

ACC/AHA/ACP CLINICAL COMPETENCE STATEMENT

American College of Cardiology/ American Heart Association 2006 Update of the Clinical Competence Statement on Invasive Electrophysiology Studies, Catheter Ablation, and Cardioversion

A Report of the American College of Cardiology/
American Heart Association/American College of Physicians
Task Force on Clinical Competence and Training

Developed in Collaboration With the Heart Rhythm Society

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PREAMBLE

The granting of clinical staff privileges to physicians is a primary mechanism used by institutions to uphold the

quality of care. The Joint Commission on Accreditation of Health Care Organizations requires that the granting of continuing medical staff privileges be based on assessments of applicants against professional criteria specified in the medical staff bylaws. Physicians themselves are thus charged with identifying the criteria that constitute professional competence and with evaluating their peers accordingly. Yet the process of evaluating physicians' knowledge and competence is often constrained by the evaluator's own knowledge and ability to elicit the appropriate information, problems compounded by the growing number of highly specialized procedures for which privileges are requested.

The American College of Cardiology Foundation/American Heart Association/American College of Physicians (ACCF/AHA/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 utilized to formulate recommendations. Indications and contraindications for 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 health care providers entering practice for the first time and/or those who are in practice and undergo periodic review of their practice 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 electrophysiology, catheter ablation, and cardioversion and is authored by representatives of the ACCF, the AHA, and the Heart Rhythm Society (HRS).

The ACCF/AHA/ACP Task Force makes every effort to avoid any actual or potential conflicts of interest that might arise as a result of an outside relationship or a personal interest of a member of the ACCF/AHA/ACP Writing Committee. Specifically, all members of the Writing Committee are asked to provide disclosure statements of all such relationships that might be perceived as real or potential conflicts of interest relevant to the document topic. These changes 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 Appendix 2, respectively.

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INTRODUCTION

This statement is a revision and extension of the 2000 ACP/ACC/AHA document on clinical competence in invasive cardiac electrophysiologic studies (EPS) (1), 1994 ACP/ACC/AHA competency document, and the 1993

report on elective direct current cardioversion (DCCV) (2). This statement is designed to assist in the assessment of physicians' competence on a procedure-specific basis. The minimum education, training, experience, and cognitive and technical skills necessary for the competent performance of invasive cardiac EPS, catheter ablation, and cardioversion are specified. It is important to note that these are the minimum training and experience requirements for the assessment of competence in these disciplines (or procedures) in the broadest sense. Whenever possible, the specifications are based on published data that link these factors with competence or, in the absence of such data, on the consensus of expert opinion. The specifications are applicable to any practice setting and can accommodate a number of ways in which physicians can substantiate competence in the performance of specific procedures (3). Expertise in the performance of these procedures in patients with infrequently encountered diagnoses or of less commonly performed variations of standard procedures may require additional experience or training. It is therefore expected that even highly competent practitioners will occasionally benefit from consultation with colleagues who have even more highly specialized interests, experience, or skills. This document in large part does not deal with pacing and defibrillator therapies. Competencies regarding these devices are covered in the HRS competency statement (4).

In addition to members of ACC and AHA, the Writing Committee included a representative from the HRS. Representation by an outside organization does not necessarily imply endorsement. In addition to content peer reviewers, "official" reviewers were provided by ACC and AHA. This document was approved for publication by the governing bodies of ACC and AHA. In addition, HRS's governing board formally endorsed this document.

CLINICAL COMPETENCE IN INVASIVE EPS, CATHETER ABLATION, AND CARDIOVERSION: OVERVIEW OF THE PROCEDURE

Catheter techniques for the recording of the His bundle potential in humans were first reported in 1969 by Scherlag et al. (5). Initially, data from EPS were used to determine the mechanisms of spontaneously occurring arrhythmias, including atrioventricular (AV) conduction abnormalities, premature complexes, and a variety of tachycardias (6,7). Subsequently, techniques for programmed electrical stimulation were developed, which permitted the reproducible initiation of both supraventricular (7,8) and ventricular (9-11) arrhythmias in the laboratory. Pacing protocols to characterize sinus node function (12) and AV conduction (13) were also introduced. Because sustained arrhythmias are often episodic in nature or can terminate spontaneously or require intervention before full clinical evaluation, invasive EPS have become a standard means of reproducing an arrhythmia in a controlled laboratory setting.

In this report, the term "EPS" refers to a procedure that involves the recording of intracardiac electrical signals and

programmed electrical stimulation. The EPS either may be performed for diagnostic purposes only or may be part of a combined diagnostic and therapeutic (e.g., ablation) procedure. Although a thorough description of EPS is beyond the scope of this document, the procedure is briefly outlined here.

An EPS requires the placement of electrode catheters for pacing and recording in multiple cardiac chambers. The designs of the catheters and the sites appropriate for their placement are determined according to the nature of the arrhythmia under investigation. Typically, each catheter will have multiple electrode poles for both recording and local stimulation. Many types of specially designed catheters have been developed to facilitate recording and stimulation, and new catheters are frequently introduced into clinical practice. The intracardiac signals are acquired, amplified, filtered, displayed, stored, and analyzed, either in real time or for subsequent offline review. A potentially important part of an EPS is the use of intracardiac recordings to determine activation sequences during arrhythmias. This process is usually called "mapping." Analysis of the responses of an arrhythmia to various pacing techniques is also a component of the mapping process.

Electrophysiologic studies provide clinically valuable diagnostic information. In patients with bradyarrhythmias, EPS are occasionally necessary to clarify electrocardiographic phenomena or to explain symptoms that are possibly due to a transient, clinical bradyarrhythmia. Electrophysiologic studies are useful to determine the mechanisms and physiological characteristics and drug responses of supraventricular tachycardias and to determine whether arrhythmias are suitable for drug, device, or ablation therapy, as described later in this document. In patients with ventricular tachycardia, EPS are useful to confirm the mechanism of the arrhythmia, to assess the effects of pharmacologic therapy, and to select patients for nonpharmacologic treatment. Acute or follow-up testing for antiarrhythmic device efficacy falls under the definition of "EPS." These studies can often be performed noninvasively through the device, but the placement of temporary catheters may be necessary.

Electrophysiologic studies have also been used to assess the future risk of serious antiarrhythmic events and to provide data on which prophylactic therapy may be based

(14). In patients with undocumented symptoms that suggest an arrhythmia that was not previously documented (e.g., syncope or palpitations), EPS are frequently used to assess the patient's predisposition for spontaneously occurring arrhythmias (15).

Physicians involved in the performance of invasive EPS should be cognizant of the indications, contraindications, and potential complications of the procedure in a given patient (15,16). Absolute contraindications to EPS are few but include unstable angina, bacteremia or septicemia, acute decompensated congestive heart failure not caused by the arrhythmia, major bleeding diathesis, and acute lower extremity venous thrombosis, if femoral vein cannulation is desired. The appropriate use of invasive EPS, therefore, requires a careful nonprocedural assessment to ensure that the patient is stable and able to tolerate the procedure. In the vast majority of situations, an EPS is performed on an elective basis. However, an EPS is justifiable in such situations if an arrhythmia is the main or major cause of the emergency, as occurs in patients with incessant ventricular or supraventricular tachycardia. General indications for invasive EPS were described by the ACC/AHA Task Force on Practice Guidelines, in conjunction with the HRS (17).

JUSTIFICATION FOR RECOMMENDATIONS

The recommendations for minimum education, training, experience, and skills necessary to perform EPS are based on a review of statements by the ACP, the ACC, and the AHA (1,18); the Canadian Cardiovascular Society (19); and the British Cardiac Society and Royal College of Physicians (20); a report from a Core Cardiology Training Symposium (COCATS) (21); and policies of the Accreditation Council of Graduate Medical Education (ACGME) (22) and the American Board of Internal Medicine (ABIM) (23) (Table 1). The American groups (Table 1) recommend training after the completion of 3 years of a general cardiology fellowship. The British statement discusses specialized training in the last year (year 6) of a cardiology fellowship. The Canadian Cardiovascular Society describes 2 levels of specialized training: Level 2 may be achieved during 3 years of a general cardiology fellowship program, whereas Level 3 requires additional years of training. In preparation of this docu-

Table 1. Invasive Electrophysiologic Studies (EPS): Recommendation for Training to Achieve Competence

Source	Training, yrs	EPS, n	EPS in Patients With Supraventricular Tachycardia, n	Catheter Ablation, n	Antiarrhythmic Devices, n
ACP/ACC/AHA 1994*	1	100	NS	NS	NS
Canadian Cardiovascular Society (19)					
Level 2	1-2	100	NS	NS	NS
Level 3*	1-2	NS	NS	NS	NS
British Cardiac Society (20)*	1	70	NS	50	NS
COCATS (21)*	1	100	50	50	50
ACGME (22)*	1	150	NS	75	25
ABIM (23)*	1	159	NS	75	25
Present document*	1	100	≥50	50-75†	NS

*Recommendations for last year of training. †Not including 30-50 if training in atrial fibrillation ablation is pursued.
 n = number performed or implanted; NS = not specified.

ment, 63 program directors were surveyed regarding training and competency issues; 33 directors (52.4%) responded. Where results pertaining to this document are available, they will be indicated as Clinical Cardiac Electrophysiology (CCEP) Training Program Directors' Survey results.

The technical and cognitive skills required for CCEP are listed in Tables 2 and 3. Expertise in invasive EPS requires the ability to safely and efficiently perform the catheterization procedures for intracardiac recording and stimulation. The operator must possess a thorough understanding of the basic electrophysiologic mechanisms and clinical manifestations of arrhythmias; the applications and limitations of the available recording and stimulation technologies; the pharmacologic effects of medications used during the studies; and the risks, benefits, and applications of nonpharmacologic therapy. Because knowledge in all of these areas has increased, the interpretation and application of data acquired in the electrophysiologic laboratory have become increasingly complex. The accurate interpretation of data is critical for optimal prescription of both pharmacologic and nonpharmacologic therapies.

MINIMUM TRAINING NECESSARY FOR COMPETENCE

There is general agreement that a minimum of 1 year of specialized training in EPS is needed to acquire the cognitive and technical skills required to become expert in CCEP. This is in addition to time spent during general cardiology fellowship training learning to diagnose and manage arrhythmias. Training should take place in a laboratory that offers experience with a diverse patient population who manifest a broad variety of arrhythmias. During the specialized training year, it is recommended that each trainee be a primary operator and analyze 100 to 150 initial

Table 2. Technical Skills Needed to Perform Electrophysiologic Studies

Operational skills to perform right and left heart catheterization with percutaneous techniques via femoral and other venous and arterial access sites
Manual dexterity to safely place and manipulate electrode catheters in the appropriate chambers for the arrhythmia under study
Ability to obtain appropriate recordings from various locations
Ability to safely perform programmed electrical stimulation
Ability to recognize and manage procedural complications (e.g., vascular or cardiac perforation)
Proficiency in the use of external defibrillation and intravenous cardiac medications
Proficiency in the appropriate use of sedation during procedures, including airway management
Proficiency in the testing, interrogation, and programming of implantable antiarrhythmic devices, including pacemakers and defibrillators
Technical knowledge regarding the use of recording equipment, including knowledge of electrical safety and pertinent radiation-related issues

Table 3. Cognitive Skills Needed to Perform Electrophysiologic Studies (EPS)

Knowledge of current indications for an EPS
Knowledge of contraindications for an EPS
Knowledge of potential complications and management of such complications
Knowledge of normal and abnormal cardiac anatomy and electrophysiology
Knowledge of the anatomy and physiology of the normal atrioventricular conduction system and accessory pathways
Understanding of the intracardiac electrocardiographic signals
Knowledge of various methods of programmed electrical stimulation
Ability to measure conduction intervals and refractory periods; knowledge of their significance in normal and pathological states
Knowledge of the predictive value of electrophysiological-testing in patients with various arrhythmias and clinical syndromes
Ability to interpret data derived from electrophysiological testing
Knowledge of the indications for and complications of therapy with antiarrhythmic devices
Knowledge of the pharmacology of antiarrhythmic drugs and of sympathetic and parasympathetic agonists and antagonists
Knowledge of the indications for and complications of ablative therapy
Detailed knowledge of recent clinical trials that affect the selection of patients for EPS

diagnostic studies. At least 50 of these procedures should involve patients with supraventricular arrhythmias. Because therapy with antiarrhythmic devices forms a major part of current electrophysiology practice, the trainee should also have been a primary operator during greater than or equal to 25 implantation and electrophysiologic evaluations of implantable antiarrhythmic devices. The trainee's experience should be documented in writing and confirmed by the laboratory supervisor. For each procedure during the training period, the following facts should be documented: date, patient identification number, patient age, indication, type of procedure, findings, and complications. The 1-year training period is considered to be the minimum required for most individuals to become proficient in basic pacemaker and implantable cardioverter-defibrillator implantation and management, performance, and interpretation of diagnostic EPS, and catheter ablation of the common forms of paroxysmal supraventricular tachycardia. One year of training also is consistent with ACGME and ABIM requirements. This minimum training period however would not be optimal for an individual who planned on performing more complex procedures. Responders to the CCEP Training Program Directors' Survey strongly felt that 2 years of training would be preferred for those individuals who desire training above the basic level needed to satisfy certification requirements. Because the number and complexity of electrophysiologic procedures continue to expand, electrophysiologists should be committed to structured, continuing education throughout their careers.

ALTERNATE ROUTES TO ACHIEVE COMPETENCE

In the absence of completion of the formal 1-year training program, competence in CCEP is difficult to achieve. The current requirement for residency education in CCEP as stated by the ACGME is 1 year of training in an ACGME electrophysiology program after the completion of an accredited cardiovascular disease residency program (22). This requirement must be met to sit for the ABIM subspecialty examination in CCEP (23). For those who choose to gain competency in the performance of EPS but not within an accredited U.S. program, training should still be completed in a structured environment. The operator should perform the same number of the above-listed procedures as currently recommended for U.S. trainees. He or she should also participate in courses designed to provide specific instruction in CCEP. Prior competency statements have suggested a minimum of 30 h of continuing medical education (CME) every 2 years; this recommendation is endorsed in the present document. Any such training should be performed under the supervision and mentorship of a recognized expert in the field of cardiac electrophysiology who has achieved board certification by the ABIM in CCEP or an equivalent degree of training in countries outside the U.S. The trainee who completes this latter program in a training program that is not approved by the ACGME will not be eligible to take the ABIM examination.

MAINTENANCE OF COMPETENCE

As is true for many other procedures, a minimum number of cases is necessary to ensure continued proficiency in quality of care. The individual should participate in greater than or equal to 100 diagnostic EPS per year to maintain skills and should attend greater than or equal to 30 h of formal CME (Level 1 category) every 2 years to remain abreast of changes in knowledge and in technology. These cases can include the diagnostic portions of ablation procedures.

CATHETER ABLATION: OVERVIEW OF THE PROCEDURE

Catheter ablation has revolutionized the field of electrophysiology. The performance of catheter ablation was initially accomplished through the delivery of high-energy, direct current (DC) shocks (24,25). These early procedures had limitations in usefulness and safety because of barotrauma. They also carried the potential for significant complications, such as cardiac tamponade and the early or late occurrence of sudden death (26,27). Technological advancements in the late 1980s led to the ability to apply continuous-wave unmodulated radiofrequency energy through catheters to heat myocardium at the catheter-tissue interface, creating ablative lesions (28). Although initial success rates were modest (28,29), further development in technology resulted in a technique that has replaced DC energy delivery (30,31). Radiofrequency ablation has also quickly supplanted open-heart surgery for several arrhythmias and is an acceptable alternative to long-term drug treatment.

The lesions created by radiofrequency are well demarcated. This characteristic, along with improved catheter technology, allows very specific and focal energy delivery, which permits the cure or modification of many arrhythmias. Through targeting of the specific site of origin of the arrhythmia, as with atrial tachycardia, or through interruption of a critical pathway needed for the maintenance of a re-entrant arrhythmia, such as an accessory pathway, many arrhythmias of various mechanisms can be eliminated. Since its inception, catheter ablation has grown tremendously in its application. The number of reported ablation procedures performed annually in the U.S. has increased from 450 in 1989 to 15000 annually in the most recent U.S. survey (32). The success rates reported in the 1995 Scheinman (32) survey of 157 laboratories in the U.S. were 97% for AV node ablations, 90% for accessory pathways in all locations, 94% for AV node modifications in the treatment of AV nodal re-entry, 72% for the treatment of atrial flutter, and 71% for the treatment of atrial tachycardia. Complication rates derived from the Scheinman (32) survey and the 1993 Multicentre European Radiofrequency Survey (MERFS) from 86 institutions (33) were reported in just under 4% of AV node interruptions, 2.6% of accessory pathway ablations, 1.7% of AV node modifications, and 1.6% of flutter and atrial tachycardia ablations.

Although the incidence of complications is low, serious complications can occur and include valvular disruption, coronary occlusion, cerebrovascular accident, and death. In U.S. centers, procedural deaths occur in 0.2% of patients who undergo AV node ablation and 0.1% of patients with accessory pathways (32). The most common complication in AV node modification has been the development of heart block through the inadvertent ablation of both the fast and slow AV nodal pathways. In the 1996 study from the MERFS (Multicenter European Radiofrequency Survey) (34), 4.7% of patients developed heart block during AV node modification. Heart block was significantly higher in patients in whom the fast pathway was targeted (5.3%) rather than the slow pathway (2%). This is higher than the overall rate of inadvertent heart block reported by Calkins et al. (35) from the Akhtar Multicenter Ablation Investigators Group, in which the incidence of inadvertent heart block in patients who underwent AV node modification was 1.3%. Importantly, a slow pathway ablation approach was used in this study. This study also reported serious complications in 3% of patients and minor complications in 8%.

Despite these complications, studies have clearly shown that symptomatic patients are afforded important improvements in the quality of life with catheter ablation (36-39). The benefit gained through arrhythmia treatment with catheter ablation is superior to that achieved through medical therapy. The cost of catheter ablation, although not trivial, is less over time than the cost of alternatives such as medical therapy or surgical interventions (36,40).

Catheter ablation provides a safe and highly effective treatment for symptomatic patients with supraventricular tachycardia. Ablation should not be reserved as a last resort

treatment but is appropriate to consider, in some cases, as first-line therapy (e.g., a symptomatic patient with Wolff-Parkinson-White syndrome) (41-46). However, for patients with rhythm disturbances that are likely to spontaneously resolve (e.g., atrial tachycardia) or unlikely to recur (e.g., a first episode of atrial flutter), ablation would not be appropriate first-line therapy (47). Its role would be limited to patients in whom medical therapy is intolerable or in whom there is evidence for adverse consequences of the arrhythmia. The complete list of indications is detailed in the ACC/AHA guidelines for CCEP and catheter ablation procedures (17).

Atrioventricular node re-entry in a structurally normal heart typically is a benign arrhythmia, and there is a reasonable chance that no therapy is required (48). However, if patients have other compounding heart disease, such as coronary artery disease, or if the arrhythmia produces hemodynamic compromise or intolerable side effects, ablation can be considered as first-line treatment because of the high likelihood of recurrence or of serious consequences to the arrhythmia (48).

The area of atrial fibrillation (AF) ablation has undergone rapid evolution over the last 3 to 5 years. Initial attempts at catheter ablation attempting to recreate the maze procedure were only marginally successful and carried relatively high complication rates. However, the transition to focal ablation and to now substrate modification with wide area circumferential ablation has led to greater application of this technique.

In a recent survey of electrophysiologists, 30% (n = 92 of 304 respondents) reported that they performed AF ablations. In this self reporting study, the number of reported AF ablations from 2000 to 2003 was 5592 AF ablations of 72575 total ablation procedures during the same time period. The self reported 1-month, 1-year, and 2-year success rates were: $71 \pm 4\%$, $66 \pm 5\%$, $63 \pm 6\%$, respectively. Respondents reported procedure times of 4.5 ± 0.4 h (49). Other published series of ablation for paroxysmal AF ablation report success rates of approximately 85%, which may require more than 1 ablation procedure to achieve (50,51). Large series report complications in the 2% to 11% range including perforation, tamponade, stroke, pulmonary vein stenosis, and, with certain lesion sets, atriopharyngeal fistula, which is often fatal (52).

It is not anticipated that all trainees would want to pursue training in AF ablation nor should it be a mandatory part of training. Atrial fibrillation ablation is of higher risk than ablation of other arrhythmia substrates, and the trainee must be aware of the special risks such as pulmonary vein stenosis; atriopharyngeal fistula; and the higher risk of stroke, perforation, and tamponade. They must also be proficient in acute management of potential complications.

While the exact lesion set required to treat AF remains debatable, there are several common elements to the ablation procedures that are currently being performed (53,54). Access to the left atrium is achieved via transseptal puncture. It is anticipated that the operator will have already

acquired experience at performance of transseptal punctures before performing AF ablation. There are no established norms for achieving competency in transseptal puncture, but, for a reasonably experienced operator, it would be expected that performance of 20 supervised transseptal punctures would display a reasonable amount of competence (55). The operator should have ready access to transthoracic echocardiography and be proficient in performing pericardiocentesis.

Often visualization with intracardiac echocardiography is utilized to improve safety and to monitor therapy during energy delivery during AF ablation (56-58). As such, the electrophysiologist should be familiar with the placement of the intracardiac echocardiography catheter and the use of and interpretation of data acquired. Frequently, AF ablation is facilitated by using imported 3-dimensional images of the left atrium acquired either through cardiac magnetic resonance imaging or computed tomography scan (59,60). These imported data are used in conjunction with real-time 3-dimensional images created with 1 of several electroanatomic mapping systems during the ablation procedure. The electrophysiologist must be familiar with the utility of and interpretation of these data.

Radiofrequency ablation has been applied in the treatment of ventricular tachycardia in ischemic disease, bundle-branch re-entry, and idiopathic tachycardia (61-64). A decision to perform an ablation in a patient with ventricular tachycardia must take into account the risks and benefits of doing so as well as subsequent risks of arrhythmia occurrence in abnormal but unablated tissue. Techniques such as ablation of ventricular fibrillation are not within the realm of standard training in CCEP.

JUSTIFICATION FOR RECOMMENDATIONS

The performance of catheter ablation requires skills detailed previously as necessary for the performance of diagnostic electrophysiologic testing. The indications, contraindications, and complications for catheter ablation are largely derived from the ACC/AHA Guidelines for Clinical Intracardiac Electrophysiologic and Catheter Ablation Procedures (17). The performance of catheter ablation requires the ability and dexterity to successfully manipulate catheters in all locations of the heart to achieve adequate contact between the catheter and the myocardium to create curative lesions. This requires detailed knowledge of cardiac anatomy. Left-sided arrhythmia substrates such as left atrial foci usually require the ability to perform transseptal catheterization (65). In some laboratories, this approach is routinely used for left-sided accessory pathways as well. For these pathways, knowledge of trans-septal catheterization and the retrograde aortic technique is needed (65,66). A thorough knowledge of arrhythmia mechanisms and the treatment of complex arrhythmias, including pharmacologic effects, is a prerequisite to catheter ablation. The ability to interpret complex mapping with multiple intracardiac electrograms is required.

Because the possibility of creating AV heart block through the application of radiofrequency energy exists either as a desired end point or as an inadvertent result of energy application, physicians who perform ablations should be capable of managing the bradyarrhythmia and AV heart block.

MINIMUM TRAINING NECESSARY FOR COMPETENCE

Program requirements for residency education in CCEP are outlined by the ACGME and are effective as of July 1999 (22). Training in an accredited program is required for admission to the ABIM examination for certification in CCEP. Programs accredited for training in CCEP must function as a part of an accredited subspecialty fellowship in cardiovascular disease. These programs should also meet the training in specialized electrophysiology, cardiac pacing, and arrhythmia management guidelines outlined by the COCATS Task Force (21).

The performance of catheter ablation procedures requires skills that are developed over time. Several studies have shown that success rates improve and fluoroscopy times decrease with experience (67-70). Although there are many determinants of arrhythmia recurrences, recurrence rates drop with operator experience (71). Each of these studies involved operators with extensive prior experience in electrophysiology, and it would be expected that the number of procedures required for a new trainee to gain expertise in ablation would be higher than that for an experienced electrophysiologist. The risks of ablation similarly have been reported by experienced operators. The MERFS volunteer registry reported an overall complication rate of 4.6% at high-volume centers (100 ablations/year) compared with 5.6% at low-volume centers (50 ablations/year) (33). Similar data were reported in the 1994 North American Society of Pacing and Electrophysiology survey, with a 1.5% complication rate at high-volume centers (50 cases/year) and a 3.2% rate at low-volume centers (20 ablations/year) (64).

It is strongly recommended that all physicians who perform ablations in the U.S. meet the minimum ACGME training requirements for education in CCEP. Although credentialing at most institutions does not require board certification in CCEP, applicants should have met board requirements. As stated by the ACGME, the current program requirements for training in electrophysiology are for 12 months of specialty training after the completion of training in cardiovascular disease. This should provide adequate training for the performance of routine electrophysiologic procedures. Training in electrophysiology and ablation techniques can occur simultaneously with incremental responsibility for the trainee during the entire period. However, most training program directors agree that to gain proficiency in interventional electrophysiology and catheter ablation, additional training is required. Adequate training in all aspects of electrophysiology, including ablation, is expected to take up to 2 years depending on the skills of the trainee. The certified year in EP must occur after the completion of a 3-year training program in cardiovascular disease

(19,38,40,41,72,73). Much discussion is underway to recognize the sentiment that 2 years of training in CCEP is optimal but may require adjustment in the overall training of the cardiovascular specialist, but this is beyond the purview of this paper.

It is anticipated that the more experienced the electrophysiologist, the quicker she or he will learn new techniques. As such, it is difficult to set requirements for a number of procedures to gain proficiency. The HRS Ad Hoc Committee on Catheter Ablation has recommended that a physician who performs catheter ablation procedures should have been the primary operator on 30 ablations (74); this should include 15 accessory pathway ablations. The Canadian Cardiovascular Society Committee (19) recommends a training experience that includes the performance of 50 transvenous catheter ablations. The ACGME recommends a minimum of 75 catheter ablative procedures, including a mix of AV nodal re-entrant tachycardia, atrial flutter, AV junction ablation, and ventricular tachycardia (22). For left-sided mapping procedures, the COCATS guidelines (21) recommend 15 cases with the retrograde aortic approach. For transseptal catheterization experience, greater than 10 procedures are recommended. The COCATS guidelines also recommend participation in 75 catheter ablation procedures. It is the consensus of this task force that, for new trainees, the physician should be involved in 75 ablation procedures. It is notable that, for candidates who take the first cardiac electrophysiology examination given by the ABIM, the pass rates were significantly higher for those who performed a greater number of ablations compared with those who performed a lesser number of procedures (75). The CCEP Training Program Directors' Survey indicated that a minimum of 90 (mean; median, 100) cases were required to acquire clinical competence in catheter ablation.

No numeric guidelines have been established for training in AF ablation, but it is anticipated that the trainee should participate in 30 to 50 mentored AF ablations. These are in addition to the 75 procedures required to achieve competency for other ablation procedures.

ALTERNATE ROUTES TO ACHIEVE COMPETENCE

At this time, it is anticipated that physicians who perform ablations will have either received instruction during their training or been among those who developed the technique. In the rare instance of a board-eligible or -certified electrophysiologist who desires to learn the techniques required for ablation, mentoring by an electrophysiologist who is trained in ablation should be pursued. Documentation of satisfactory completion of such training should be kept in a log book. It is anticipated that, depending on the level of skill, a minimum of 75 procedures will be required. In addition, such an individual should participate in courses designed to provide specific instruction in the cognitive and technical skills required for catheter ablation as listed earlier.

MAINTENANCE OF COMPETENCE

The field of interventional electrophysiology is evolving rapidly. Although it is anticipated that most physicians who perform ablations will have received instructions during their training, newer techniques will arise that require new skills or adaptations of old skills. The maintenance of skills needed to perform ablations successfully with acceptably low complication rates requires continued clinical activity. It is recommended that physicians who perform ablations maintain a volume of 20 to 50 ablations/year. The CCEP Training Program Directors' Survey respondents indicate that, to maintain competency in catheter ablation, a mean of 38 (median, 50) cases/year are required.

With the future development of new techniques, it is likely that some form of retraining will be required. Every 2 years, physicians who are involved in ablation therapy should attend CME activities that pertain to interventional electrophysiology. For novel treatments, some form of monitoring should be considered. The CCEP Training Program Directors' Survey results indicated that, to maintain competency in the performance of diagnostic EPS, a mean of 49 (median, 50) cases/year was required and that a mean of 49 (median, 50) could be in association with the performance of ablation procedures.

USE OF EMERGING TECHNOLOGY AND NEW TECHNIQUES: ASSESSMENT OF CLINICAL COMPETENCE IN INVASIVE CARDIAC ELECTROPHYSIOLOGIC PROCEDURES

During the past 10 years, the technology of cardiac electrophysiology has evolved rapidly. The rather straightforward electrophysiologic procedures from the diagnostic era have given way to the multicatheter techniques and accompanying technologies that are necessary for interventional practice. The 8- to 16-channel analog recording systems are being replaced in routine procedures with 16- to 48-channel, computer-based digital recording platforms. Furthermore, 48- to 128-channel mapping capabilities are being developed and increasingly applied in cardiac ablation procedures. These systems not only simultaneously record and display activation from multiple regions of the heart but also format both activation and voltage information in 3- and 4-dimensional renderings.

Electroanatomic magnetic mapping capabilities, for example, are being applied to aid in the diagnosis and nonpharmacologic treatment of arrhythmias (76,77). These systems involve the interaction of a sensing unit in the catheter tip positioned within a triangulating magnetic field to display temporal activation in a 3-dimensional pseudo-anatomic context. Noncontact mapping probes are also being used to record actual and virtual electrograms from the endocardial surface of each heart chamber. With this technology, cardiac activation can be displayed in terms of 3-dimensional isochronal and full cardiac cycle isopotential maps (78,79). Several other systems that use active signaling

between multiple exclusively intracardiac catheter electrodes or the body surface and catheter electrodes are being developed to provide a 3-dimensional framework for cardiac arrhythmias (80). In each case, these new technologies increase the amount and complexity of data generated during a mapping procedure.

Use of cryoablation is gaining popularity in certain patient populations although its use has not become widespread (81,82). Those in training or who have completed training must be aware of ongoing developments in energy delivery systems including new energy sources and other components of energy delivery systems (e.g., catheter modifications, manipulable sheaths, and so on).

Two-dimensional fluoroscopic imaging is also being supplemented with intracardiac echocardiography. This approach has capabilities of visualizing cardiac structures, endocardial surfaces, and the interaction between interventional catheters and targeted structures that are superior to those available with fluoroscopy (83-85). Although not yet established as requisite or "core" equipment for the electrophysiology laboratory, these and other emerging technologies have had, and will continue to have, a major impact on the practice of cardiac arrhythmia management. It is also anticipated that additional new technologies will be developed at ever faster rates in the future.

COMPETENCE IN THE USE OF EMERGING TECHNOLOGY

This evolution of new means of diagnosing and treating arrhythmias is accompanied by an ever-increasing challenge to the practicing electrophysiologist. Specifically, the use of additional techniques and technologies will require the acquisition of sufficient cognitive and technical expertise to ensure safe and effective application. Although cardiac electrophysiology trainees may encounter these approaches and systems during their fellowships, by default, the majority of clinical electrophysiologists will first be exposed to, and begin using, emerging techniques and technologies outside of their training experience. As such, the skills required to record, compile, synthesize, integrate, render, interpret, and apply the resulting data will be acquired through alternative educational pathways.

SPECIFIC TRAINING REQUIREMENTS

The training required for proficiency in the application of new technologies and techniques will depend on the technology and procedures under consideration. When emerging techniques and technology represent straightforward incremental progress, their use may rely on already resident cognitive and technical skills. For example, many new intracardiac mapping technologies involve the same venous and arterial access skills, arrhythmia induction protocols, catheter positioning and mapping techniques, electrogram pattern recognition, and arrhythmia mechanism deduction previously acquired through years of training and clinical practice. In these cases, training should be focused on the

appropriate operation of the system and interpretation and application of data displays.

In other cases, however, application of the emerging techniques and technology will undoubtedly represent a major paradigm shift in interventional approaches thus requiring the accumulation of very different technical and cognitive skills than those required to use the current procedures or technology. In such cases, sufficient education and experience are imperative for both understanding the general operational principles behind that technology and ensuring sufficient technical abilities for the safe and efficient application of the technology. This exposure may come from national and local CME seminars; emerging scientific information from reputable, established scientific journals; local or regional training sessions; or on-site teaching by certified industry engineers. In any event, sufficient experience should be acquired such as the actual application of the technology and performance of the procedure are conducted safely under the direction of the practicing physician, without relegation of this responsibility to an industry representative. This obviously requires that a practitioner have a sufficient understanding of appropriate indications, contraindications, and risks for the application of that technology.

The duration of training or number of procedures required to establish competence will be dependent on the new techniques or technology used. This should be based on definable measures of individual competence and should include appropriate documentation of the specific cases undertaken, arrhythmias under study, general techniques and approaches used, and outcomes of the technology-related procedures. It is fully anticipated that some new technologies and techniques will lead to sufficiently specialized and frequent applications so as to require subsequent, independent competency guidelines. This has been the case in both pacemaker and defibrillator implantation and in cardiac ablation, as discussed in the preceding guidelines.

Finally, because of the additional complexity of interventions enabled through emerging technology, cardiac electrophysiology trainees may require additional time to acquire the fundamental proficiency necessary for an interventional practice. In any event, it remains increasingly critical that the practicing physician acquire and maintain an understanding of relevant fundamental principles of electrophysiology. Although technological advancements may be exciting, it should be kept in mind that the technology for technology's sake is to be avoided, especially if there is no value to the patient. Training in CCEP should include gaining the insight into when and in whom to intervene. Patient selection and use of alternate therapy is a skill set that all trainees must acquire.

CLINICAL COMPETENCE IN ELECTIVE DCCV: OVERVIEW OF THE PROCEDURE

Since the introduction of DC transthoracic electrical shock (86), its use has become fairly routine for the termination of

tachycardias. A variety of clinical scenarios are now encountered in which transthoracic and, more recently, intracardiac DC electrical shock of variable energies is delivered (25,27,63,87–90). In urgent settings such as hemodynamic collapse associated with ventricular tachycardia or ventricular fibrillation, high-energy shock (i.e., greater than 200 J) is used. However, lower energies are used for elective cardioversion in more hemodynamically stable patients. Due to the potential risks involved, it is imperative that physicians be familiar with proper indications, precautions, techniques, and complications (91). Elective DCCV that requires sedation or general anesthesia is the subject of this report. At the present time, DCCV can be carried out externally with chest electrodes (transthoracic) or endocardially with the use of electrode catheters (or leads). The 2 procedures are discussed separately where appropriate.

A. External Cardioversion

External cardioversion (2) is carried out in a fasting, post-absorptive state with the patient under sedation or general anesthesia. Adequate electrocardiogram monitoring is maintained throughout. The electrodes (paddles or pads) are placed in the anteroposterior or base-apex location. For atrial defibrillation, a more superoanterior left paddle position is often more effective. A clearly visible artifact that indicates the timing of the shock in relation to QRS is identified. A DC shock is synchronized to the peak of the QRS. Under no circumstances should the shock be delivered on the T-wave. Physicians in charge should be thoroughly familiar with the device that is used for elective DCCV.

Significantly lower defibrillation thresholds for both AF and flutter have been identified with rectilinear biphasic waveform external defibrillators. These devices are available in most hospitals (92). The initial shock energy may be as low as 50 J depending on the type of arrhythmia. However, higher initial energy is significantly more effective than lower levels, and an initial shock energy of 200 J or greater is recommended for electrical cardioversion of AF. No definitive guidelines have been established for biphasic synergy cardioversion, but the same principles would apply (93).

After shock delivery, the rhythm is noted, and, if conversion is unsuccessful, repeat DCCV is attempted with higher energy. This can be repeated until the arrhythmia terminates or a decision is made to abandon DCCV.

Before elective DCCV is performed, several precautions are worth noting:

1. Anticoagulation (94–96). The most common arrhythmia subjected to elective DCCV is AF. The operator should be familiar with and follow the guidelines for anticoagulation in AF (93).
2. Although elective DCCV is effective in terminating a variety of tachycardias, it has no role in the prevention of subsequent episodes.

3. The use of transesophageal echocardiography has been advocated to identify small atrial thrombi that are not visible on transthoracic echocardiography. The operator must be familiar with the appropriate use of this tool in the evaluation of patients in whom earlier cardioversion is desired. Anticoagulation with heparin can be initiated and transesophageal echocardiography performed. If no clots are seen, cardioversion can be undertaken. Routine anticoagulation must still be maintained after cardioversion (97).
4. Several untoward and potentially life-threatening events may occur after DCCV shock; these include: 1) the induction of ventricular tachycardia/fibrillation; 2) asystole; and 3) transient depression of myocardial function, particularly with repeated shocks and higher energies. Techniques to deal with these situations should be readily available to prevent potential complications. The operator should have familiarity with the use of an intravenous antiarrhythmic such as ibutilide and other drugs that may result in the restoration of sinus rhythm, or facilitation of DCCV (98,99). The requirements for anticoagulation are the same regardless of whether cardioversion is accomplished through DCCV or pharmacologically.

B. Internal Cardioversion

The use of biphasic defibrillators and the use of ibutilide to lower the defibrillation threshold in patients refractory to standard DCCV has lowered the number of patients in whom cardioversion cannot be achieved. However, in patients for whom external DCCV was unsuccessful, an internal shock with the use of electrode catheters has been successful (100,101). Evolution of this technology has facilitated the development and assessment of stand-alone implantable atrial defibrillators (89). Internal cardioversion may also be performed during the performance of pulmonary vein isolation (102). Internal cardioversion is performed with the patient under conscious sedation or general anesthesia (103,104). Specially designed electrode catheters with large surface areas are introduced percutaneously and placed in the right atrium and coronary sinus. The large surface area is achieved with either a coil or the connection of several electrodes to a common terminal (88). A standard bipolar catheter is placed in the right ventricle for precise timing of ventricular activation and shock delivery. The 2 atrial catheters are used for DCCV (i.e., between the coronary sinus and right atrium).

Up to 10 J of energy can be safely delivered with the right atrium–coronary sinus vector, whereas 200 J has been safely delivered via an intracardiac–thoracic patch combination. It is important that the electrode catheters are kept away from the region of the AV node–His bundle when internal DCCV is performed. Because of the potential risk of bleeding, warfarin therapy is usually withheld and resumed after the procedure. Temporary anticoagulation before and after the procedure can be accomplished with heparin. Pre-procedural and post-procedural antiarrhythmic therapy

considerations are similar to those for external DCCV. The possible risks of both right heart catheterization with electrode catheters and the fact that the DC shock is delivered within the myocardial structures add to specific complications. The settings in which these procedures are carried out must be equipped to handle all potential untoward sequelae.

JUSTIFICATION FOR RECOMMENDATIONS

The use of external as well as intracardiac DCCV is associated with a variety of serious risks to the patient. It is therefore important that the physicians have the cognitive skills and the technical know-how to safely conduct these therapies. Tables 4 to 7 summarize the requirements that will be considered essential to acquire. The transthoracic procedure is widely used for the termination of tachycardias in both chronic and emergent settings. There is a broad-based pool of knowledge available regarding the clinical settings in which DCCV is used, including indications, contraindications, complications, and technologies that are used. However, there is no formal mechanism to determine the expertise of an individual who is qualified to perform DCCV. In previous publications regarding external DCCV, the ACP/ACC/AHA Task Force collected data from accredited cardiology training programs and made the recommendations. For internal DCCV, a separate level of knowledge and skill is required because of the invasive nature. Tables 4 and 5 outline the cognitive and technical skills needed to perform effective and safe DCCV.

MINIMUM TRAINING NECESSARY FOR COMPETENCE

For external DCCV, the minimum training should include: 1) competence in the interpretation of 12-lead electrocardiograms; and 2) cognitive knowledge and skills, outlined in Tables 6 and 7. It is imperative that the technical skills required to perform cardioversion are applied by those with an overall understanding of the procedure. Improperly performed DCCV can be both ineffective and harmful. Previous task force recommendations of a minimum of 8

Table 4. Cognitive Skills Necessary to Perform Internal DCCV

Physicians should have knowledge of the following:
Intracardiac EPS principles as discussed in this report
Principles of intracavitary cardioversion with catheter technology, catheters, chest electrodes, or whatever variant the operator plans to use
Indications and complications associated with transvenous catheterization and with the intracavitary delivery of DC shock
The safe delivery of DC shock and the limit of energy that can be delivered via electrode catheters
The use of conscious sedation or, when appropriate, anesthesia
The use of intravenous antiarrhythmic medications
Cognitive skills necessary for external DCCV (see Table 6)

DC = direct current; DCCV = DC cardioversion.

Table 5. Technical Skills Necessary to Perform Intracardiac DCCV

Competency in diagnostic cardiac electrophysiologic studies

Ability to place electrode catheters in appropriate locations for intracardiac synchronization and DCCV

Familiarity with the catheter characteristics, synchronization, and DCCV equipment

Ability to confirm the timing and energy of the shock for safe shock delivery

Adequate electrocardiographic and rhythm monitoring equipment

Ability to handle complications, including the use of temporary pacing and defibrillation

Proficiency in the appropriate use of sedation during procedures, including airway management

DCCV = direct current cardioversion.

supervised DCCVs seem appropriate as a minimum requirement. Although typical training in cardiovascular disease during a 3-year period may provide such an experience, it should be documented by the trainee and certified by appropriately trained supervisors. If formal training in cardiovascular disease does not provide adequate exposure to a sufficient number of DCCVs, competence in DCCV is not achieved. Conversely, the competence in DCCV may be achievable without formal training in cardiovascular disease.

For competency in internal DCCV, all of the above-mentioned requirements for external DCCV must be met. It is inconceivable that someone could meet the competency criteria for internal DCCV without prior established minimum training needed for external DCCV. In addition, however, the candidate must meet the minimum competency requirement for the following:

Table 6. Cognitive Skills Necessary to Perform External DCCV

Physicians should have knowledge of the following:

Electrophysiological principles of DCCV

Indications for the procedure

Anticoagulation management

The proper use and administration of antiarrhythmic therapy

The use of sedation and the management of overdose

DCCV equipment, including the selection of appropriate energy and synchronization

How to treat all possible complications, including the use of bradycardia pacing, defibrillation, and advanced cardiovascular life support

Proper placement of external paddles or pads

Appropriate monitor display and recognition of pre- and post-DCCV arrhythmias

Ability to differentiate failure to convert atrial fibrillation from an immediate recurrence of atrial fibrillation

Baseline 12-lead electrocardiogram reading, recognition of acute changes, drug toxicity, contraindications to DCCV

DCCV = direct current cardioversion.

Table 7. Technical Skills Necessary to Perform External DCCV

Proper preparation of the skin and electrode placement, including the application of saline jelly

Achievement of artifact-free monitored strips and synchronization signal/marker

Technically acceptable 12-lead electrocardiograms before and after DCCV

Temporary pacing and defibrillation capabilities

Ability to perform advanced cardiovascular life support, including proper airway management

DCCV = direct current cardioversion.

1. Diagnostic invasive EPS as mentioned elsewhere here.
2. Cognitive and manual skills to ensure the proper placement of electrode catheters and additional chest electrodes when necessary for internal DCCV.
3. Management of complications arising due to the procedure. With the advent of biphasic external defibrillators, the number of patients undergoing internal cardioversion has decreased except in specialized circumstances. It is not anticipated that all CCEP trainees will perform this technique. However, for those undertaking this procedure, a minimum of 5 intracavitary DCCVs under experienced (in intracardiac DCCV) individual supervision is recommended. Demonstration of adequate reading of didactic material and attendance of meetings that address intracavitary DCCV with catheter technology are also recommended. The supervisor must also document in writing exactly what was accomplished with the didactic exposure and during the procedures. Privileges in diagnostic EPS and even radiofrequency ablation do not automatically qualify one to perform intracardiac DCCV.
4. Periodic random examination of the outcomes may be necessary to comply with standards of care, including proper attention to record keeping regarding indications, efficacy, and complications.

MAINTENANCE OF COMPETENCE

A minimum of 4 external DCCV procedures annually should be necessary to maintain initial certification. It is also important that a new body of knowledge be acquired as additional reliable data become available. Varying and changing technology also necessitates that the operator be familiar with the proper use of external DCCV equipment used in his or her clinical settings.

The maintenance of competence in intracardiac DCCV requires a minimum of 2 annual procedures. In addition, necessary knowledge of upkeep and equipment changes must be maintained. This, of course, is done with the understanding that competency for diagnostic EPS is monitored concurrently. Individuals with experience in internal DCCV within the institution should look at the issue from the quality control perspective on a periodic basis. An

outside consultant may be necessary if institutional expertise is not available.

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APPENDIX 1. Author Relationships With Industry—ACCF/AHA/ACP Clinical Competence Statement on Invasive Electrophysiology Studies, Catheter Ablation, and Cardioversion—2006 Update

Name	Consultant	Research Grant	Scientific Advisory Board	Speakers' Bureau	Steering Committee	Stock Holder	Other
Dr. Akhtar	None	None	None	None	None	None	None
Dr. DiMarco	<ul style="list-style-type: none"> • Guidant • Medtronic • St. Jude • Novartis 	<ul style="list-style-type: none"> • Guidant 	None	<ul style="list-style-type: none"> • Guidant • Medtronic • St. Jude 	None	None	None
Dr. Packer	None	<ul style="list-style-type: none"> • CryoCath • Biosense Webster • Prorhythm • Endocardial Solutions • Siemens/Acuson • EP Limited • St. Jude 	<ul style="list-style-type: none"> • CryoCath • Biosense Webster • Prorhythm • Endocardial Solutions • Siemens/Acuson • EP Limited • St. Jude 	<ul style="list-style-type: none"> • CryoCath • Biosense Webster • Prorhythm • Endocardial Solutions • Siemens/Acuson • EP Limited • St. Jude 	None	<ul style="list-style-type: none"> • EP Limited • St. Jude 	None
Dr. Tracy	None	None	None	None	None	None	None
Dr. Weitz	None	None	None	None	None	None	None

This table represents the relationships of committee members with industry that were reported as relevant to this topic. It does not necessarily reflect relationships with industry at the time of publication.

APPENDIX 2. Peer Reviewer Relationships With Industry—ACCF/AHA/ACP Clinical Competence Statement on Invasive Electrophysiology Studies, Catheter Ablation, and Cardioversion—2006 Update

Name	Representation	Consultant	Research Grant	Scientific Advisory Board	Speakers' Bureau	Steering Committee	Stock Holder	Other
Dr. Hugh Calkins	• ACCF EP Committee	None	None	None	None	None	None	None
Dr. Mark D. Carlson	• ACCF EP Committee	• Guidant • St. Jude	None	None	• Medtronic	None	• Cameron Health • AtriCure	None
Dr. Leonard S. Dreifus	• ACCF EP Committee	None	None	None	None	None	None	None
Dr. N. A. Mark Estes	• AHA	None	None	None	• Medtronic • Guidant • St. Jude Medical	None	None	None
Dr. Michael D. Ezekowitz	• AHA	None	None	None	None	None	None	None
Dr. Alan D. Forker	• ACCF BOG	• Novartis	• Novartis • Pfizer • Merck • Takeda • KOS • Sankyo • Bristol Myers Squibb • Sanofi-Aventis • Reliant	None	• Pfizer • Merck • Takeda	None	None	None
Dr. Michael Kienzle	• ACCF BOT	None	None	None	None	None	• Merck • Pfizer	None
Dr. Peter Kowey	• ACCF EP Committee	None	None	None	None	None	None	None
Dr. Bradley Knight	• AHA	• Medtronic • Guidant	• Medtronic • Guidant • St. Jude	None	None	None	None	• Stock Options-Cardio Optics
Dr. Andrea Russo	• ACCF EP Committee	None	• Medtronic • Guidant • St. Jude • Procter & Gamble	None	None	None	None	None
Dr. Claudio Schuger	• ACCF EP Committee	None	None	None	None	None	None	None
Dr. D. George Wyse	None	• Sanofi-Aventis	• Cardiome/Astellas • Medtronic • Organon/Sanofi-Aventis	• Medtronic • Boehringer Ingelheim	• Cardiome/Astellas • Medtronic • Sanofi Aventis • Chugai Pharma • Daiichi Pharma	• Cardiome/Astellas • Orion/Abbott • Medtronic • Bristol Myers Squibb • Sanofi-Aventis • Organon/Sanofi-Aventis	None	None

This table represents the relationships of committee members with industry that were reported by the peer reviewers as relevant to this topic. It does not necessarily reflect relationships with industry at the time of publication.