ACCF/AHA/ACP/HFSA/ISHLT 2010 Clinical Competence Statement on Management of Patients With Advanced Heart Failure and Cardiac Transplant

A Report of the ACCF/AHA/ACP Task Force on Clinical Competence and Training

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TABLE OF CONTENTS

Preamble....645
1. Introduction....646
1.1. Writing Committee Organization....646
1.2. Document Development Process....646
1.2.1. Relationships With Industry and Other Entities....646
1.2.2. Consensus Development....646
1.2.3. External Peer Review....646
1.2.4. Final Writing Committee and Task Force Sign-Off on Document....646
1.2.5. Document Approval....646
1.3. Document Overview....646
1.4. Purpose....647
2. Pathways to Competence....647
2.1. Formal Training....647
2.2. ABIM Certification....649
2.3. Alternative Pathways....650
2.3.1. Pediatric Advanced HF and Transplantation....650
2.3.2. Pathways to Establishing Competence in Pediatric Advanced HF and Transplantation....650

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2.4. Pathway to Competence in Cardiac Transplantation....651
3. Components of Competence Required for the Management of Patients With HF....651
3.1. Cognitive Knowledge Base....651
3.2. Knowledge Base in Cardiovascular Biology and Physiology....651
3.3. Technical Skills....651
3.4. Referral for Cardiac Surgery....651
3.5. Referral of Patients With Advanced HF for Noncardiac Surgery....652
3.5.1. Surgery-Specific Components....652
3.5.2. Patient-Specific Components....653
3.5.3. Perioperative Management....653
4. Components of Competence Required for Management of Patients With Heart Transplantation or Mechanical Circulatory Assist Devices....653
4.1. Evaluation of Patients for Cardiac Transplantation....653
4.2. Perioperative Management of Patients Undergoing Heart Transplantation....653
4.3. Posttransplant Care....655
4.4. Mechanical Support of the Patient With Advanced HF....656
4.5. Perioperative Management of Patients Requiring Mechanical Devices....657
5. Additional Skills Required for Diagnosis and Treatment of Patients With Acute HF....657
5.1. Initial Diagnosis and Management of Patients With Acute Decompensated HF....657
5.2. Inpatient Management of Patients With ADHF....659
5.3. Avoiding Repeated Hospital Admissions....660
6. The Cognitive and Technical Competence Required for Referring and Monitoring of Patients With Electrophysiologic and Hemodynamic Devices....660
6.1. Referral of Patients for Electrophysiologic Devices: ICDs....660
6.1.1. Monitoring Patients With Electrophysiologic Devices: ICDs....661
6.1.1.1. Coordination of Care....661
6.1.1.2. Respond to Changes in the Clinical Status of the Patient, and Consider the Impact on Appropriate ICD Management....661
6.1.1.3. Participate in Management of Arrhythmias in the Patient With an ICD....662
6.2. Cardiac Resynchronization Therapy....662
6.3. Interpreting Data From Implantable Devices That Monitor Volume Status....662
7. Management of Advanced HF and Transplantation in Patients With Congenital Heart Disease....662
7.1. Heart Failure Management....662
7.2. Transplantation Evaluation....663
7.3. Mechanical Device Support....663
7.4. Transplantation....663
7.5. Summary....663
8. End-of-Life Issues....664
8.1. Referring Patients With Advanced HF for Palliative Care....664
8.2. Withdrawal of Life-Support Measures....664
9. Maintaining Expertise....665
9.1. Maintenance of Competence—Clinical Experience....665
9.2. Continuing Medical Education....665
10. Institutional Competence....665
References....666
Appendix 1....670
Appendix 2....671

Preamble

Granting clinical staff privileges to physicians is a primary mechanism institutions use to uphold quality care. The Joint Commission on Accreditation of Healthcare Organizations requires that medical staff privileges be based on professional criteria specified in medical staff bylaws. Physicians themselves are charged with defining the criteria that constitute professional competence and with evaluating their peers accordingly. The process of evaluating physicians' knowledge and competence has become more complex as various subspecialties have evolved over time.

The American College of Cardiology Foundation (ACCF)/American Heart Association (AHA)/American College of Physicians (ACP) Task Force on Clinical Competence and Training was formed in 1998 to develop recommendations for attaining and maintaining the cognitive and technical skills necessary for the competent performance of a specific cardiovascular service, procedure, or technology. These documents are evidence based, and where evidence is not available, expert opinion is used to formulate recommendations. Indications for and contraindications to specific services or procedures are not included in the scope of these documents. Recommendations are intended to assist those who must judge the competence of cardiovascular healthcare providers entering practice for the first time and/or those in practice undergoing periodic review of their expertise. The assessment of competence is complex and multidimensional; therefore, isolated recommendations contained herein may not necessarily be sufficient or appropriate for judging overall competence. The current document addresses competence in the management of patients with advanced heart failure (HF) and those undergoing cardiac transplantation and is authored by representatives of the ACCF, ACP, AHA, Heart Failure Society of America (HFSA), and the International Society for Heart and Lung Transplantation (ISHLT). Competence in the management of advanced HF in special populations such as children and patients with primary pulmonary hypertension and congenital heart disease is addressed in several sections; however, comprehensive recommendations for competence in these areas are beyond the scope of this document.

Advanced HF and heart transplantation are now formally linked, though there are many highly competent experts in the care of patients with HF who do not manage patients during or after heart transplantation. The first board examination for certification in advanced HF and heart transplantation is scheduled for November 8, 2010. The ACCF/AHA/ACP Task Force makes every effort to avoid actual or potential conflicts of interest that may arise as a result of outside relationships or personal interests of members of the writing committee. Specifically, all members of the writing committee were asked to disclose all such relationships that might be perceived as real or potential conflicts of interest relevant to the documented topic. These are reviewed by the writing committee and updated as changes occur. The relationships with industry information for authors and peer reviewers are published in Appendix 1 and 2, respectively.

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on Clinical Competence and Training

1. Introduction

1.1. Writing Committee Organization

The writing committee consisted of acknowledged experts in the field of HF and cardiac transplantation, including 1 liaison from the ACCF/AHA/ACP Task Force on Clinical Competence and Training—the oversight group for this document—3 ACCF representatives, 3 AHA representatives, 3 HFSA representatives, 2 ISHLT representatives, and 1 ACP representative. Representation by an outside organization does not necessarily imply endorsement.

1.2. Document Development Process

1.2.1. Relationships With Industry and Other Entities

At its first meeting, each member of the writing committee reported all relationships with industry and other entities relevant to this document topic. This information was updated, if applicable, at the beginning of all subsequent meetings and full-committee conference calls. As noted in the Preamble, relevant relationships with industry and other entities of writing committee members are published in Appendix 1.

1.2.2. Consensus Development

During the first meeting, the committee discussed the topics to be covered in the document and assigned lead authors for each section. Authors conducted literature searches and drafted their sections of the document outline. Over a series of meetings and conference calls, the writing committee reviewed each section, discussed document content, and ultimately arrived at consensus on a document that was sent for external peer review. Following peer review, the writing committee chair engaged authors to address reviewer comments and finalize the document for document approval by participating organizations.

1.2.3. External Peer Review

This document was reviewed by 12 official representatives from the ACCF, ACP, AHA, HFSA, and ISHLT; as well as 5 additional content reviewers, resulting in 208 peer review comments. See the list of peer reviewers, affiliations for the review process, and corresponding relationships with industry and other entities in Appendix 2. These comments were entered into a table and reviewed in detail by the writing committee chair. The chair engaged writing committee members to respond to peer review comments. The document was revised to incorporate reviewer comments where deemed appropriate by the writing committee.

In addition, a member of the ACCF Task Force on Clinical Expert Consensus Documents (TF CECD) served as lead reviewer for this document. This person conducted an independent review of the document at the time of peer review. Once the writing committee documented its response to reviewer comments and updated the manuscript, the lead reviewer assessed whether all peer review issues were handled adequately or whether there were gaps that required additional review. The lead reviewer reported to the chair of the ACCF TF CECD that all comments were handled appropriately and recommended that the document go forward for final review and sign-off.

1.2.4. Final Writing Committee and Task Force Sign-Off on Document

The writing committee formally signed off on the final document, as well as the relationships with industry that would be published with the document. The ACCF TF CECD also reviewed and formally approved the document to be sent for organizational approval.

1.2.5. Document Approval

The final version of the document, along with the peer review comments and responses to comments were circulated to the participating organizations for review and approval. The document was approved for publication by the ACCF and AHA in June 2010 and the ACP in April 2010. The document was then sent to the governing boards of the HFSA and ISHLT for endorsement consideration, along with the peer review comments and responses for their respective official peer reviewers. HFSA and ISHLT formally endorsed this document in May 2010. This document will be considered current until the ACCF TF CECD revises it or withdraws it from publication.

1.3. Document Overview

This statement is the first ACCF/AHA/ACP/HFSA/ISHLT document on clinical competence for management of patients with advanced HF and cardiac transplantation. These patients, defined essentially as having Stage D HF, are usually hospitalized with refractory HF requiring specialized interventions. For example, they may be candidates for intra-aortic balloon counterpulsation or other external pumping devices, ultrafiltration, dialysis, mechanical support devices, experimental surgery, experimental drugs, transplantation, and end-of-life measures such as hospice care. This statement is not meant to limit physicians who care for patients with Stage A, B, and C HF. Moreover, patients with earlier stages of cardiomyopathy may require a HF specialist to be involved in their care when there is a need for specialized genetic counseling for complex inherited disease or other requirements because of complex, unique features. Patients with Stage D HF often receive complicated drug regimens and often have implanted cardioverter-defibrillators (ICDs) or

biventricular pacemakers. The current statement describes the level of experience, knowledge, and technical skills necessary for competent performance in caring for these complex patients. When no literature or data are available upon which to base the evaluation of competence, the specifications are based on consensus of expert opinion. The specifications are applicable to various practice settings and training backgrounds and accommodate a number of ways physicians can demonstrate competence. Expertise in specific, uncommonly performed procedures or unusual diagnoses in patients with advanced HF or following heart transplantation may require additional training or experience. Therefore, it is expected that even highly competent practitioners will occasionally benefit from consultation with colleagues who have specialized skills, such as in sleep medicine.

This document describes competence of HF specialists who have completed formal training in clinical cardiology and in some cases have completed additional training in advanced HF and heart transplantation. The committee recognizes that there are very capable cardiologists who do not have formal training in advanced HF and heart transplantation but who care for patients with Stage D HF failure. The American Board of Internal Medicine (ABIM) plans to accommodate such physicians toward certification through various alternative pathways based on their overall training and experience; however, it is our expectation that eventually certification will depend on formal training and testing. Training guidelines are distinguished from competence statements. Training guidelines are covered in the Core Cardiology Training Statement (COCATS) for cardiology training and HF/transplantation.[1] This document also addresses additional competencies required for the care of special populations of patients with advanced HF, such as children or those with primary pulmonary hypertension or congenital heart diseases, but it should not be viewed as a comprehensive statement on competence in these areas.

1.4. Purpose

The purpose of this document is to delineate the knowledge base and skills necessary for expertise in the care and management of patients with advanced HF and heart transplantation. It is intended to be used by hospitals, institutions, and credentialing bodies that must at times distinguish specialists in the management of patients with advanced HF and heart transplantation from other well-trained physicians who care for the majority of patients with less advanced forms of HF. The document is not meant to limit physicians who care for patients with HF. The committee recognizes that most patients with HF are cared for by noncardiologists. This document attempts to specify the required knowledge base and skills required to competently care for patients with advanced HF and heart transplantation.

2. Pathways to Competence

2.1. Formal Training

The development of the specialist called the advanced HF and transplant cardiologist is related fundamentally to an expanding array of surgical, medical, and device-based therapies that improve the quality and/or extend the lives of patients with various cardiovascular diseases. The era of vasodilator-based regimens for HF began with publication of the V-HeFT (Vasodilator-Heart Failure Trial) in June 1986.[2] Heart transplantation was undertaken with renewed enthusiasm in the same decade with introduction of cyclosporine-based immunosuppressive therapy.[3,4] In 1984, the US Congress passed the National Transplant Act,[5] which facilitated procurement of donor hearts and increased the availability of heart transplantation. Although many clinicians caring for patients with HF are not cardiologists,[6,7] this document addresses training pathways for the advanced HF and transplant cardiologist, and includes not only patients with Stage D disease, but also patients with less advanced but more unique myocardial diseases such as infiltrative and hereditary cardiomyopathies.

COCATS 3 (Version 3 of the Adult Cardiovascular Medicine Core Cardiology Training Statement) has articulated tiers of training in cardiology and its subspecialties.[8] Training in HF, likewise, can be viewed in terms of 3 ascending levels of intensity.[1] Level 1 represents the basic training and competence that every cardiology fellowship trainee must experience and demonstrate. Table 1 outlines the scope of training in a 3-year cardiovascular fellowship at Level 1, as well as the intensified experience for competence in HF and the other subspecialties of cardiology. Many Level 1 training components in cardiology are fundamental to the experience for the advanced HF cardiologist. These include the fundamentals of cardiovascular hemodynamics, cardiac imaging, exercise cardiovascular physiology, acute critical coronary care, and the perioperative care of patients undergoing cardiac surgery. Additional elements relevant to the advanced HF subspecialty include arrhythmia management, management of ischemic and valvular heart disease, basic cardiovascular pharmacology, understanding of neurohumoral activation, cardiomyocyte biology, and the phenotypical manifestations of cardiac dysfunction, including HF with dilated cardiomyopathy and HF with preserved ejection fraction.

Level 1 training introduces a number of important issues with respect to the management of patients with HF, including the clinical trial evidence relevant to management of HF; indications for prescription of nonpharmacological or nondevice treatment modalities in patients with HF; diet and activity recommendations; indications for cardiac transplantation; and the evidence for differences in management and response to therapy based on etiology, cardiac structure and function, age, gender, ethnic background, and comorbidity.

Level 2 training involves intensified instruction and experience in HF-related activities, so the trainee can focus subsequent clinical effort on the evaluation and management of patients with HF or on research. COCATS suggests that this training should occur over approximately 6 months, and might encompass prolonged clinical experience in a HF clinic, hospital unit for HF patients, heart transplantation program, or where mechanical circulatory assist device (MCAD) surgery is performed. Level 2 training should expose physicians to patients receiving an MCAD or heart transplant. One to 2 months of the 6 months should be spent at an implanting center/transplant center if the

Table 1. Summary of Training Requirements

Task Force	Area	Level	Minimal Number of Procedures	Cumulative Duration of Training (Months)	Minimal Cumulative Number of Procedures	Comments
1	Clinical cardiology	1		36		
2	Electrocardiography	1	3500*†	36	3500	*Can be taken throughout the training program. †The committee strongly recommends that cardiologists achieve Level 2 training in ECG interpretation.
		2	3500			
	Ambulatory monitoring	1	150*		150	*Can be taken throughout the training program.
		2	75		225	
	Exercise testing	1	200*		200	*Can be taken throughout the training program.
		2	100		300	
3	Diagnostic catheterization	1	100	4	100	
		2	200	8	300	
	Interventional catheterization	3	250	20	550	
4	Echocardiography	1	(75/150)	3	75/150	
		2	(75/150)	6	150/300	
		3	(150/450)	12	300/750	
5	Nuclear cardiology	1	100 cases	2	100 cases	
		2	300 cases	4–6	300+ cases	
		3	600 cases	12	600+ cases	
6	Electrophysiology, pacing, and arrhythmias	1	20	2	10 temporary pacemakers 10 DC cardioversions	
		2	100	6	100 pacemaker interrogation/ reprogramming	
		3	300* prior procedure volume during Level 1 and 2 training is cumulative and counts towards overall numbers recommended for Level 3 training	12–24	150+ EP cases 75 ablations 75+ pacemaker/ICDs	*Can be taken throughout the training program.
7	Research	1		6–12‡		‡Can be taken as part of 9 months of required nonlaboratory clinical practice rotation.
		2		24		
		3		24–36		
8	Heart failure and transplantation	1		1‡§		‡Can be taken as part of 9 months of required nonlaboratory clinical practice rotation. §It is assumed that trainees will obtain additional training in heart failure and preventive cardiovascular medicine beyond the 1-month core training as part of the experience during other clinical months, such as consult services and CCU.
		2		6		
		3		12		
9	Congenital heart disease	1		Core lectures‡	40 catheterizations 300 TTE cases	‡Can be taken as part of 9 months of required nonlaboratory clinical practice rotation.
		2				
		3		12	50 TEE cases	
				24		
10	Preventive cardiovascular medicine	1		1‡§		‡Can be taken as part of 9 months of required nonlaboratory clinical practice rotation. §It is assumed that trainees will obtain additional training in preventive cardiovascular medicine beyond the 1-month core training as part of the experience during other clinical months, such as consult services and CCU.
		2		6–12		
		3		12		

(*Continued*)

Table 1. Continued

Task Force	Area	Level	Minimal Number of Procedures	Cumulative Duration of Training (Months)	Minimal Cumulative Number of Procedures	Comments
11	Vascular medicine	1		2*		*Can be taken throughout the training program.
	Vascular medicine specialist	2	475+ noninvasive vascular cases‖ 100 diagnostic peripheral angiograms, 50 peripheral angioplasties/stents, 10 peripheral thrombolytic infusions/thrombectomy	12¶ 12#	475+ noninvasive vascular cases‖ 100 diagnostic peripheral angiograms, 50 peripheral angioplasties/stents, 10 peripheral thrombolytic infusions/ thrombectomy	¶The prerequisite for Level 2 training is Level 1 training in vascular medicine. ¶In addition to all other clinical requirements for Level 2 training. #The prerequisite for Level 3 training includes Level 1 training in vascular medicine, and Level 1 and 2 training in diagnostic cardiac catheterization. Requirements for Level 3 training in peripheral vascular intervention can be fulfilled during a 4th year of inter-ventional training focused on peripheral vascular intervention or concurrently with cardiac interventional training.
	Peripheral vascular intervention	3				
12	Cardiovascular magnetic resonance	1		1**	25 cases	**Can be taken as part of 7 months of noninvasive imaging rotation.
		2		3–6	150 cases	
		3		12	300 cases	
13	Computed tomography	1		1**	50 cases	**Can be taken as part of 7 months of noninvasive imaging rotation.
		2		2	150 CTA cases	
		3		6	300 CTA cases	

Reprinted from Beller et al.[8]

CCU indicates coronary care unit; CTA, computed tomography angiography; DC, direct current; ECG, electrocardiogram; EP, electrophysiology; ICD, implantable cardioverter-defibrillator; TEE, transesophageal echocardiography; and TTE, transthoracic echocardiography.

parent training site does not implant MCADs or perform heart transplantation.

Level 3 training provides an opportunity to acquire the competence required for physicians specializing in advanced HF and transplant cardiology. The necessary experience includes advanced training in cardiac transplantation, MCADs, and HF disease management. Level 3 requires more than just a proficiency in the evaluation of patients undergoing MCADs or cardiac transplantation. Physicians need to acquire the skills to manage these patients perioperatively and postventricular assist device (VAD) implant as well as after cardiac transplantation. The training must encompass the use of echocardiography to facilitate adjustment of pulsatile and nonpulsatile pumps. In addition, the physician needs to have an intimate knowledge of the complications in patients following cardiac transplantation including rejection, infection, malignancy, vasculopathy, and the adverse risks of immunosuppressant therapies. Many cardiology programs offer sufficient exposure in the Level 3 curriculum to qualify the trainee for the United Network of Organ Sharing (UNOS) designation of heart transplantation physician (see the following text). Advanced training requires demonstration of proficiency in the management of challenging HF patient cohorts, including those requiring chronic inotropic drug infusion support or hospice-based end-of-life care, and those undergoing evaluation for cardiac transplantation or MCADs.

The writing committee believes that competence in advanced HF requires training in selecting patients for cardiac transplantation, and in all other aspects of posttransplantation care. This is reflected in the COCATS document,[8] and in the criteria for certification in the secondary subspecialty of advanced HF and transplantation cardiology approved by the American Board of Medical Specialties and the ABIM. Accordingly, if training in cardiac transplantation is not offered at the primary training institution, experience should be sought during outside rotations at an institution that performs at least 10 heart transplants per year. Please note, in order to become a certified UNOS-transplant cardiologist, the requirements involve a higher number of transplant patients.[9] We acknowledge that a number of highly competent HF specialists have practiced and published research findings during the early stages of evolution of this secondary subspecialty, when heart transplantation surgery was uncommon. As this field moves forward, however, the HF specialist will be expected to develop competence in all validated forms of therapy for patients with advanced HF and heart transplantation.

2.2. ABIM Certification

The American Board of Medical Specialties and the ABIM approved certification of adult cardiologists in the secondary subspecialty of advanced HF and transplant cardiology. Requirements for fellowship training in advanced HF and

transplantation cardiology are concordant with those outlined for the Level 3 training in COCATS.[8] A physician may apply for certification by the following pathway:

1. Complete a 3-year cardiovascular fellowship to establish Board eligibility in the medical specialty of cardiovascular diseases
2. Complete a 1-year fellowship in advanced HF and transplant
3. Successfully complete the certifying examination of the ABIM

2.3. Alternative Pathways

Cardiologists who have completed general cardiology training and have focused the majority of their professional effort on the care and management of patients with HF may apply for ABIM certification in the secondary subspecialty of advanced HF and transplant cardiology. Eligibility for certification along this alternative pathway requires attestation by professional colleagues and/or the division chair to their experience and competence in HF, as determined by the ABIM. Further details are to be worked out, but the applicant is expected to be eligible to take the certifying examination. This alternative pathway will be available for several years after initiation of the certifying examination in advanced HF and transplant cardiology. DO cardiologists with appropriate advanced HF and transplant cardiology training may, by virtue of their internal medicine certification, not be eligible to take the ABIM examination. If their training has met all of the herein-described criteria, those cardiologists should be considered no less qualified.

2.3.1. Pediatric Advanced HF and Transplantation

In parallel with the adult experience, heart transplantation in children was first performed in the late 1970s as a therapy for both end-stage congenital heart disease and cardiomyopathy. Experience with pediatric heart transplantation grew exponentially during the 1980s and early 1990s; since 1992, however, the number of pediatric heart transplantation procedures has remained stable at 375 to 400 per year because of limited donor availability.[10] Between 2004 and 2006, 17 centers in the United States performed more than 10 heart transplant procedures per year in children.

Given improved results with medical and device-based therapies reported in children less than 18 years of age,[11,12] the need has grown for pediatric cardiologists with subspecialty training in advanced HF and transplantation. The management of children with cardiomyopathy, HF, and transplantation is included in the core knowledge base of the current ACCF/AHA/ACP recommendations for training in general pediatric cardiology; however, specific competence criteria are not provided.[13] The small number of pediatric cardiology training programs with active pediatric heart transplantation programs limits the first-hand exposure of many general pediatric cardiology trainees to the care of children with advanced HF undergoing heart transplantation. Although no formal process exists for certification in pediatric advanced HF and transplantation, a small number of pediatric heart transplant centers offer fourth-year fellowships with specific training in HF and heart transplantation.

Many of the competencies for the adult HF specialist detailed in this document are applicable to the pediatric HF specialist. The underlying causes of advanced HF in the pediatric age range include genetic, metabolic, idiopathic and acquired cardiomyopathies, congenital heart disease, and rare instances of ischemic heart disease. A comprehensive statement of competencies for the pediatric HF specialist is beyond the scope of this document; however, some general competencies are outlined in the following section:

- Knowledge of the manifestations of HF in children and an ability to assess HF severity using medical history, physical examination, genetic testing, biomarkers, imaging modalities, exercise stress testing, and hemodynamic measurements
- Expertise in the evaluation and management of advanced HF and transplantation in the patient with congenital heart disease
- Understanding of age-related differences in the pharmacokinetics and pharmacodynamics of medications used to treat advanced HF in children
- Ability to evaluate the indications, risks, benefits, and limitations of ICD placement, cardiac resynchronization therapy (CRT), and mechanical assist devices in the pediatric size and age range
- Understanding of the indications for heart transplant in specific age groups and diagnostic categories
- Understanding of the age-related differences in the pharmacokinetics and pharmacodynamics of immunosuppressive medications in children
- Familiarity with the infectious disease risks of immunosuppression in the pediatric age range
- Understanding of the neurodevelopmental and psychosocial impact of HF and transplant on the child and family and a ability to coordinate the services needed to provide the appropriate interventions
- Expertise in palliative and end-of-life care in the pediatric population

2.3.2. Pathways to Establishing Competence in Pediatric Advanced HF and Transplantation

The pediatric HF specialist should be board-eligible to obtain certification in pediatric cardiology from the American Board of Pediatrics Sub-Board of Cardiology and have completed an additional year of fellowship at a pediatric transplant center or have focused the majority of his or her professional efforts on the care and management of children with advanced HF.

Additional evidence of competence includes designation as a primary heart transplant physician by the Organ Procurement Transplant Network (OPTN)/UNOS Membership and Professional Standards Committee. For a pediatric HF specialist to function as the primary heart transplant physician, she or he must demonstrate to the satisfaction of the Committee and Board of Directors that his/her training and/or experience in the care of heart transplant patients is equivalent to that described in the requirements outlined for adult heart transplant physicians. In addition, the physician must demonstrate maintenance of satisfactory knowledge through direct involvement in all aspects of heart transplantation and patient care within the past 2 years.[14]

2.4. Pathway to Competence in Cardiac Transplantation

UNOS has developed standards and established a pathway of training for designation of cardiologists as specialists in cardiac transplantation. It is expected that cardiologists can acquire this experience and competence during 1 year as a fellow in advanced HF and transplantation. Alternatively, cardiologists may acquire the experience and develop competence though clinical practice.

An advanced HF and transplant cardiologist should hold an MD, DO, or equivalent degree from another country, have a valid license to practice medicine in his or her state, and be certified by the Cardiovascular Disease ABIM, American Osteopathic Board of Internal Medicine, or its foreign equivalent. The applicant shall provide a letter from the chair of the credentialing committee of the hospital where the applicant practices stating that he or she is a member of the cardiology staff in good standing. The training/experience requirement for qualification as a heart transplant physician can be met through a variety of pathways summarized in the UNOS Bylaws.[9]

3. Components of Competence Required for the Management of Patients With HF

3.1. Cognitive Knowledge Base

Competence in advanced HF and transplantation requires a broad base of knowledge in internal medicine, especially as it pertains to organ systems that are often affected by HF. The HF specialist recognizes the risk factors associated with the development of HF such as hypertension, diabetes mellitus, and coronary artery disease and understands the preventive measures necessary to control these risk factors. Strategies used to prevent HF include control of blood pressure, promotion of physical fitness, smoking cessation, treatment of hyperlipidemia, and maintenance of ideal body weight and healthy lifestyle. It is important that the HF specialist have a penetrating understanding of organ physiology, pathophysiology of HF, cardiomyopathy, pharmacology, electrophysiology, performance measures, and many other elements as they pertain to the care of patients with advanced HF and/or heart transplantation. Rigorous training in general clinical cardiology with emphasis on areas most pertinent to the diagnosis and management of patients with HF is an important requirement in the development of competence in the care of these complex patients. This presumes cost-consciousness care and history taking. As a practical matter, it would be extremely difficult for an individual who has not received accredited training in internal medicine and cardiovascular disease to acquire this knowledge and experience.

A key skill that the HF specialist should have is the ability to administer and interpret formal quality-of-life assessment. The HF specialist should be able to assess quality of care and should be able to adopt mechanisms to ensure continuous quality improvement. A detailed knowledge of HF guidelines is essential. In addition, the HF specialist should have a basic knowledge of clinical trial design and should be able to analyze and understand new scientific data in the context of the care of advance HF and heart transplantation.

3.2. Knowledge Base in Cardiovascular Biology and Physiology

The specialist in advanced HF should have a thorough understanding of normal cardiovascular physiology and pathophysiology. Important components are as follows:

- Excitation–contraction coupling and the contractile properties of the cardiomyocyte
- Ventricular systolic and diastolic function
- Ventricular structure, geometry, and remodeling, including extracellular matrix biology
- Physiology and pathophysiology of cardiomyopathy, including genetics, arrhythmias, biomarkers, exercise physiology, and the different pathophysiology of restrictive cardiomyopathy, dilated cardiomyopathy, and hypertrophic cardiomyopathy
- Physiological modulation of cardiomyocyte and ventricular function
- Physiology and pathophysiology of the peripheral and pulmonary vasculature, including endothelial function and dysfunction
- Pathophysiology of coronary allograft vasculopathy
- Neurohumoral control of the heart and circulation and alterations in patients with HF, including the sympathetic and parasympathetic nervous systems, the renin-angiotensin-aldosterone systems and the natriuretic peptides
- Effects of vasoactive and inflammatory cytokines
- Hypercoagulable states and risks of arterial and venous thromboembolic complications

3.3. Technical Skills

Some technical skills are required for competence in advanced HF and transplantation beyond those acquired as part of general cardiology training. In many medical centers, HF specialists perform cardiopulmonary exercise testing, right-heart catheterization, and myocardial biopsy procedures. Management of assist devices, interrogation of ICDs, and interpretation of CRT data are considered “technical” by some cardiologists. The specialist caring for patients with advanced HF must demonstrate a thorough understanding of hemodynamic measurements obtained by right-heart catheterization. Familiarity with normal, abnormal, and artifactual waveforms and measurements of pressure and flow may be critical in determining the correct diagnosis, course of treatment, and response to therapy in this patient population. There should also be familiarity with vasodilator drug testing for the diagnosis and treatment of pulmonary arterial hypertension. HF specialists should understand the indications for endomyocardial biopsy and knowledge of when special preparation of the sample is required (eg, specialized handling for suspected amyloid infiltration).

3.4. Referral for Cardiac Surgery

The HF specialist should be able to identify potentially reversible causes of HF that are amenable to surgical intervention. The HF specialist should have a thorough understanding of surgical interventions available for patients with

advanced HF, including myocardial revascularization with coronary bypass surgery, valvular repair and replacement, myectomy, pericardiectomy, ventricular restoration procedures, and the use of mechanical circulatory support as a bridge to recovery, a destination therapy (ie, permanent device implantation without plans for heart transplantation), and a bridge to heart transplantation.[15–19] Surgical therapies for the treatment of advanced HF are associated with fewer evidence-based recommendations from randomized trials to guide decisions with respect to patient selection and comparison of benefits and risks of alternative strategies. Several of these surgical therapies are currently undergoing evaluation in rigorous trials, and HF specialists are expected to keep abreast of results and recommendations through continuous education.[20] The HF specialist must incorporate the best available evidence with respect to potential benefit and risk in the context of the individual patient, and must be able to critically evaluate novel surgical therapies.

This principle is especially important in assessing patients with advanced HF who have comorbidities that affect the estimation of benefit and risk associated with surgical intervention. Accordingly, the specialist should be able to identify, assess, and treat comorbid conditions in patients with advanced HF being considered for cardiac surgical intervention. Among the most frequently encountered of these comorbidities are poor functional capacity, advanced age, cognitive impairment, renal dysfunction, hepatic dysfunction, coagulopathy, pulmonary hypertension, diabetes, malnutrition, cachexia, respiratory disorders, anemia, altered immune status, and psychological depression.[21–25]

The evaluation of patients with advanced HF for surgical therapy may require diagnostic studies beyond those used in less severely ill patients. The HF specialist should have knowledge of diagnostic modalities used to define the presence and extent of coronary disease and assess myocardial ischemia and viability. The specialist should be able to identify the presence and severity of valvular, congenital, and pericardial disease that compromises cardiac function. Typically, patients with advanced HF require a more thorough evaluation to identify potentially reversible causes of HF. Examples include the patient with ischemic heart disease in whom identification of hibernating myocardium is critical to the decision to recommend myocardial revascularization and the patient with aortic stenosis, severe left ventricular dysfunction, and a low transvalvular gradient who may benefit from aortic valve replacement.[26,27] The HF specialist should be able to design a strategy that comprises the use of multiple imaging modalities (eg, dobutamine stress perfusion and metabolic imaging by positron emission tomography, and assessment of cell membrane integrity and contractile reserve by either thallium or technetium-99m Tc-sestamibi single photon emission computed tomography) if necessary. The HF specialist must be able to integrate information from established and emerging modalities, including cardiovascular magnetic resonance. The HF specialist should be able to interpret results of cardiovascular magnetic resonance obtained to detect myocardial viability and enhance diagnostic capabilities in the evaluation and management of valvular, congenital, and pericardial disease. The HF specialist must also be able to employ the results of exercise testing for determination of peak exercise oxygen consumption, right-heart catheterization, and myocardial biopsy to formulate a management strategy and choose between surgical and medical therapy or between different types of surgical intervention (eg, coronary bypass grafting versus heart transplantation).

It is important that the HF specialist, in collaboration with other specialists and an experienced surgical team, should be competent in devising a coordinated care plan to address the overall health of the patient and mitigate perioperative risk.[28] Thus, the HF specialist must recognize factors associated with perioperative morbidity and mortality and be familiar with strategies for treating these conditions. The HF specialist should have specific knowledge of perioperative management of anticoagulation, parenteral administration of cardiac and noncardiac drugs, particularly those required for hemodynamic support of critically ill patients, including vasopressor, vasodilator, and inotropic drugs. The HF specialist should have a thorough understanding of temporary mechanical circulatory support devices that may be required for patients with decompensated HF who have become refractory to standard therapy and require optimization of clinical status prior to surgical intervention. The HF specialist must be able to recognize postoperative complications, including cardiac arrhythmias, myocardial ischemia, cardiac tamponade, and other conditions that adversely affect cardiac function.

3.5. Referral of Patients With Advanced HF for Noncardiac Surgery

Although there have been many studies of the risk of ischemic events in patients with and without coronary disease undergoing noncardiac surgery, few systematic studies have addressed the risks of noncardiac surgery in patients with HF, much less in those with advanced HF.[29]

The specialist in advanced HF should be thoroughly familiar with published guidelines on reducing the risk of coronary events in patients undergoing noncardiac surgery. The lack of definitive evidence specific to patients with HF requires that the specialist have the judgment to estimate the relative risks and benefits of specific surgical procedures in patients with advanced HF.

The HF specialist must be able to assess the importance of the planned surgical procedure and its relationship to the patient's long-term well-being from both the patient's perspective and in the context of estimated risks from both known and unanticipated causes. The HF specialist should be able to assess the risks derived from the surgery-specific and patient-specific components listed below to provide guidance to the surgeon, anesthesiologist, and other caregivers throughout the perioperative period.

3.5.1. Surgery-Specific Components

- Elective or urgent timing of intervention
- Anticipated level of hemodynamic stress during anesthesia, surgery, and the postoperative period
- The experience of the surgeon and anesthesiologist in patients with advanced HF

3.5.2. Patient-Specific Components

- Etiology of HF
- Severity of underlying cardiac dysfunction
- Status and stability of HF compensation
- Presence and severity of comorbidities (eg, renal, pulmonary, or hepatic disease)
- The patient's understanding of risks and benefits
- Advance directives in the event of complications or unfavorable outcome

3.5.3. Perioperative Management

If a decision is made to proceed with surgery, the advanced HF specialist must be competent to provide expert assistance in management during the perioperative period, with particular attention to the following potential needs:

- Additional diagnostic testing (eg, to assess cardiac function or the risk of myocardial ischemia)
- Preoperative stabilization, including revascularization, in relation to the timing of surgery
- Perioperative hemodynamic monitoring
- Management of medications throughout the perioperative period, including anticoagulation and administration of medications by parenteral routes
- Indications for intravenous diuretic or inotropic support
- Mechanical circulatory support
- Prophylaxis against or management of disturbances of cardiac rate or rhythm (eg, accelerated ventricular rate with atrial fibrillation)
- Management of postoperative problems related to changes in cardiac loading conditions and intravascular volume

4. Components of Competence Required for Management of Patients With Heart Transplantation or Mechanical Circulatory Assist Devices

4.1. Evaluation of Patients for Cardiac Transplantation

Cardiac transplantation and destination VAD placement are the only established surgical treatments for advanced, end-stage HF. Improvement in other therapeutic options available for patients with HF and a persistent shortage of donor hearts make it critical that the HF specialist be able to identify patients with poor prognosis who could most benefit from transplantation. The AHA Statement on the "Selection and Treatment of Candidates for Heart Transplantation" specifies that a multidisciplinary team with expertise in HF should evaluate candidates for cardiac transplantation.[30] The HF specialist should have the skills to manage the team and be able to reevaluate patients periodically and monitor and adjust therapy as outlined in Table 2. In most instances, the "team" caring for these patients includes HF transplant specialists, cardiothoracic surgeons, internists, nurse coordinators, nurses, fellows, social workers, psychologists, and financial managers. The HF specialist should interact with other physicians in such a way so as to facilitate communication with the families and the patient. This means working closely with internists, primary care physicians, and other referring doctors. Additionally, the HF specialist should include these physicians in regular peer education exercises in order to facilitate interaction and communication.

The COCATS Task Force Section 8 on "Training in Heart Failure" specifies that the clinician competent in Advanced HF and Transplantation should be familiar with the indications for transplantation, criteria for the evaluation of potential candidates, and techniques for managing patients as a member of the team of transplant professionals.[1] The HF specialist should be very familiar with the most recent ACC/AHA guidelines for the management of chronic HF, which recommend that eligible patients with Stage D HF be referred for cardiac transplantation (Class I, Level of Evidence: B),[28] as well as the HFSA guidelines[31] and ISHLT guidelines.[32,33] The HF specialist should be able to assess prognosis and advise both patient and family about management choices, including transplantation and mechanical devices.

The HF specialist should be able to search for a potentially reversible etiology of HF that may be amenable to specific medical or surgical intervention[34] and should be able to identify those patients who either fail to improve or have contraindications to these treatment modalities. The HF specialist should be thoroughly versed in the current indications for cardiac transplantation, shown in Table 3, which focus on patients who are severely limited and who may need continuous inotropic therapy or a mechanical device for survival.[28]

Specific skills are necessary for competence in the evaluation of candidates for cardiac transplantation. Interpretation of cardiopulmonary testing for peak oxygen uptake (Vo_2) is an important skill to help in patient selection, but patient selection should not be based solely on functional capacity. Appropriate integration of the peak Vo_2 information with other clinical data is an essential skill set. Interpretation of hemodynamic values (Table 4) and assessment of the reversibility of pulmonary hypertension are also important skill sets of the HF specialist involved with pretransplant evaluation.[32] Other parameters are also pertinent, and the evaluation process requires the HF specialist to review and integrate the information listed in Table 2 into the evaluation process and collaborate with other members of the multidisciplinary HF transplantation team to determine the need for listing.[32]

4.2. Perioperative Management of Patients Undergoing Heart Transplantation

The immediate postoperative care of the cardiac transplant recipient requires the HF specialist to be knowledgeable regarding the problems that may arise and be able to coordinate patient care with other members of the team, including anesthesiologists, critical care physicians, and surgeons. If the development of competence in the care of patients with heart transplantation is not available at the primary training site, experience in cardiac transplantation should be obtained during rotations at an institution where more than 10 transplants are performed yearly. The writing committee recognizes that some flexibility will be needed

Table 2. Schedule of Examinations in Candidates for Cardiac Transplantation

Test	Repeat				
	Baseline	3 Months	6 Months	9 Months	12 Months (and Yearly)
Complete H & P	X				
Follow-up assessment		X	X	X	X
Weight/BMI	X	X	X	X	X
Immunocompatibility					
ABO	X				
Repeat ABO	X				
HLA tissue typing	Only at transplant				
PRA and flow cytometry	X				
• >10%	Every 1–2 months				
• VAD	Every 1–2 months				
• Transfusion	2 weeks after transfusion and then 9 months × 6 months				
Assessment of heart failure severity					
Cardiopulmonary exercise test with RER	X				X
Echocardiogram	X				X
Right heart catheter (vasodilator challenge as indicated)	X		X		X
ECG	X				X
Evaluation of multiorgan function					
Routine lab work (BMP, CBC, LFT)	X	X	X	X	X
PT/INR More frequent per protocol if on VAD or warfarin	X	X	X	X	X
Urinalysis	X	X	X	X	X
GFR (MDRD quadratic equation)	X	X	X	X	X
Unlimited urine sample for protein excretion	X	X	X	X	X
PFT with arterial blood gasses	X				
CXR (PA and lateral)	X				X
Abdominal ultrasound	X				
Carotid Doppler (if indicated or >50 y)	X				
ABI (if indicated or >50 y)	X				
DEXA scan (if indicated or >50 y)	X				
Dental examination	X				X
Ophthalmologic examination (if diabetic)	X				X
Infectious serology and vaccination					
Hep B surface Ag	X				
Hep B surface Ab	X				
Hep B core Ab	X				
Hep C Ab	X				
HIV	X				
RPR	X				
HSV IgG	X				
CMV IgG	X				
Toxoplasmosis IgG	X				
EBV IgG	X				
Varicella IgG	X				
PPD	X				
Flu shot (q 1 y)	X				
Pneumovax (q 5 y)	X				
Hep B immunizations: 1_2_3	X				
Hep B surface Ab (immunity)	6 weeks after third immunization				

(*Continued*)

Table 2. Continued

Test	Baseline	Repeat			
		3 Months	6 Months	9 Months	12 Months (and Yearly)
Preventive and malignancy					
Stool for occult blood × 3	X				X
Colonoscopy (if indicated or >50 y)	X				
Mammography (if indicated or >40 y)	X				X
Gyn/Pap (if indicated ≥18 y sexually active)	X				X
PSA and digital rectal examination (men >50 y)	X				X
General consultations					
Social work	X				
Psychiatry	X				
Financial	X				
Neuro/psych (if applicable)	X				

Reprinted with permission from Mehra et al.[32]

Ab indicates antibody; ABI, ankle brachial index; ABO, blood type ABO; Ag, antigen; BMI, body mass index; BMP, basal metabolic pattern; CBC, complete blood count; CMV, cytomegalovirus; CXR, chest x-ray; DEXA, dual energy x-ray absorptiometry; EBV, Epstein-Barr virus; ECG, electrocardiogram; GFR, glomerular filtrate rate; Gyn/Pap, gynological/Papanicolau test; Hep B, hepatitis B; Hep C, hepatitis C; H & P, history and physical; HLA, human leukocyte antigen; HSV, herpes simplex virus; LFT, liver function test; MDRD, Modification of Diet in Renal Disease; Neuro/psych, neurological/psychological; PA, posterior/anterior; PT/INR, prothrombin time-international normalized ratio testing; PFT, pulmonary function test; PPD, purified protein derivative; PRA, panel reactive antibodies; PSA, prostate-specific antigen test; RER, respiratory exchange ratio; RPR, rapid plasma reagin; and VAD, ventricular assist device.

in individual cases regarding this requirement for competence.

The development of competence in the evaluation and care of patients with heart transplant requires that the HF specialist understand the physiology of the denervated heart and the differences in therapeutic response to medications in patients with native heart disease and following transplantation. Recognition of causes of early mortality, such as acute graft rejection and infection, and identification and management of right ventricular failure and pulmonary hypertension are also important measures of competence of the HF specialist. In addition, the HF specialist should be competent in early postoperative management of patients following heart transplantation, including the need for implantation of a right-VAD.[35] The HF specialist should have experience with and knowledge of pre- and postoperative nutritional support and rehabilitation of the patient following heart transplantation.

UNOS clearly delineates the requirements of a cardiac transplant physician as part of a UNOS-certified transplant program.[9] These are reinforced in the COCATS Task Force 8 document.[8]

4.3. Posttransplant Care

As the survival of patients undergoing cardiac transplantation improves, many return to the community and receive care

Table 3. Indications for Cardiac Transplantation

Absolute Indications in Appropriate Patients
For hemodynamic compromise due to HF
• Refractory cardiogenic shock • Documented dependence on IV inotropic support to maintain adequate organ perfusion • Peak Vo_2 less than 10 mL per kg per min with achievement of anaerobic metabolism
Severe symptoms of ischemia that consistently limit routine activity and are not amenable to coronary artery bypass surgery or percutaneous coronary intervention
Recurrent symptomatic ventricular arrhythmias refractory to all therapeutic modalities
Relative Indications
Peak Vo_2 11 to 14 mL per kg per min (or 55% predicted) and major limitation of the patient's daily activities
Recurrent unstable ischemia not amenable to other intervention
Recurrent instability of fluid balance/renal function not due to patient noncompliance with medical regimen
Insufficient Indications
Low left ventricular ejection fraction
History of functional class III or IV symptoms of HF
Peak Vo_2 greater than 15 mL per kg per min (and greater than 55% predicted) without other indications

Reprinted from Hunt et al.[28]

HF indicates heart failure; IV, intravenous; and Vo_2, oxygen consumption per unit time.

Table 4. Hemodynamic Criteria for Evaluation of Candidates for Cardiac Transplantation

- Pulmonary artery hypertension and elevated PVR should be considered as a relative contraindication to cardiac transplantation when the PVR is >5 Wood units or the PVRI is >6 or the TPG exceeds 16 to 20 mm Hg
- If the PAS exceeds 60 mm Hg in conjunction with any 1 of the preceding 3 variables, the risk of right heart failure and early death is increased
- If the PVR can be reduced to <2.5 with a vasodilator but the systolic blood pressure falls <85 mm Hg, the patient remains at high risk of right heart failure and mortality after cardiac transplantation

Calculations: transpulmonary gradient (TPG [PAMP − PCWP]); pulmonary vascular resistance (PVR [TPG/CO Wood units]); pulmonary vascular resistance index (PVRI [TPG/CI]). Reprinted with permission from Mehra et al.[32]

from local cardiologists. Successful management, therefore, extends beyond the initial concern about rejection. The HF specialist should be familiar with ISHLT Registry data[36] that indicate that malignancy and coronary artery vasculopathy (CAV) are the major causes of death in post-heart transplant patients. This is particularly important 5 years following transplantation, when the frequency of myocardial biopsy diminishes and patients typically receive care outside the transplant center.[37,38] Most heart transplant patients continue to receive at least some of their care from a transplant center. HF specialists should be competent to provide ongoing care even late after transplant.

Long-term immunosuppressive therapy may potentiate the emergence of hypertension, hypercholesterolemia, renal dysfunction, glucose intolerance, osteoporosis, malignancy, and other adverse conditions.[37] Competence in posttransplantation patient care requires understanding of the risk factors that threaten the graft and compromise patient survival, and knowledge of the often complex therapeutic regimens used with this patient group.[39] There has been a suggestion that clinical experience in the care of no fewer than 30 posttransplant patients, at least 5 of whom are followed immediately following the transplantation surgery is a reasonable goal in the development of competence in the care of the posttransplant patient.[39]

As posttransplant antirejection therapy has advanced from cyclosporine-based regimens to combinations of immunosuppressive agents, the HF specialist should have in-depth knowledge of the pharmacology of various immunosuppressive therapeutic agents and combinations, including pharmacokinetics, drug–drug interactions and contraindications, and dose adjustment based on measurement of drug levels to achieve the desired therapeutic effect and avoid toxicity.[39] The HF specialist should have competence regarding immune monitoring of the cardiac allograft. Familiarity with the types of rejection (cellular and antibody-mediated) and their diagnostic features on endomycardial biopsy and serologic of antibody-mediated rejection and allograft dysfunction is required as is an understanding of the usefulness and limitation of the endomyocardial biopsy for the diagnosis and follow-up of rejection. The HF specialist must be able to integrate the results of these diagnostic modalities into the plan for the early and long-term treatment of the different types of rejection.[40–43] The HF specialist must be familiar with the risks of opportunistic infections and therefore must be competent in the diagnosis and treatment of these conditions. This includes knowledge of both prophylaxis and treatment of associated infectious diseases in patients that are immunosuppressed.[44]

The risk of developing malignancy is increased among transplant recipients, requiring competence in providing education regarding routine malignancy awareness and systematic cancer surveillance by colonoscopy, mammography, gynecological or prostate examinations, periodic skin examination, and serological testing (eg, measurement of the serum prostate-specific antigen) familiar to the HF specialist. If a malignancy occurs, the HF specialist should be able to obtain consultative support in oncology.[45]

Coronary allograft vasculopathy increases in severity over time following heart transplantation. The HF specialist should be able to detect CAV using noninvasive and sometimes invasive testing and should be knowledgeable regarding various treatments. As patients return to their daily activities, the HF specialist should have knowledge of the physiology of the denervated heart in response to exercise and be able to make knowledgeable recommendations regarding the type, frequency, and intensity of physical activity the patient can pursue. The HF specialist should be familiar with the physiologic and immunologic changes that occur during pregnancy, especially as they affect pregnancy in the HF and transplant patient.

4.4. Mechanical Support of the Patient With Advanced HF

The HF specialist should have the ability to synthesize a longitudinal plan that accounts for both the short-term need to resuscitate and stabilize the patient. The HF specialist should recognize the need for long-term support in patients with progressive circulatory impairment despite appropriate pharmacological, electrical, catheter-based, and surgical interventions. Thus, the specialist should have a thorough understanding of prognosis and be fully versed in application of conventional evidenced-based therapies prior to use of mechanical support, including neurohumoral blockade, revascularization, valve repair, ICDs, CRT, and such emerging procedures as ventricular aneurysmectomy or ventricular remodeling. Specialists in this field must be familiar with a growing list of devices and surgical interventions. The nuances are complex and the initiation of this type of therapy requires surgical consultation and appropriate timing of referral to multidisciplinary teams. Competence implies understanding of indications and contraindications, timing of referral, and potential complications. If the patient deteriorates rapidly (over minutes to days), the HF specialist should be aware of the indications and contraindications of the various modalities that can temporarily reverse cardiogenic shock, such as an intra-aortic balloon pump, transseptal left ventricular assist device (LVAD), or extracorporeal cardio-

pulmonary bypass. The HF specialist should also understand the natural history and potential for recovery following acute HF in situations such as acute myocardial infarction, peripartum cardiomyopathy, and fulminant myocarditis.[46–48] In patients with marked cardiac dysfunction that persists despite temporary support, the HF specialist must be able to determine the indications for long-term mechanical support, cardiac transplantation, or withdrawal of support and palliative care. Although surgical implantation of an LVAD is the most common type of mechanical support for chronic HF,[49] knowledge of biventricular or total artificial heart support is required, including an understanding of certain technical features and their relative strengths and weaknesses.[50,51] The HF specialist should have experience with pulsatile versus axial/continuous flow devices,[18,52–54] intracorporeal versus extracorporeal support, and left ventricular versus biventricular or total artificial heart support. Programming and troubleshooting devices are useful skills but are not critically necessary if other team members are able to perform these procedures.

Whereas acute decompensated HF is often apparent, the gradual progression of chronic HF from ACCF/AHA Stage C to Stage D[28] may be subtle. Cognitive skills are therefore required to determine when mechanical support is indicated for advanced chronic HF[18] before the patient has become too ill to benefit. In this regard, therapeutic decision making overlaps and parallels that for cardiac transplantation.

Multidisciplinary teams are required that allow close collaboration between cardiologists, medical specialists, and cardiac surgeons. The HF specialist must be participatory in managing these teams. Adverse postoperative outcomes are related to the severity of preoperative noncardiac organ dysfunction.[37,55] The HF specialist should be familiar with the need to evaluate right ventricular function and associated tricuspid regurgitation prior to placement of a LVAD. Because the postoperative management of the LVAD and cardiac transplant patient is focused on right ventricular management, the HF specialist should be skilled in the management of right ventricular failure. Compared with successful cardiac transplantation, exercise capacity is less following chronic outpatient mechanical support[56,57] and the patient's daily concerns are typically greater (eg, battery exchange or recharging, driveline maintenance). The HF specialist should be able to interpret the results of exercise testing following LVAD placement and make activity level recommendations.

Mechanical support can be applied short-term in an individual patient as a bridge to transplantation or can be applied long-term as in destination therapy. For example, if a patient with myocardial infarction and cardiogenic shock experiences a cardiac arrest that requires a prolonged resuscitation, the HF specialist would know that percutaneous mechanical support could precede a potential LVAD until neurologic status is determined. If an LVAD is subsequently implanted, the patient's candidacy for transplantation versus discharge and long-term LVAD maintenance therapy (ie, destination therapy) must be considered. This requires experience, skill, and judgment.

The HF specialist should be able to thoroughly inventory the risks of continued HF therapy for individual patients compared with their ability to tolerate surgery. The HF specialist should be able to assess the prognosis of HF on the basis of symptoms, clinical events, physical findings, and laboratory and hemodynamic data—including measurements of oxygen consumption during exercise testing.[58] Risk factors for LVAD placement, including hemodynamic, hematological, hepatic, renal, nutritional, and neuropsychiatric aspects, should be familiar to the HF specialist.[55] The HF specialist should be able to assess patient preferences related to quality of life and survival and coordinate the decision-making process among the referring physician, the family, and the patient.

4.5. Perioperative Management of Patients Requiring Mechanical Devices

Because chronic mechanical support usually involves an LVAD,[49] the HF specialist should be knowledgeable about LVAD-related cardiac physiology at rest and during exercise,[57,59,60] including the interpretation of hemodynamic data and responses to pharmacological manipulation. Unique to mechanical support is interpretation of LVAD console readings and driveline assessment.

Complications following LVAD implantation should be recognized on the basis of immediate, recent, and long-term postoperative time periods. The HF specialist should be knowledgeable regarding the following:

- Mechanical problems related to the LVAD, valve conduit, right ventricular dysfunction or ischemia, tricuspid regurgitation, aortic regurgitation with shunting of LVAD output, pulmonary vascular resistance, systemic vascular resistance, and patent foramen ovale with hypoxemia[61,62]
- Interpretation of LVAD-related hemodynamics based on noninvasive, invasive, and console data
- Supraventricular and ventricular arrhythmias pertinent to the device, such as suction events with axial flow devices[63]
- Hematological issues, including bleeding and thrombosis associated with antiplatelet and anticoagulant therapy,[64] and device-related hemolysis
- Infectious complications[65]

This HF specialist should also be knowledgeable in the following areas:

- Common symptoms and signs—dyspnea, fatigue, fever, anemia
- Device alarms
- Physiological and device-related factors affecting longevity
- Nutritional deficiency[66]
- Psychosocial status and quality of life[18]
- Right-heart catheterization data
- The role of exercise and rehabilitation therapy

5. Additional Skills Required for Diagnosis and Treatment of Patients With Acute HF

5.1. Initial Diagnosis and Management of Patients With Acute Decompensated HF

Episodes of acute decompensated heart failure (ADHF) are the most common cause of hospitalization for patients with advanced chronic HF and, indeed, the most common reason

for hospitalization in all patients over age 65 years, resulting in nearly 1 million hospitalizations annually in the United States.[67] Approximately 80% of ADHF cases present to the hospital emergency department (ED),[68] whereas the remainder are identified during urgent visits to physicians' offices or clinics. Patients with ADHF often have chronic HF, although as many as 30% of patients presenting with ADHF have no prior diagnosis of HF.[68]

The HF specialist is experienced and knowledgeable regarding ADHF, and knows that rather than a single homogenous syndrome, ADHF encompasses multiple syndromes with varying presentations. These include sudden "flash" pulmonary edema or cardiogenic shock, or the more insidious exacerbation of HF resulting from myocardial ischemia or injury, chronic cardiomyopathy, hypertension, volume overload, cardiac arrhythmias, and other scenarios.[34,69–71] There may be a history of cardiac disease and evidence of either systolic or diastolic ventricular dysfunction, cardiac rhythm abnormalities, or preload/afterload mismatch.[70,72,73] The HF specialist caring for patients with ADHF should have the cognitive skills to use the clinical history and findings on physical examination to form an accurate initial diagnostic assessment, supplementing this with the results of laboratory studies (including biomarkers), hemodynamic studies, and imaging.

Although ADHF is commonly the result of progressive myocardial dysfunction, it is often precipitated by concomitant cardiac or systemic disease (Table 5). Among the most frequent are myocardial ischemia, arrhythmias (eg, atrial fibrillation), and uncontrolled hypertension. The latter is a particular problem in patients of African-American ethnicity.[74] The HF specialist should demonstrate the cognitive skills outlined in Table 5 so as to identify these and other potential causes of decompensation and develop a plan to modify these etiological factors through judicious therapeutic intervention. The HF specialist should make use of knowledge of the pertinent circulatory, respiratory, and neurohumoral abnormalities to design an initial treatment plan in the ED or urgent care setting. These abnormalities, reviewed later, form the core competencies in this area.

The HF specialist knows that assessment of the hemodynamic status of the patient with ADHF is essential to developing the initial management plan. They know how to make decisions regarding the need for invasive versus noninvasive assessments of hemodynamics. They should be able to categorize the patient's status according to a 2×2 profile as either *warm* or *cold* (warm is equivalent to normal perfusion and cold implies impaired systemic perfusion) or as *wet* or *dry* (wet being elevated and dry being low-to-normal ventricular filling pressure),[75] as this rubric is useful in formulating an initial approach to management. The majority of patients with ADHF are either normotensive or hypertensive (ie, warm).[76] The HF specialist recognizes that the possible need for urgent pharmacological or mechanical circulatory support must be considered for the minority who has hypotension.

The HF specialist is aware that many patients with ADHF display impaired systemic perfusion due to decreased cardiac output, and in these cases, early initiation of vasodilator pharmacotherapy may be beneficial. A retrospective review of nearly 8000 such cases in the Acute Decompensated HF Registry (ADHERE) found that vasodilator therapy started in the ED, rather than delayed until the patient was admitted to a hospital ward, was associated with an abbreviated hospital stay and lower inpatient mortality.[77] The HF specialist should have a working knowledge of vasodilators such as nitroprusside, nitrates, hydralazine, and nesiritide, each of which has unique pharmacological pathways.[78] As many patients with ADHF have acute or chronic renal insufficiency, knowledge of the effects of vasodilator agents on renal perfusion and function is important to guide selection of the appropriate agent and dose. This allows for rapid deployment of these therapies leading to improved short and long-term outcomes. Furthermore, for those patients with chronic HF, the specialist initiating treatment must consider adjustment of chronic vasodilator therapies such as angiotensin-converting enzyme inhibitors, angiotensin-II receptor blockers, hydralazine, and organic nitrates.

The HF specialist should be competent to recognize patients with diminished cardiac output who are unable to tolerate vasodilator therapy and who need agents that increase myocardial contractility or mechanical circulatory support. In ADHF, patients often present with life-threatening respiratory failure necessitating rapid treatment. Assessment of the adequacy of

Table 5. Precipitating Factors and Comorbidities Requiring Specialized Cognitive Skills to Identify and Treat Patients With Acute Decompensated Heart Failure

Precipitant	Skill
Myocardial ischemia/infarction	Electrocardiography, acute coronary syndrome management
Atrial or ventricular arrhythmia	Electrocardiography, arrhythmia management
Valvular disease (mitral regurgitation)	Cardiac auscultation, echocardiography
Infection, cardiac or systemic	Cardiac auscultation, radiography interpretation, echocardiography
Dietary/pharmacological nonadherence	Knowledge of cardiovascular pharmacology
Concomitant administration of agents that cause sodium retention (eg, nonsteroidal anti-inflammatory agents) or nephrotoxicity (intravenous contrast dye)	Knowledge of renal pharmacology
Anemia	
Uncontrolled hypertension	Intravenous vasodilator administration
Hyperthyroidism	
Hypothyroidism	
Pregnancy	

ventilation and oxygenation is an important aspect of the initial evaluation. Recent advances in noninvasive techniques, such as continuous positive airway pressure and bi-level positive pressure ventilation, may reduce the need for endotracheal intubation.[79,80] HF specialists caring for patients with ADHF should be familiar with the deployment of these therapies and/or anxiolytic and other adjunctive agents that may improve the patient's ability to tolerate and benefit from noninvasive ventilatory support. The specialist must also be able to identify situations in which noninvasive ventilation is inappropriate or unsuccessful and mechanical ventilation is necessary.

Approximately 70% of patients with ADHF have signs and symptoms of elevated ventricular filling pressures such as dyspnea, edema, or pulmonary congestion[81] resulting either from retention of sodium and water or central redistribution of intravascular volume. Loop diuretics such as furosemide, torsemide, and bumetanide are the mainstay of treatment for volume overload, and knowledge of the pharmacology of each these agents enables the specialist to select the most appropriate agent, dose, and route of administration. The HF specialist should also recognize the deleterious effects of excessive use of diuretics mediated by neurohumoral activation,[82] and select the lowest effective dose. Conversely, resistance to diuretic therapy also occurs, and HF specialists must be able to reassess the initial diuretic treatment plan, and adjust the dose of diuretic medication, make use of synergistic diuretic agents, and initiate therapies that augment cardiac output and renal blood flow as indicated on the basis of the patient's response and changing status.

The HF specialist must assess how to balance the patient's chronic medical regimen, including neurohumoral blockade, against the hemodynamic derangements arising during ADHF. The HF specialist knows that the initial treatment of a patient with ADHF should be directed not only toward correction of symptoms and hemodynamic abnormalities, but also at minimizing further myocardial and other end-organ injury.

Once the initial management plan is developed for the patients with ADHF, the HF specialist must decide whether hospitalization is necessary or the patient may be safely released from the urgent care setting with close outpatient follow-up. Indications for hospitalization of patients with ADHF are summarized in practice guidelines issued by the HFSA,[83] outlined in Table 6. In addition, patients with a new diagnosis of HF or other comorbidities not mentioned in the guidelines should be considered for hospital admission. The HF specialist must be able to identify these characteristics and select an appropriate level of inpatient monitoring and nursing care. The specialist practicing in a facility without advanced invasive cardiac monitoring or mechanical support capabilities should be able to identify patients likely to require these services and arrange the patient's transfer to a fully equipped institution. The HF specialist should have thorough knowledge of physiologic changes that occur in women who experience routine pregnancy, who have HF, and who have undergone heart transplantation and be thoroughly knowledgeable how to manage these patients.

Table 6. Characteristics of Patients With Acute Decompensated Heart Failure Indicative of the Need for Hospitalization

Respiratory distress (respiratory rate >40 breaths/min) or hypoxia (oxygen saturation <90%)
Pulmonary edema (determined by radiograph)
Anasarca or significant edema (≥+2) or a weight gain of >5 kg over optimum weight
Syncope or hypotension (systolic blood pressure ≤80 mm Hg)
Diminished end-organ perfusion, as may be evidenced by worsening renal function or altered mental status
Hemodynamically significant atrial or ventricular arrhythmia
Major metabolic or electrolyte disturbance
Congestive heart failure of recent onset (no past history)
Evidence of myocardial ischemia or infarction (chest pain symptoms)
Inadequate social support for outpatient management
Failure of outpatient management
Concomitant acute medical illness

5.2. Inpatient Management of Patients With ADHF

Following hospital admission, care of the patient with ADHF should adhere to principles addressed initially while assessing the effectiveness of therapy and modifying the regimen as indicated. This may include titration of vasodilator or inotropic therapy and invasive hemodynamic monitoring in those with uncertain hemodynamic status or worsening symptoms and signs of HF. HF specialists must thus be proficient at noninvasive assessment of volume and perfusion status, and have access to personnel skilled in right and left heart catheterization. The specialist should be able to interpret hemodynamic data obtained by invasive monitoring, and alter therapy in response to hemodynamic variation.

ADHF (Table 5) may develop in hospitalized patients as a result of myocardial ischemia, arrhythmia, infection, or exposure to nephrotoxic agents, and the HF specialist must be skilled in the identification of these etiologies as a component of initial evaluation and treatment. HF specialists should also be able to recognize and manage common pulmonary and renal comorbidities, particularly in patients refractory to diuretic therapy or in those whose renal function deteriorates. Depending on the definition, the cardiorenal syndrome develops in 25% to 45% of patients with ADHF,[84] and increases mortality.[85] The HF specialist should have experience managing patients with multisystem organ failure in collaboration with consultants in other subspecialties.

As symptoms of ADHF improve and volume status is corrected, the HF specialist should be competent to develop a transitional treatment plan to address appropriate criteria for hospital discharge (Table 7). At this point, the HF specialist understands how to assess the patient's long-term treatment program, including consideration of such advanced therapies as electrical resynchronization, transplantation, or mechanical circulatory support, based upon a fund of knowledge that includes current practice guidelines and appropriate use criteria. Perhaps most important, the ADHF hospitalization represents a valuable opportunity for the HF specialist to review avoidable events that may have provoked decompensation. In many centers, the team

Table 7. Discharge Criteria for Patients With Heart Failure

Recommended for all HF patients	• Exacerbating factors addressed
	• Near optimal volume status achieved
	• Transition from intravenous to oral diuretic successfully completed
	• Patient and family education completed, including clear discharge instruction
	• LVEF documented
	• Smoking cessation counseling initiated
	• Near optimal pharmacologic therapy achieved, including ACE inhibitor and beta-blocker (for patients with reduced LVEF), or intolerance documented
	• Follow-up clinic visit scheduled, usually for 7 to 10 d
Should be considered for patients with advanced HF or recurrent admissions for HF	• Oral medication regimen stable for 24 h
	• No intravenous vasodilator or inotropic agent for 24 h
	• Ambulation before discharge to assess functional capacity after therapy
	• Plans for postdischarge management (scale present in home, visiting nurse or telephone follow up generally no longer than 3 d after discharge)
	• Referral for disease management, if available

Reproduced with permission from the Heart Failure Society of America.[34]
ACE indicates angiotensin-converting enzyme; HF, heart failure; and LVEF, left ventricular ejection fraction.

approach is used to care for patients with Stage D HF, including pretransplant and posttransplant needs. The HF specialist should be skilled in team management. These teams usually include advanced nurses, fellows, technicians, and others.

The HF specialist is competent to organize and supervise a HF disease management program, and should be familiar with the multidisciplinary disease management approach. Though systems of care vary, most focus on patient education and self-monitoring, identification of comorbidity and application of evidence-based therapy. Many include home visits and/or telephonic or video monitoring, some of which reduce hospital readmission, cost, and to a lesser extent, mortality.[86–91] Awareness of the availability of such programs in the specialist's practice region becomes especially important at the time of hospital discharge.

5.3. Avoiding Repeated Hospital Admissions

Hospital readmissions for HF are common and consume a large parcel of healthcare dollars. The major causes of readmission include dietary indiscretion, medication noncompliance, and intercurrent illness such as a respiratory tract infection. Prevention of readmission is an important aspect of the management of HF patients, and the HF specialists caring for patients who have been repeatedly hospitalized must be able to identify and ameliorate the factors contributing to readmission.

The HF specialist should be thoroughly familiar with the transition of care at the time of hospital discharge and identify patients likely to decompensate and require readmission. This skill set allows the specialist to manage frequent follow-up visits, carefully adjust medications, and develop a strategy for surveillance of electrolytes and renal function.

The HF specialist should provide comprehensive education to both patient and family about the disease process, nonpharmacological therapy and elements of self-management, including but not limited to dietary sodium restriction, and adherence to the medication regimen and follow-up appointments[92] (Table 8). The HF specialist must recognize that patients who are repeatedly hospitalized with decompensation may benefit from comprehensive HF management. Both the ACCF/AHA guidelines for the diagnosis and management of chronic HF in the adult[28] and the HFSA Comprehensive Heart Failure Guideline[34] recommend multidisciplinary disease management programs for patients at risk of clinical deterioration or readmission to address barriers to adherence and reduce hospitalization. If a program is not available at the clinician's institution, the HF specialist should be familiar with and establish a referral relationship with a disease management program elsewhere. The HF specialist should facilitate integration and coordination of care with primary care physicians, internists, and other groups, including cardiac rehabilitation and home nursing services. They should be familiar with the variable roles of the advanced practice nurse and the registered nurse in the disease management clinic to maintain compliance with the board of nursing.

6. The Cognitive and Technical Competence Required for Referring and Monitoring of Patients With Electrophysiologic and Hemodynamic Devices

6.1. Referral of Patients for Electrophysiologic Devices: ICDs

A considerable body of evidence, including definitive randomized trials, indicates that ICDs prolong life by preventing

Table 8. Patient Self-Care Practices After Hospital Discharge

Knowledge of clinical follow-up visit
Performing daily weigh-in
Following specific sodium restriction
Following specific fluid restriction
Not smoking
Plan for reporting worsened symptoms
Performing physical activity ≥3 times/wk
Flexible diuretic regimen for weight gain

Adapted with permission from Koelling et al.[92]

sudden cardiac death both in primary and secondary prevention settings.[93–102] The HF specialist should be fully familiar with guidelines for selection of appropriate patients for device implantation.[103] An ICD should be considered in a variety of clinical scenarios, and the advanced HF specialist must develop a consistent approach to evaluation of patient candidacy. The HF specialist should have a coordinated plan of collaboration with the ICD implanting and monitoring physicians with common understandings of appropriate indications. The HF specialist should be competent to manage the following scenarios:

Scenario 1: A patient with newly discovered HF is admitted emergently to hospital for initial evaluation. The etiology of HF is determined, and appropriate, evidence-based therapy is initiated. Depending on the etiology, comorbid conditions, response to therapy, and long-term treatment plan, there is ambiguity about the optimum timing of ICD implantation after the onset of HF.[104,105] The HF specialist should weigh the evidence supporting early implantation (within 3 months after onset of symptoms), and develop a strategy for the use of ICD technology in the individual patient on the basis of the likelihood of improvement in cardiac function and other factors. More important, follow-up must be arranged so that the need for implantation can be re-evaluated over time on the basis of changes in the patient's clinical condition.

Scenario 2: A patient with chronic Stage C HF and left ventricular ejection fraction above 35% followed as an outpatient has not been a candidate for ICD implantation in the absence of pertinent symptoms. The HF specialist must be competent to reevaluate symptoms and cardiac function (left ventricular ejection fraction), as eligibility for an ICD may change over time. The HF specialist must have the necessary skills to explain to the patient how the treatment regimen may change to incorporate such a device.

Scenario 3: A patient with long-standing, advanced HF and low left ventricular ejection fraction is hospitalized repeatedly. In view of its questionable ability to prolong life because of the patient's advanced age or comorbidities, an ICD may not be recommended in this case. Alternatively, this or other HF therapy, pacemaker or cardiac resynchronization devices, or investigational approaches such as a permanent mechanical circulatory assist device (ie, destination VAD) therapy may be appropriate. The HF specialist must weigh the potential benefits of ICD implantation and other advanced interventions in complex clinical situations.

These clinical scenarios, and others too numerous to catalogue, indicate the need for integrated knowledge derived from randomized trials, clinical practice guidelines, experience with HF patients with ICD devices, and seasoned clinical judgment. The HF specialist must be prepared to serve as a clinical resource in reaching decisions about these vital issues in the care of individual patients.

6.1.1. Monitoring Patients With Electrophysiologic Devices: ICDs

The optimal management of a patient with HF and an ICD begins with identification of the responsible clinicians involved in the patient's care to facilitate communication and documentation. Fragmentation of care between primary care clinicians, electrophysiologists, cardiologists, and HF specialists is detrimental. With respect to the HF patient with an ICD, the HF specialist has 3 general areas of responsibility, delineated as follows.[106–113]

6.1.1.1. Coordination of Care

It is a reasonable expectation that in some settings, the HF specialist will manage HF therapy and monitor implantable devices in patients with complex HF. This reflects the specialized skills and required competence of secondary subspecialties that have developed in cardiac electrophysiology and advanced HF cardiology. The equipment necessary to interrogate ICDs and other cardiac arrhythmia devices may not be readily available in the office of the HF clinician, though in the future, this barrier may be overcome by the availability of downloaded device information on a secure Web site, making it accessible to all of the patient's providers. Nevertheless, the HF specialist must integrate information derived from ICD interrogation with other elements of the evaluation and management of the patient with HF. If device interrogation detects episodes of atrial high-rate activity suggestive of paroxysmal atrial fibrillation (eg, mode switches), or a decrease in maximum heart rate suggestive of reduced physical activity, it may be appropriate to modify other aspects of the HF treatment regimen accordingly. Training requirements for certification in advanced HF and transplant will eventually include competence in ICD and CRT interrogation, but this is not a requirement for competence at present. Nevertheless, it is a useful skill set.

A number of device features, including estimation of volume status, are emerging that may facilitate earlier prediction of HF decompensation. The additional data derived from these ICD features will provide the HF specialist additional information, and the HF specialist may consider development of a method for information management that includes timely data acquisition, storage and retrieval, linkages to treatment protocols, and communication among members of a well-organized team of clinicians to assure optimal patient care.[114–116]

6.1.1.2. Respond to Changes in the Clinical Status of the Patient, and Consider the Impact on Appropriate ICD Management

Advanced HF often necessitates adjustment of ICD settings, and the HF specialist or a member of the HF team should be prepared to adjust (or recommend adjustment of) ICD settings in response to changes in the patient's HF status. Examples include the onset of atrial fibrillation with rapid ventricular response, development of symptomatic bradycardia, development of a need for CRT, the development of increasing frequency of ventricular tachycardia and other arrhythmias leading to ICD discharges as a risk factor for clinical deterioration, or irreversible deterioration in HF

symptoms warranting hospice care. These and other common clinical developments mandate not only a change in the course of HF therapy, but also discussion with the clinician managing the ICD to ensure appropriate implementation and adjustment of detection algorithms, and upgrading or inactivation of the device.

6.1.1.3. Participate in Management of Arrhythmias in the Patient With an ICD

The HF specialist must understand the risks and benefits of the various options available for management of atrial and ventricular arrhythmias in the patient with HF.[109,111,113] Cardiac electrophysiologists involved in the care of patients with HF sometimes seek input from the HF specialist to select the appropriate treatment. Ongoing arrhythmias may prompt additional diagnostic testing, such as coronary imaging or myocardial biopsy. Likewise, arrhythmias such as atrial flutter, atrial fibrillation, recurrent monomorphic ventricular tachycardia requiring ICD appropriate or inappropriate therapies; or arrhythmias that reduce the hemodynamic impact of CRT may require consideration of catheter or surgical ablative procedures. Finally, acceleration of arrhythmias coincident with advanced HF may prompt a decision about cardiac transplantation or VAD therapy.

6.2. Cardiac Resynchronization Therapy

Patients with New York Heart Association functional class III or ambulatory class IV HF on appropriate medical therapy who have QRS durations greater than 120 ms have a class I indication for CRT. This type of device, with or without ICD capabilities, has been demonstrated to improve symptoms and reduce mortality in patients with HF. The HF specialist should understand the clinical utility of this technology, support its use when appropriate, and assist in the longitudinal care of patients with this type of implanted device.

Successful CRT use requires that the HF specialist or a member of the HF team understand the indications, short- and long-term complications, methods of device optimization, and elements of long-term follow-up. This is a challenging task and is best embraced with a team approach. An emerging model is the CRT/HF clinic, where the necessary component resources (including a HF specialist, cardiac electrophysiologist, and echocardiographer), are assembled to provide a rarefied level of care that facilitates identification of appropriate candidates, longitudinal monitoring, and device troubleshooting. Likewise, the HF specialist should understand the importance of and encourage direct lines of communication between dedicated electrical device nurse specialists and HF advanced practice and disease management nurses, with oversight and input from the HF specialist and electrophysiologist.

The cognitive competencies required include:

- Skill in optimizing evidence-based medical therapy for HF.
- Familiarity with the guidelines regarding indications for CRT versus combined CRT with ICD.
- Awareness of the acute complications associated with CRT, including the identification of lead placement errors, especially lead migration.
- Familiarity with the uses and limitations of echocardiographic measures of mechanical dyssynchrony.*
- Understanding the use of echocardiography to optimize biventricular pacing, including interventricular and atrioventricular synchrony.*

6.3. Interpreting Data From Implantable Devices That Monitor Volume Status

Certain implantable devices provide adjunctive clinical assessments beyond arrhythmia surveillance, pacing, or defibrillation and have the potential to augment clinical decision making. Impedance monitoring is presently available, whereas implantable hemodynamic monitoring remains investigational. The HF specialist should be aware of various strategies that may be used to monitor volume and hemodynamic status in ambulatory patients with HF. The HF specialist should be prepared to access, interpret, and apply such data in clinical practice as these new devices emerge and are approved.

7. Management of Advanced HF and Transplantation in Patients With Congenital Heart Disease

Vast improvement in the outcomes of surgery to repair complex congenital heart disease over the past 25 years has created a growing population of survivors who develop HF.[10,117–120] The most common etiologies of HF in this population are systemic ventricular dysfunction, right heart dysfunction, and low cardiac output due to poor flow through a palliated Fontan circuit. In addition, hypoxemia related to cyanosis can worsen ventricular function and exacerbate HF. Advanced HF is found in all age ranges of patients with congenital heart disease, but occurs more commonly in the adolescent and young adult. The HF specialist caring for the congenital heart disease patient with advanced HF should be able to identify the need for the services of an adult or pediatric cardiologist and surgeon with expertise in congenital heart disease and be able to coordinate the care of these patients across the multiple disciplines. It is not expected that the nuances in the care of patients with congenital heart disease in need of heart transplantation or MCADs is a core competence of the HF specialist. However, the HF specialist should be familiar with such patients and the need for ancillary services of other experts in this field.

7.1. HF Management

The common congenital heart defects that result in chronic HF are obstructive lesions of the left ventricular outflow tract, systemic right ventricular anatomy—such as corrected *l*-transposition or *d*-transposition following an atrial-switch procedure and single ventricular anatomy.

*It is assumed that the physician interpreting echocardiograms for the purposes of CRT implantation and management will have at least Level 2 training (consistent with that of a cardiology fellow).

The HF specialist† should be able to recognize the manifestations of systolic and diastolic dysfunction associated with these lesions. In addition, the HF specialist should be able to recognize primary right ventricular dysfunction and right HF following repair of the tetralogy of Fallot or resulting from pulmonary vascular disease. The HF specialist† must also be able to evaluate the causes of low cardiac output in patients with a Fontan circuit and normal ventricular function. Neurohumoral activation in patients with HF due to congenital heart disease is different from that in patients with LV dysfunction, particularly when the systemic ventricle is not a morphological left ventricle.[121] As a result, HF patients with congenital heart disease have variable responses to angiotensin-converting enzyme inhibition and beta-adrenergic blockade, and the HF specialist† must be able to tailor medical therapy to the specific congenital defect.[122] The HF specialist† should be able to recognize tachyarrhythmias and bradyarrhythmias in patients with congenital heart disease and possess the cognitive skills to determine the benefit of different pacing modalities to enhance cardiac output and lessen the risk of sudden death. Although retrospective studies have suggested clinical and echocardiographic improvement with the use of CRT in patients with congenital heart disease, prospective studies of efficacy have not been performed.[123] The HF specialist† should be able to assess the potential benefit of CRT therapy in selected patients with congenital heart disease.

7.2. Transplantation Evaluation

The HF specialist† should also be able to interpret additional studies, such as lung ventilation and perfusion scans, cardiovascular magnetic resonance or computed tomography imaging, and pulmonary and liver function testing that are often necessary to evaluate the transplant candidacy of patients with congenital heart disease. The HF specialist† should have expertise in the use of pulmonary vasodilators for evaluation and therapy in congenital heart disease patients with elevated pulmonary vascular resistance. He or she should be able to identify anatomic and surgical factors associated with the underlying congenital defect that would require surgical intervention at the time of transplantation. Human leukocyte antigen sensitization is common in patients following congenital heart disease surgery, and the HF specialist† should be familiar with the evaluation and treatment of human leukocyte antigen sensitization pre- and posttransplantation. The HF specialist should have the skill to evaluate functional capacity in a patient with congenital heart disease in the context of lower than normal expected values.[124–126]

An increasing number of patients with single ventricle physiology palliated with the Fontan procedure are being referred for transplantation due to ventricular failure or complications from high venous pressures in the Fontan circuit. These complications include intractable atrial arrhythmias, protein-losing enteropathy, cachexia, ascites, and chronic pleural or pericardial effusions. The need for extensive reconstructive surgery and the debilitated pretransplant state of these patients has resulted in a higher mortality following transplantation compared to patients with cardiomyopathy.[127] The HF specialist† must have the cognitive abilities to assess the suitability of transplantation in the Fontan patient and be able to counsel the patient and the family regarding the potential risks and benefits.

The patient with congenital heart disease often has a strong family support system, and the HF specialist† should be able to provide family-centered care, particularly in the setting of palliative or end-of-life care. The HF specialist† should be able to coordinate services such as social work, psychiatry, and hospice to support not only the patient, but the family as well.

7.3. Mechanical Device Support

In a large multicenter series of pediatric patients, 22% of those receiving device support (other than an extracorporeal membrane oxygenator, or ECMO) had a diagnosis of congenital heart disease, which was an independent risk factor for adverse outcome.[11] The use of mechanical device support in the congenital heart disease patient requires knowledge of the anatomic and physiologic factors such as body size, residual intracardiac shunts, the presence of a single ventricle, or venous anomalies and/or arterial anomalies that may impact the success of device implantation, and the effectiveness of the VAD support. The HF specialist† should have the cognitive skills to evaluate the indications for VAD use in patients with congenital heart disease and be able to compare the relative risks of VAD support with medical therapy or palliative care.

7.4. Transplantation

Previous congenital heart disease has important implications for posttransplantation management. The heart transplantation specialist should be aware of the potential for residual anatomical defects, such as pulmonary artery or aortic arch stenosis, venous anomalies, aortopulmonary collaterals, or arteriovenous malformations. These can lead to low cardiac output following transplantation. The HF specialist† should be able to assess the indications and contraindications of the catheter- or surgical-based interventions available to treat these residual defects. Bacterial and viral infectious complications are common following transplantation in patients with congenital heart disease, and the specialist should be aware of the need for increased surveillance.

7.5. Summary

The HF specialist is not expected to be as well-versed in the nuances of congenital heart disease as pediatric congenital heart disease subspecialists; conversely, congenital heart disease subspecialists may not be able to fully assess the impact of advanced HF management and transplantation in this population. Collaboration between physicians with expertise in these areas is necessary to provide optimal patient care. Thus, the HF specialist who undertakes the care of a patient with congenital heart disease and advanced HF must practice in an environment with the expertise in the medical, surgical, and allied health care of the patient with complex congenital heart disease. In general,

†This mention of *HF specialist* refers to adult, pediatric, or surgical colleagues with special expertise in the care of adolescents and adults with congenital heart disease.

this would be a center with an active pediatric and adult congenital heart disease program.

8. End-of-Life Issues

8.1. Referring Patients With Advanced HF for Palliative Care

Despite advances in pharmacology and devices, advanced HF remains a disorder with substantial morbidity and mortality. At the end stage of HF, therapies such as CRT, ICD, LVAD, and cardiac transplantation may not be appropriate or desired because of disability, comorbidity, or the patient's preferences. Providers specializing in the care of patients with advanced HF should be able to recognize end-stage disease. HF can be associated with episodes of acute decompensation with subsequent improvement, or the course may be interrupted by sudden death unheralded by worsening HF symptoms. Palliative care decisions require expertise in diagnosis and treatment of HF and its comorbidities, and judgment about prognosis in the face of uncertainty. HF care across the disease continuum should transition gradually from aggressive intervention to palliation, comfort, and ultimately bereavement care.[128]

The HF specialist should be knowledgeable regarding palliative care. The goal of palliative care is to prevent and relieve suffering and support the best possible quality of life for patients and their families, regardless of the stage of disease or the need for concomitant therapy. Palliative care expands traditional disease-model medical treatment to include the goals of enhancing quality of life for patients and family members, helping with decision-making, and providing opportunities for personal growth. Palliative care may be rendered concurrently with life-prolonging treatment or as the main focus of care.[129] Class I recommendations for palliative care for patients with advanced (Stage D) HF are outlined in the ACCF/AHA guidelines for the diagnosis and management of chronic HF in the adult.[28]

HF specialists should be equipped to screen for social, environmental, and spiritual concerns that arise with debilitating illness. The HF specialist must have communication skills to discuss the patient's wishes and offer palliative care options when appropriate, and should be acquainted with the means available to manage symptoms such as pain, dyspnea, low mood, and anxiety.[130,131] These include pharmacological and nonpharmacological modalities, patient and family education, and psychosocial and spiritual support. HF specialists should be comfortable discussing the spiritual, social, and emotional aspects of debilitating illnesses, including those specific to the patient's cultural background. The HF specialist should understand the management of terminal symptoms and the natural history and management of grief and bereavement.[132,133] Specifically, the HF specialist should master the skills enumerated in the Institute of Medicine's report on end-of-life issues, as appropriate for patients with advanced HF (Table 9)[134] The HF specialist or a member of the management team should be aware of and familiar with complex social, financial, or legal issues that may occur in patients with advanced HF (Table 10).

Table 9. Professional Preparation for End-of-Life Patient Care

Scientific and clinical knowledge and skills, including:
- Learning the biological mechanisms of dying from major illnesses and injuries
- Understanding the pathophysiology of pain and other physical and emotional symptoms
- Developing appropriate expertise and skill in the pharmacology of symptom management
- Acquiring appropriate knowledge and skill in nonpharmacological symptom management
- Learning the proper application and limits of life-prolonging interventions
- Understanding tools for assessing patient symptoms, status, quality of life, and prognosis

Interpersonal skills and attitudes, including:
- Listening to patients, families, and other members of the healthcare team
- Conveying difficult news
- Understanding and managing patient and family responses to illness
- Providing information and guidance on prognosis and options
- Sharing decision making and resolving conflicts
- Recognizing and understanding one's own feelings and anxieties about dying and death
- Cultivating empathy
- Developing sensitivity to religious, ethnic, and other differences

Ethical and professional principles, including:
- Doing good and avoiding harm
- Determining and respecting patient and family preferences
- Being alert to personal and organizational conflicts of interests
- Understanding societal/population interests and resources
- Weighing competing objectives or principles
- Acting as a role model of clinical proficiency, integrity, and compassion

Organizational skills, including:
- Developing and sustaining effective professional teamwork
- Understanding relevant rules and procedures set by health plans, hospitals, and others
- Learning how to protect patients from harmful rules and procedures
- Assessing and managing care options, settings, and transitions
- Mobilizing supportive resources (eg, palliative care consultants, community-based assistance)
- Making effective use of existing financial resources and cultivating new funding sources

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8.2. Withdrawal of Life-Support Measures

At the end stage of HF, patients and/or their surrogates may ask the specialist to withhold or withdraw life-prolonging therapy and provide supportive or comfort-oriented care. The decision to do so represents a specialized form of palliative care, and assumes that the HF specialist has acquired the cognitive and technical skills to provide palliative care.

HF specialists engaging in decisions about withdrawal of life support should possess the skills needed to meet the goals of care enumerated in the Liverpool care pathway for the dying patient, as appropriate for the patient with end-stage heart disease (Table 11).[136] A detailed description of the technical skills needed to withdraw mechanical ventilation is beyond the scope of this guideline and discussed else-

Table 10. Social Issues Regarding Heart Transplantation and Ventricular Assist Device Replacement

The advanced heart failure specialist should:
• Have a close working relationship with the institution's social worker and region's social service agencies
• Have familiarity with the state's laws with respect to the care of the indigent and under- or uninsured
• Be aware of programs maintained by county and state agencies and pharmaceutical firms, device manufacturers, and home care agencies to provide aid to those incapable of paying for their medication
• Be thoroughly familiar with the rights patients have under the Americans With Disabilities Act[135] and should be comfortable assessing patients' claims for disability

where.[137] Considerations specific to the HF specialist include weaning inotropic support, intra-aortic balloon pump support, and LVADs, and deactivation of defibrillators when the decision is made to withdraw support.

9. Maintaining Expertise

9.1. Maintenance of Competence—Clinical Experience

Maintaining Level 3 competence in advanced HF requires ongoing experience evaluating and managing complex HF patients in the face of an ever-increasing number of available treatments. The literature does not support specific volume targets to maintain competence in nonprocedural aspects of patient care. Competence can be maintained through frequent opportunities to care for expanded HF populations, including those requiring end-of-life hospice care, chronic inotropic drug infusion support, and individuals with HF and noncardiac organ transplantation. The more challenging cohorts of HF patients in the purview of the HF specialist are described in the ACCF 2008 COCATS 3 training statement[8] as follows:

1. Patients evaluated for cardiac transplantation or mechanical assist devices
2. Patients who have undergone cardiac transplantation
3. Patients with HF and mechanical circulatory assist devices
4. Patients with HF evaluated for ICD and CRT devices
5. Device interrogation and interpretation in patients with implanted ICD or ICD-CRT devices

Establishing clinical requirements for physicians who care for patients undergoing heart transplantation is equally difficult, due in part to the relatively small number of heart transplants performed each year in the United States (2192 in 2006).[138] To maintain competence in heart transplantation, the committee recommends participation as a member of a team in an institution with a robust transplant program, one that cares for patients during all phases of the transplant process—pretransplant, perioperatively, and posttransplant.

Table 11. Goals of Care for Dying Patients

Comfort measures
Goal 1—Current medication assessed and nonessentials discontinued
Goal 2—As required, subcutaneous drugs written up according to protocol (pain, agitation, respiratory tract secretions, nausea, vomiting)
Goal 3—Discontinue inappropriate interventions (blood tests, antibiotics, intravenous fluids or drugs, turning regimens, vital signs); document not for cardiopulmonary resuscitation
Psychological and insight issues
Goal 4—Ability to communicate in English assessed as adequate (translator not needed)
Goal 5—Insight into condition assessed
Religious and spiritual support
Goal 6—Religious and spiritual needs assessed with patient and family
Communication with family or others
Goal 7—Identify how family or other people involved are to be informed of patient's impending death
Goal 8—Family or other people involved given relevant hospital information
Communication with primary healthcare team
Goal 9—General practitioner is aware of patient's condition
Summary
Goal 10—Plan of care explained and discussed with patient and family
Goal 11—Family or other people involved express understanding of plan of care

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9.2. Continuing Medical Education

Continuing medical education (CME) is an important pathway to sustained competence in a field as broad as HF management. Remaining current with research and guidelines presents a particular challenge to the HF specialist because of the rapidly changing nature of the field. All states require CME as a condition of licensure. It is not the intent of this document to stipulate the number of credits required, or to specify in which of the many currently available forums these credits should be obtained. HF specialists should concentrate a considerable proportion of their CME time in HF; related areas in cardiology; and other related disciplines, as delineated in Section 3 of this document (Components of Competence Required for the Management of Patients With Heart Failure). Category 1 CME credits should be obtained from organizations certified by the Accreditation Council for Continuing Medical Education.

10. Institutional Competence

It is not the purpose of this committee to pass judgment on the competence of an individual's institution. However, the committee recognizes that the advanced HF and transplantation specialist should practice in association with an institution that provides the personnel and infrastructure necessary to deliver comprehensive, integrated care. The advanced HF and transplantation specialist should be part of a multidisciplinary team composed of specialists with competence in the management of HF, transplantation, and their associated comorbidities. The availability of cardiothoracic surgeons with expertise in management of high-risk patients with ischemic or valvular heart disease, VADs, and transplantation is essential. In centers where transplantation is performed in patients with congenital heart disease, expertise in complex congenital heart disease surgery should be available. Subspecialists in nephrology, neurology, anesthesiology, critical care, infectious diseases, immunology, and oncology who

have competence in the management of comorbidities associated with HF and transplantation should be available.

The benefits of a comprehensive disease management approach to patients with HF has been well documented in terms of morbidity and long-term survival.[139,140] The institutional competencies that contribute to successful HF care delivery include the ability to develop and disseminate educational and counseling materials, the inclusion of specialized nurses and/or nurse practitioners, the availability of social service and financial counseling, and the implementation of clinical information systems that facilitate transfer of information among providers.[141] Dietary counseling and cardiac rehabilitation have also been identified as making important contributions to a comprehensive HF management program. The above competencies apply as well to institutions providing care to patients requiring VADs or transplantation, despite the diverse clinical situations associated with these therapies.

The institutional competencies required to implant VADs as destination therapy and transplantation procedures are under close regulation by the Centers for Medicare & Medicaid Services (CMS) and, in the case of transplantation, the OPTN. The CMS facility criteria for hospitals seeking reimbursement for VADs when implanted under the destination therapy clinical criteria can be found at http://www.cms.hhs.gov/MedicareApprovedFacilitie/05_VADrecert.asp. The expectations for the delivery of high-quality transplantation services in a Medicare-participating facility are published in the Federal Register as the Final Rule: Medicare Program; Hospital Conditions of Participation: Requirements for Approval and Re-Approval of Transplant Centers to Perform Organ Transplants.[142] This extensive document outlines the conditions that must be met to obtain approval from the CMS to perform heart transplantation. A transplant center must abide by the approved rules and requirements of the OPTN established and operated in accordance with 372 of the Public Health Service Act (42 USC section 274).

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KEY WORDS: AHA Scientific Statements ■ competence ■ heart failure ■ cardiac transplant

Appendix 1. Author Relationships With Industry and Other Entities—ACCF/AHA/ACP/HFSA/ISHLT 2010 Clinical Competence Statement on Management of Patients With Advanced Heart Failure and Cardiac Transplant

Committee Member	Consulting Fees/ Honoraria	Speaker	Ownership/ Partnership/ Principal	Research	Institutional, Organizational, or Other Financial Benefit	Expert Witness
Gary S. Francis, Chair	• ARCA BioPharma, Inc. • Biosite Inc. • Boehringer Ingelheim • Forest • GlaxoSmithKline • Medtronic • Nile • Nitromed • Novartis • Otsuka • Scios, Inc.	None	None	• National Institutes of Health*	None	None
Barry H. Greenberg	• ARCA BioPharma, Inc. • AstraZeneca • CHF Solutions • GlaxoSmithKline* • Nitromed • Orqis Medical* • Sanofi-Aventis	• AstraZeneca* • GlaxoSmithKline* • Medtronic • Merck* • Nitromed • Novartis • Scios, Inc.	None	None	None	None
Daphne T. Hsu	• Berlin Heart, Inc • Merck	None	None	None	None	None
Brian E. Jaski	• Boston Scientific • CHF Solutions	• GlaxoSmithKline	None	None	None	None
Mariell Jessup	• Acorn • CardioMems • GlaxoSmithKline • Medtronic • Scios, Inc. • Ventracor	None	None	• Scios, Inc.	None	None
Martin M. LeWinter	• Medtronic • Merck • Novartis	• Novartis	None	• Medtronic* • Novartis*	None	None
Francis D. Pagani	None	None	None	• Terumo Heart Corporation • Thoratec Corporation	None	None
Ileana L. Piña	• Food and Drug Administration, Center for Devices and Radiological Health* • Sanofi-Aventis	• Astellas • AstraZeneca • Novartis	None	• National Institutes of Health*	None	None
Marc J. Semigran	• GlaxoSmithKline • Medtronic	None	None	None	None	None
Mary Norine Walsh	• BioControl • Boston Scientific • Medtronic • St. Jude • UnitedHealthcare	• GlaxoSmithKline • Scios, Inc.	None	None	None	None
David H. Wiener	None	None	None	None	None	None
Clyde W. Yancy, Jr.	• Arc Discovery • GlaxoSmithKline • Medtronic • NitroMed • Scios, Inc.	• GlaxoSmithKline • Novartis	None	None	None	None

This table represents the relationships of committee members with industry and other entities that were reported orally at the initial writing committee meeting and updated in conjunction with all meetings and conference calls of the writing committee during the document development process. It does not necessarily reflect relationships with industry at the time of publication. A person is deemed to have a significant interest in a business if the interest represents ownership of 5% or more of the voting stock or share of the business entity, or ownership of $10 000 or more 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 noted in this table are modest unless otherwise noted.

*Significant (greater than $10 000) relationship.

Appendix 2. Reviewer Relationships With Industry and Other Entities—ACCF/AHA/ACP/HFSA/ISHLT 2010 Clinical Competence Statement on Management of Patients With Advanced Heart Failure and Cardiac Transplant

External Reviewer	Representation	Consultant	Speaker	Ownership/ Partnership/ Principal	Research	Salary	Institutional, Organizational, or Other Financial Benefit	Expert Witness
Allen S. Anderson	Official Reviewer—ISHTL	None	None	None	None	None	None	• Defense, medical malpractice, 2008 • Defense, medical malpractice, 2009
Roberta C. Bogaev	Official Reviewer—ISHLT	• Boston Scientific • Thoratec	• Thoratec	None	• Thoratec • XDC	None	None	None
Alfred A. Bove	Official Reviewer—ACCF Board of Trustees	None	None	None	None	None	None	None
Maria Crespo-Liero	Official Reviewer—ISHLT	None	None	None	• Astellas Pharma • Novartis • Roche • Wyeth	None	None	None
Steven Durning	Official Reviewer—ACP	None	None	None	None	None	None	None
Charin L. Hanlon	Official Reviewer—ACP	None	None	None	None	None	None	None
Paul J. Hauptman	Official Reviewer—AHA	• Biocontrol Medical* • GlaxoSmithKline	• GlaxoSmithKline	None	• Amgen • Novacardia/Merck* • Novartis	None	None	None
Paul A. Heidenreich	Official Reviewer—AHA	None	None	None	None	None	None	None
Marvin A. Konstam	Official Reviewer—HFSA	• Astra-Zeneca • Biogen • Boehringer-Ingleheim • Merck* • Novartis • Otsuka* • Sanofi-Aventis*	None	• Orqis Medical*	None	• Orqis Medical*	None	None
Wai Hong W. Tang	Official Reviewer—HFSA	• Amgen • Boston-Scientific • Medtronic • Merck	• Abbott Diagnostics • NxStage	None	• Abbott Diagnostics	None	None	None
Howard H. Weitz	Official Reviewer—CCS Task Force Lead Reviewer	None	None	None	None	None	None	None
Mark J. Zucker	Official Reviewer—ACCF Board of Governors	• Circulite • Organ Transport Systems	None	None	• Acorn Cardiovascular • Actelion • Biogen • Bioheart • Gilead • Ventracor	None	None	None
Charles E. Canter	Content Reviewer	• Blue Cross Blue Shield • University of Miami	• St. Louis Children's Hospital Symposia, 2008	None	• NIH 1U01A1077867-01* • NIH NL068210 • NIH NL053391-11 • NIH 1-P50HL074732-01*	None	None	• Defense, heart failure, 2008 • Defense, heart failure, 2007 • Defense, heart failure, 2007

(*Continued*)

Appendix 2. Continued

External Reviewer	Representation	Consultant	Speaker	Ownership/ Partnership/ Principal	Research	Salary	Institutional, Organizational, or Other Financial Benefit	Expert Witness
Jeffrey A. Feinstein	Content Reviewer—AC/PC Council	None	None	None	None	None	None	None
Gerard R. Martin	Content Reviewer—AC/PC Council	None	None	None	None	None	None	None
David Rosenthal	Content Reviewer	• Berlin Heart	None	None	None	None	None	None
Robert N. Vincent	Content Reviewer—AC/PC Council	None	None	None	None	None	None	None

This table represents the relevant relationships of peer reviewers with industry and other entities that were disclosed at the time of peer review. It does not necessarily reflect relationships with industry at the time of publication. A person is deemed to have a significant interest in a business if the interest represents ownership of 5% or more of the voting stock or share of the business entity, or ownership of $10 000 or more 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 in this table are modest unless otherwise noted.

*Significant (greater than $10 000) relationship.

ACCF indicates American College of Cardiology Foundation; ACP, American College of Physicians; AC/PC, Adult Congenital and Pediatric Cardiology Council; AHA, American Heart Association; CCS, clinical competence statement; HFSA, Heart Failure Society of America; ISHLT, International Society of Heart and Lung Transplantation.

ACCF/AHA/ACP/HFSA/ISHLT 2010 Clinical Competence Statement on Management of Patients With Advanced Heart Failure and Cardiac Transplant: A Report of the ACCF/AHA/ACP Task Force on Clinical Competence and Training

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