDA. Such courses should discuss the procedure in detail (selection of patients; baseline assessment; procedural technique; potential complications and their management and how to avoid such complications).
4. The operator should perform a simulated case if available.
5. At a minimum, the first three cases should be performed under the supervision of a proctor. Proctorship is essential in tPVR and at the end of the proctoring session the trainee should be cleared by the proctor to proceed with tPVR independently.

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APPENDIX

TABLE AI **Author Relationships With Industry (RWI) and Other Entities (Relevant)-SCAI/AATS/ACC/STS Operator and Institutional Requirements for Transcatheter Valve Repair and Replacement, Part III-Pulmonic Valve**

Committee Member	Consultant	Speakers Bureau	Ownership/ Partnership/ Principal	Personal Research	Institutional, Organizational or Other Financial Benefit	Expert Witness
Ziyad M. Hijazi, MD	Venus Medtech	None	Colibri Heart Valve[a]	None	PICS Foundation[a]	None
Carlos E. Ruiz, MD	None	None	None	None	None	None
Evan Zahn, MD	Medtronic[a]	None	None	None	None	None
Gabriel S. Aldea, MD	None	None	None	None	None	None
Emile A. Bacha, MD	None	None	None	None	None	None
Joseph Bavaria, MD	St. Jude Medical	None	None	Edwards Lifesciences,[a] Medtronic[a]	None	None
R. Morton Bolman III, MD	None	None	None	None	None	None
Duke E. Cameron, MD	None	None	None	None	None	None
Larry S. Dean, MD	None	None	None	Edwards Lifesciences[b]	None	None
Ted Feldman, MD	WL Gore, Edwards Lifesciences, Boston Scientific, Abbott	None	None	WL Gore,[a] Edwards Lifesciences,[a] Abbott,[a] Boston Scientific[a]	None	None
David Fullerton, MD	None	None	None	None	None	None
Eric Horlick, MDCM	St. Jude Medical,[b] Medtronic, WL Gore, Edwards Lifesciences	None	None	None	None	None
Michael J. Mack, MD	None	None	None	Edwards Lifesciences[a]	None	None
D. Craig Miller, MD	Abbott, Medtronic	None	None	Edwards Lifesciences[a]	None	None
Marc R. Moon, MD	None	None	None	None	None	None
Alfredo Trento, MD	None	None	None	None	None	None
Carl L. Tommaso, MD	None	None	None	None	None	None
Debabrata Mukherjee, MD	None	None	None	None	None	None
Richard Ringel, MD	None	None	None	Medtronic-NuMed[a]	None	None

This table represents all healthcare relationships of committee members with industry and other entities that were reported by authors determined to be relevant to this document at the time this document was under development. The table does not necessarily reflect RWI at the time of publication. A person is deemed to have a significant interest in a business if the interest represents ownership of ≥5% of the voting stock or share of the business entity, or ownership of ≥$10,000 of the fair market value of the business entity; or if funds received by the person from the business entity exceed 5% of the person's gross income for the previous year. Relationships that exist with no financial benefit are also included for the purpose of transparency. Relationships in this table are modest unless otherwise noted. Please refer to http://www.acc.org/guidelines/about-guidelines-and-clinical-documents/relationships-with-industry-policy for definitions of disclosure categories or additional information about the American College of Cardiology (ACC) Disclosure Policy for Writing Committees.

[a]No financial benefit.

[b]Significant relationship.

TABLE AII **Author Relationships with Industry (RWI) and Other Entities (Comprehensive)-SCAI/AATS/ACC/STS Operator and Institutional Requirements for Transcatheter Valve Repair and Replacement, Part III: Pulmonic Valve**

Committee Member	Consultant	Speakers Bureau	Ownership/ Partnership/ Principal	Personal Research	Institutional, Organizational or Other Financial Benefit	Expert Witness
Ziyad M. Hijazi, MD	Occlutech,[b] NuMED Inc.[b]	None	Colibri Heart Valve[a]	None	PICS Foundation[a]	None
Carlos E. Ruiz, MD	None	None	None	None	None	None
Evan Zahn, MD	Medtronic[a]	None	None	None	None	None
Gabriel S. Aldea, MD	None	None	None	None	None	None
Emile A. Bacha, MD	Cormatrix	None	None	None	None	None
Joseph Bavaria, MD	St. Jude Medical	None	None	Sorin,[a] Edwards Lifesciences,[a] Medtronic[a]	None	2013
R. Morton Bolman III, MD	None	None	None	GlaxoSmithKline[a]	None	None
Duke E. Cameron, MD	None	None	None	None	None	None
Larry S. Dean, MD	Phillips Medical	Daiichi Sankyo, Lilly	Emageon (stock ownership)	Edwards Lifesciences[b]	None	None
Ted Feldman, MD	WL Gore, Edwards Lifesciences, Abbott, Boston Scientific	None	None	WL Gore,[a] Edwards Lifesciences,[a] Abbott,[a] Boston Scientific Corporation[a]	None	None
David Fullerton, MD	None	None	None	None	None	None
Eric Horlick, MDCM	St. Jude Medical,[b] Medtronic, Gore, Edwards Lifesciences	None	None	Gore,[a] St. Jude Medical, Medtronic[a]	None	2004, 2012
Michael J. Mack, MD	None	None	None	Edwards Lifesciences[a]	None	None
D. Craig Miller, MD	GenTAC/HHLBI under contract to RTI, Abbott Vascular MitraClip, Medtronic, Partner U.S.	None	None	Edwards Lifesciences[a]	None	None
Marc R. Moon, MD	None	None	None	Carbomedics[a]	None	2012
Alfredo Trento, MD	None	None	None	None	None	None
Carl L. Tommaso, MD	Treasurer, SCAI[a]	None	None	None	None	2004, 2006
Debabrata Mukherjee, MD	None	None	None	None	None	None
Richard Ringel, MD	None	None	None	Medtronic-NuMed[a]	None	2010, 2010, 2010, 2011, 2011, 2011

This table represents all healthcare relationships of committee members with industry and other entities that were reported by authors, including those not deemed to be relevant to this document, at the time this document was under development. The table does not necessarily reflect RWI at the time of publication. A person is deemed to have a significant interest in a business if the interest represents ownership of ≥5% of the voting stock or share of the business entity, or ownership of >$10,000 of the fair market value of the business entity; or if funds received by the person from the business entity exceed 5% of the person's gross income for the previous year. Relationships that exist with no financial benefit are also included for the purpose of transparency. Relationships in this table are modest unless otherwise noted. Please refer to http://www.cardiosource.org/ Science-And-Quality/Practice-Guidelines-and-Quality-Standards/Relationships-With-Industry-Policy.aspx for definitions of disclosure categories or additional information about the ACC Disclosure Policy for Writing Committees. According to the ACC, a person has a *relevant* relationship IF: a) The *relationship or interest* relates to the same or similar subject matter, intellectual property or asset, topic, or issue addressed in the *document;* or b) The *company/entity* (with whom the relationship exists) makes a drug, drug class, or device addressed in the *document*, or makes a competing drug or device addressed in the *document;* or c) The *person or a member of the person's household* has a reasonable potential for financial, professional, or other personal gain or loss as a result of the issues/content addressed in the *document*.
[a]No financial benefit.
[b]Significant relationship.

TABLE AIII **Reviewer Relationships with Industry (RWI) and Other Entities (Relevant)-SCAI/AATS/ACC/STS Operator & Institutional Requirements for Transcatheter Valve Repair and Replacement, Part III: Pulmonic Valve**

Peer reviewer	Representation	Consultant	Speakers Bureau	Ownership/ Partnership/ Principal	Personal Research	Institutional, Organizational, or Other Financial Benefit	Expert Witness
Carole A. Warnes, MD	ACC	None	None	None	None	None	None
Geetha	ACC	None	None	None	None	None	None
Raghuveer, MBBS							
Hani Jneid, MD	ACC	None	None	None	None	None	None
Andrew Wang, MD	ACC	None	None	None	Gilead Sciences,[a] Edwards Lifesciences,[a] Abbott Vascular[a]	None	None
Robert H. Beekman III, MD	ACC	St. Jude Medical	None	None	None	None	None
Emile Bacha, MD	ACC	Cormatrix	None	None	None	None	None
Joaquin E. Cigarroa, MD	ACC	None	None	None	None	None	None
Robert N. Piana, MD	ACC	WL Gore, HCRI, Axio Research	None	None	Amplatzer Corporation	Vascutek	None
David R. Holmes, Jr., MD	ACC	None	None	None	None	None	None
John H. Calhoon, MD	STS	None	None	None	None	None	None
Hersh S. Maniar, MD	STS	None	None	None	None	None	None
Carl Backer, MD	AATS	None	None	None	None	None	None
Joseph Dearani, MD	AATS	None	None	None	None	None	None
Daniel S. Levi, MD	SCAI	None	None	None	None	None	None
Phillip Moore, MD	SCAI	None	None	None	None	None	None

This table represents the relationships of reviewers with industry and other entities that were disclosed at the time of peer review and determined to be relevant to this document. It does not necessarily reflect RWI at the time of publication. A person is deemed to have a significant interest in a business if the interest represents ownership of ≥5% of the voting stock or share of the business entity, or ownership of ≥$10,000 of the fair market value of the business entity; or if funds received by the person from the business entity exceed 5% of the person's gross income for the previous year. A relationship is considered to be modest if it is less than significant under the preceding definition. Relationships that exist with no financial benefit are also included for the purpose of transparency. Relationships in this table are modest unless otherwise noted. Names are listed in alphabetical order within each category of review. Please refer to http://www.acc.org/guidelines/about-guidelines-and-clinical-documents/relationships-with-industry-policy for definitions of disclosure categories or additional information about the ACC Disclosure Policy for Writing Committees. According to the ACC, a person has a *relevant* relationship IF: a) The *relationship or interest* relates to the same or similar subject matter, intellectual property or asset, topic, or issue addressed in the *document;* or b) The *company/ entity* (with whom the relationship exists) makes a drug, drug class, or device addressed in the *document,* or makes a competing drug or device addressed in the *document;* or c) The *person or a member of the person's household* has a reasonable potential for financial, professional, or other personal gain or loss as a result of the issues/content addressed in the *document.*

[a]Significant relationship.