PRACTICE GUIDELINE: FOCUSED UPDATE

ACC/AHA 2008 Guideline Update on Valvular Heart Disease: Focused Update on Infective Endocarditis

A Report of the American College of Cardiology/American Heart Association Task Force on Practice Guidelines

Endorsed by the Society of Cardiovascular Anesthesiologists, Society for Cardiovascular Angiography and Interventions, and Society of Thoracic Surgeons

2008 Writing Group to Review New Evidence and Update the ACC/AHA 2006 Guidelines for the Management of Patients With Valvular Heart Disease, Writing on Behalf of the 2006 Valvular Heart Disease Writing Committee

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This document is a limited update to the 2006 guideline update and is based on a review of certain evidence, not a full literature review.

This document was approved by the American College of Cardiology Foundation Board of Trustees and by the American Heart Association Science Advisory and Coordinating Committee in May 2008.

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A primary challenge in the development of clinical practice guidelines is keeping pace with the stream of new data upon which recommendations are based. In an effort to respond more quickly to new evidence, the American College of Cardiology/American Heart Association (ACC/AHA) Task Force on Practice Guidelines has created a new “focused update” process to revise the existing guideline recommendations that are affected by the evolving data or opinion. Prior to the initiation of this focused approach, periodic updates and revisions of existing guidelines required up to 3 years to complete. Now, however, new evidence will be reviewed in an ongoing fashion to more efficiently respond to important science and treatment trends that could have a major impact on patient outcomes and quality of care. Evidence will be reviewed at least twice a year, and updates will be initiated on an as needed basis as quickly as possible, while maintaining the rigorous methodology that the ACC and AHA have developed during their more than 20 years of partnership.

These updated guideline recommendations reflect a consensus of expert opinion after a thorough review primarily of late-breaking clinical trials identified through a broad-based vetting process as important to the relevant patient population—breaking clinical trials identified through a broad-based consensus of expert opinion after a thorough review primarily of data outside North America. As such, drugs that are not currently available in North America are discussed in the text without a specific discussion of need for consistency with a new guideline or guideline revision.

In analyzing the data and developing updated recommendations and supporting text, the focused update writing group used evidence-based methodologies developed by the ACC/AHA Task Force on Practice Guidelines, which are described elsewhere (1).

The schema for class of recommendation and level of evidence is summarized in Table 1, which also illustrates how the grading system provides an estimate of the size of the treatment effect and an estimate of the certainty of the treatment effect. Note that a recommendation with Level of Evidence B or C does not imply that the recommendation is weak. Many important clinical questions addressed in guidelines do not lend themselves to clinical trials. Although randomized trials may not be available, there may be a very clear clinical consensus that a particular test or therapy is useful and effective. Both the class of recommendation and level of evidence listed in the focused updates are based on consideration of the evidence reviewed in previous iterations of the guideline as well as the focused update. Of note, the implications of older studies that have informed recommendations but have not been repeated in contemporary settings are carefully considered.

The ACC/AHA practice guidelines address patient populations (and health care providers) residing in North America. As such, drugs that are not currently available in North America are discussed in the text without a specific class of recommendation. For studies performed in large numbers of subjects outside of North America, each writing committee reviews the potential impact of different practice patterns and patient populations on the treatment effect and on the relevance to the ACC/AHA target population to determine whether the findings should inform a specific recommendation.
The ACC/AHA practice guidelines are intended to assist health care providers in clinical decision making by describing a range of generally acceptable approaches for the diagnosis, management, and prevention of specific diseases or conditions. The guidelines attempt to define practices that meet the needs of most patients in most circumstances. The ultimate judgment regarding care of a particular patient must be made by the health care provider and patient in light of all the circumstances presented by that patient. Thus, there are circumstances in which deviations from these guidelines may be appropriate. Clinical decision making should consider the quality and availability of expertise in the area where care is provided. These guidelines may be used as the basis for regulatory or payer decisions, but the ultimate goal is quality of care and serving the patient’s best interests.

Prescribed courses of treatment in accordance with these recommendations are only effective if they are followed by the patient. Because lack of patient adherence may adversely affect treatment outcomes, health care providers should make every effort to engage the patient in active participation with prescribed treatment.

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### Table 1. Applying Classification of Recommendations and Level of Evidence

<table>
<thead>
<tr>
<th>LEVEL A</th>
<th>LEVEL B</th>
<th>LEVEL C</th>
</tr>
</thead>
<tbody>
<tr>
<td>Multiple populations evaluated*</td>
<td>Limited populations evaluated*</td>
<td>Very limited populations evaluated*</td>
</tr>
<tr>
<td>Data derived from multiple randomized clinical trials or meta-analyses</td>
<td>Data derived from a single randomized trial or nonrandomized studies</td>
<td>Only consensus opinion of experts, case studies, or standard of care</td>
</tr>
</tbody>
</table>

**Suggested phrases for writing recommendations**

- **Should** should be used with **recommended**
- **Is** is** indicated**
- **Is useful/effective/beneficial**
- **May/might be considered**
- **May/might be reasonable**
- **Usual/is**
- **May/might be uncertain**
- **Is known/unlikely/unlikely**
- **Is not** indicated

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Data available from clinical trials or registries about the usefulness/efficacy in different subpopulations, such as gender, age, history of diabetes, history of prior myocardial infarction, history of heart failure, and prior aspirin use. A recommendation with Level of Evidence B or C does not imply that the recommendation is weak. Many important clinical questions addressed in the guidelines do not lend themselves to clinical trials. Even though randomized trials are not available, there may be a very clear clinical consensus that a particular test or therapy is useful or effective.

*In 2003, the ACC/AHA Task Force on Practice Guidelines developed a list of suggested phrases to use when writing recommendations. All guideline recommendations have been written in full sentences that express a complete thought, such that a recommendation, even if separated and presented apart from the rest of the document (including headings above sets of recommendations), would still convey the full intent of the recommendation. It is hoped that this will increase readers' comprehension of the guidelines and will allow queries at the individual recommendation level.*
The ACC/AHA Task Force on Practice Guidelines makes every effort to avoid any actual, potential, or perceived conflict of interest arising from industry relationships or personal interests of a writing committee member. All writing committee members and peer reviewers were required to provide disclosure statements of all such relationships pertaining to the trials and other evidence under consideration (see Appendixes 1 and 2). Final recommendations were balloted to all writing committee members. Writing committee members with significant (greater than $10,000) relevant relationships with industry were required to recuse themselves from voting on that recommendation. Writing committee members who did not participate are not listed as authors of this focused update.

With the exception of the recommendations presented here, the full guideline remains current. Only the recommendations from the affected section(s) of the full guideline are included in this focused update. For easy reference, all recommendations from any section of a guideline impacted by a change are presented with notation as to whether they remain current, are new, or have been modified. When evidence impacts recommendations in more than 1 set of guidelines, those guidelines are updated concurrently.

The recommendations in this focused update will be considered current until they are superseded by another focused update or the full-text guidelines are revised. This focused update is published in the August 19, 2008, issue of the Journal of the American College of Cardiology and the August 19, 2008, issue of Circulation as an update to the full-text guideline, and is also posted on the ACC (www.acc.org) and AHA (www.americanheart.org) Web sites. A revised version of the 2006 full-text guideline that incorporates the focused update is available on the respective Web sites (2). For easy reference, this online-only version denotes sections that have been updated.

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Chair, ACC/AHA Task Force on Practice Guidelines
Alice K. Jacobs, MD, FACC, FAHA
Vice-Chair, ACC/AHA Task Force on Practice Guidelines

1. Introduction

1.1. Evidence Review

Late-breaking clinical trials presented at the 2005 and 2006 annual scientific meetings of the ACC, AHA, and European Society of Cardiology, as well as selected other data published during the same time period, were reviewed by the standing guideline writing committee along with the parent task force and other experts to identify those trials and other key data that may impact guideline recommendations. On the basis of the criteria/considerations noted above, recent trial data and other clinical data were considered when deciding whether there was evidence important enough to prompt an update of the ACC/AHA 2006 Guidelines for the Management of Patients With Valvular Heart Disease (3).

This focused update of the ACC/AHA 2006 Guidelines for the Management of Patients With Valvular Heart Disease spotlights the 2007 AHA guidelines for infective endocarditis prophylaxis (4). Only recommendations related to infective endocarditis have been revised. Individual recommendations updated in the present focused update will be incorporated into future revisions and/or updates of the full-text guidelines. Policy on clinical areas not covered by the present focused update can be found in the 2008 Focused Update Incorporated Into the ACC/AHA 2006 Guidelines for the Management of Patients With Valvular Heart Disease (2).

1.2. Organization of Committee and Relationships With Industry

For this focused update, all members of the 2006 Valvular Heart Disease Writing Committee were invited to participate; those who agreed (referred to as the 2008 Focused Update Writing Group) were required to disclose all relationships with industry relevant to the data under consideration (1). Each recommendation required a confidential vote by the writing group members before and after external review of the document. Any writing group member with a significant (greater than $10,000) relationship with industry relevant to the recommendation was recused from voting on that recommendation.

1.3. Review and Approval

This document was reviewed by 2 external reviewers nominated by the ACC and 2 external reviewers nominated by the AHA, as well as 3 reviewers from the ACC Foundation’s (ACCF) Congenital Heart Disease and Pediatric Committee, 2 reviewers from the ACCF Cardiovascular Surgery Committee, 5 reviewers from the AHA Heart Failure and Transplant Committee, and 3 reviewers from the Rheumatic Fever, Endocarditis, and Kawasaki Disease Committee. All information about reviewers’ relationships with industry was collected and distributed to the writing committee and is published in this document (see Appendix 2 for details).

This document was approved for publication by the governing bodies of the ACCF and the AHA and endorsed by the Society of Cardiovascular Anesthesiologists, the Society for Cardiovascular Angiography and Interventions, and the Society of Thoracic Surgeons.

2.3. Endocarditis and Rheumatic Fever Prophylaxis

This focused update deals exclusively with the changes in recommendations for antibiotic prophylaxis against infective endocarditis in patients with valvular heart disease (VHD). Treatment considerations in patients with congenital heart disease (CHD) or implanted cardiac devices are reviewed in detail in other publications (5) and the upcoming ACC/AHA guideline for the management of adult patients with CHD. For an in-depth review of the rationale for the recommended changes in the approach to patients with VHD, the reader is referred to the AHA guidelines on prevention of infective endocarditis published online in April 2007 (4).
Infective endocarditis is a serious illness associated with significant morbidity and mortality. Its prevention by the appropriate administration of antibiotics before a procedure expected to produce bacteremia merits serious consideration. Experimental studies have suggested that endothelial damage leads to platelet and fibrin deposition and the formation of nonbacterial thrombotic endocardial lesions. In the presence of bacteremia, organisms may adhere to these lesions and multiply within the platelet-fibrin complex, leading to an infective vegetation. Valvular and congenital abnormalities, especially those associated with high-velocity jets, can result in endothelial damage, platelet-fibrin deposition, and a predisposition to bacterial colonization. Since 1955, the AHA has made recommendations for prevention of infective endocarditis with antimicrobial prophylaxis before specific dental, gastrointestinal (GI), and
genitourinary (GU) procedures in patients at risk for its development. However, many authorities and societies, as well as the conclusions of published studies, have questioned the efficacy of antimicrobial prophylaxis in most situations.

On the basis of these concerns, a writing group was appointed by the AHA for their expertise in prevention and treatment of infective endocarditis, with liaison members representing the American Dental Association, the Infectious Disease Society of America, and the American Academy of Pediatrics. The writing group reviewed the relevant literature regarding procedure-related bacteremia and infective endocarditis, in vitro susceptibility data of the most common organisms that cause infective endocarditis, results of prophylactic studies of animal models of infective endocarditis, and both retrospective and prospective studies of prevention of infective endocarditis. As a result, major changes were made in the recommendations for prophylaxis against infective endocarditis.

The major changes in the updated recommendations included the following:

- The committee concluded that only an extremely small number of cases of infective endocarditis may be prevented by antibiotic prophylaxis for dental procedures even if such prophylactic therapy were 100 percent effective.
- Infective endocarditis prophylaxis for dental procedures is reasonable only for patients with underlying cardiac conditions associated with the highest risk of adverse outcome from infective endocarditis.
- For patients with these underlying cardiac conditions, prophylaxis is reasonable for all dental procedures that involve manipulation of either gingival tissue or the periapical region of teeth or perforation of oral mucosa.
- Prophylaxis is not recommended solely on the basis of an increased lifetime risk of acquisition of infective endocarditis.
- Administration of antibiotics solely to prevent endocarditis is not recommended for patients who undergo a GU or GI tract procedure.

The rationale for these revisions is based on the following:

- Infective endocarditis is more likely to result from frequent exposure to random bacteremias associated with daily activities than from bacteremia caused by a dental, GI tract, or GU procedure.
- Prophylaxis may prevent an exceedingly small number of cases of infective endocarditis (if any) in individuals who undergo a dental, GI tract, or GU procedure.
- The risk of antibiotic-associated adverse effects exceeds the benefit (if any) from prophylactic antibiotic therapy.
- Maintenance of optimal oral health and hygiene may reduce the incidence of bacteremia from daily activities and is more important than prophylactic antibiotics for a dental procedure to reduce the risk of infective endocarditis.

The AHA Prevention of Infective Endocarditis Committee recommended that prophylaxis be given only to a high-risk group of patients before dental procedures that involve manipulation of either gingival tissue or the periapical region of the teeth or perforation of oral mucosa (Tables 2 to 4). High-risk patients were defined as those patients with underlying cardiac conditions associated with the highest risk of adverse outcome from infective endocarditis, not necessarily those with an increased lifetime risk of acquisition of infective endocarditis. Prophylaxis is no longer recommended for prevention of endocarditis for procedures that involve the respiratory tract unless the procedure is performed in a high-risk patient and involves incision of the respiratory tract mucosa, such as tonsillectomy and adenoidectomy. Prophylaxis is no longer recommended for prevention of infective endocarditis for GI or GU procedures, including diagnostic esophagogastroduodenoscopy or colonoscopy (Table 2). However, in high-risk patients with infections of the GI or GU tract, it is reasonable to administer antibiotic therapy to prevent wound infection or sepsis. For high-risk patients undergoing elective cystoscopy or other urinary tract manipulation who have enterococcal urinary tract infection or colonization, antibiotic therapy to eradicate enterococci from the urine before the procedure is reasonable.

These changes are a significant departure from the past AHA (7) and European Society of Cardiology (8) recommendations for prevention of infective endocarditis and may violate longstanding expectations in practice patterns of patients and health care providers. However, the writing committee for these updated guidelines consists of experts in the field of infective endocarditis; input was also obtained from experts not affiliated with the writing group. All data to date were reviewed thoroughly, and the current recommendations reflect analysis of all relevant literature. This multidisciplinary team of experts emphasizes that previously published guidelines for the prevention of endocarditis contained ambiguities and inconsistencies and relied more on opinion than on data. The writing committee delineates

<table>
<thead>
<tr>
<th>Reasonable</th>
<th>Not Recommended</th>
</tr>
</thead>
<tbody>
<tr>
<td>Endocarditis prophylaxis is reasonable for patients with the highest risk of adverse outcomes who undergo dental procedures that involve manipulation of either gingival tissue or the periapical region of teeth or perforation of the oral mucosa.</td>
<td>Endocarditis prophylaxis is not recommended for:</td>
</tr>
<tr>
<td>Routine anesthetic injections through noninfected tissue</td>
<td></td>
</tr>
<tr>
<td>Dental radiographs</td>
<td>Dental prosthetic or orthodontic appliances</td>
</tr>
<tr>
<td>Placement or removal of prosthodontic or orthodontic appliances</td>
<td>Adjustment of orthodontic appliances</td>
</tr>
<tr>
<td>Shedding of deciduous teeth</td>
<td>Placement of orthodontic brackets</td>
</tr>
<tr>
<td>Bleeding from trauma to the lips or oral mucosa</td>
<td></td>
</tr>
</tbody>
</table>

*This table corresponds to Table 6 in the 2008 Focused Update Incorporated Into the ACC/AHA 2006 Guidelines for the Management of Valvular Heart Disease (2). Adapted with permission (6).*
Table 4. Regimens for a Dental Procedure*

<table>
<thead>
<tr>
<th>Situation</th>
<th>Agent</th>
<th>Regimen: Single Dose 30 to 60 min Before Procedure</th>
</tr>
</thead>
<tbody>
<tr>
<td>Oral</td>
<td>Amoxicillin 2 g</td>
<td>Adults: 50 mg/kg Children: IM or IV 50 mg/kg IM or IV</td>
</tr>
<tr>
<td>Unable to take oral medication</td>
<td>Ampicillin 2 g IM or IV</td>
<td></td>
</tr>
<tr>
<td>Cefazolin or ceftriaxone 1 g IM or IV</td>
<td>OR</td>
<td></td>
</tr>
<tr>
<td>Allergic to penicillins or ampicillin—oral</td>
<td>Cephalaxin†‡ 2 g</td>
<td></td>
</tr>
<tr>
<td>OR</td>
<td>Clindamycin 600 mg</td>
<td></td>
</tr>
<tr>
<td>Cefazolin or ceftriaxone‡ 1 g IM or IV</td>
<td>OR</td>
<td></td>
</tr>
<tr>
<td>Clindamycin 600 mg IM or IV</td>
<td>OR</td>
<td></td>
</tr>
</tbody>
</table>

*This table corresponds to Table 7 in the 2008 Focused Update Incorporated Into the ACC/AHA 2006 Guidelines for the Management of Valvular Heart Disease (2). †Or use other first- or second-generation oral cephalosporin in equivalent adult or pediatric dosage. ‡Cephalosporins should not be used in an individual with a history of anaphylaxis, angioedema, or urticaria with penicillins or ampicillin.

<table>
<thead>
<tr>
<th>Situation</th>
<th>Agent</th>
<th>Regimen: Single Dose 30 to 60 min Before Procedure</th>
</tr>
</thead>
<tbody>
<tr>
<td>Allergic to penicillins or ampicillin and unable to take oral medication</td>
<td>Cefazolin or ceftriaxone 500 mg</td>
<td></td>
</tr>
<tr>
<td>OR</td>
<td>Clindamycin 600 mg IM or IV</td>
<td></td>
</tr>
</tbody>
</table>

IM indicates intramuscular; and IV, intravenous.

The reasons with which evolutionary refinement in the approach to infective endocarditis prophylaxis can be justified. In determining which patients receive prophylaxis, there is a clear focus on the risk of adverse outcomes after infective endocarditis rather than the lifetime risk of acquisition of infective endocarditis. The current recommendations result in greater clarity for patients, health care providers, and consulting professionals.

Other international societies have published recommendations and guidelines for the prevention of infective endocarditis. New recommendations from the British Society for Antimicrobial Chemotherapy are similar to the current AHA recommendations for prophylaxis before dental procedures. The British Society for Antimicrobial Chemotherapy did differ in continuing to recommend prophylaxis for high-risk patients before GI or GU procedures associated with bacteremia or endocarditis (9).

Therefore, Class IIa indications for prophylaxis against infective endocarditis are reasonable for VHD patients at highest risk for adverse outcomes from infective endocarditis before dental procedures that involve manipulation of either gingival tissue. This high-risk group includes: 1) patients with a prosthetic heart valve or prosthetic material used for valve repair, 2) patients with a past history of infective endocarditis, and 3) patients with cardiac valvulopathy after cardiac transplantation, as well as 4) specific patients with CHD (Table 2). Patients with innocent murmurs and those patients who have abnormal echocardiographic findings without an audible murmur should definitely not be given prophylaxis for infective endocarditis. Infective endocarditis prophylaxis is not necessary for nondental procedures that do not penetrate the mucosa, such as transesophageal echocardiography, diagnostic bronchoscopy, esophagogastroscopy, or colonoscopy, in the absence of active infection.

The committee recognizes that decades of previous recommendations for patients with most forms of VHD and other conditions have been abruptly changed by the new AHA guidelines (4). Because this may cause consternation among patients, clinicians should be available to discuss the rationale for these new changes with their patients, including the lack of scientific evidence to demonstrate a proven benefit for infective endocarditis prophylaxis. In select circumstances, the committee also understands that some clinicians and some patients may still feel more comfortable continuing with prophylaxis for infective endocarditis, particularly for those with bicuspid aortic valve or coarctation of the aorta, severe mitral valve prolapse, or hypertrophic obstructive cardiomyopathy. In those settings, the clinician should determine that the risks associated with antibiotics are low before continuing a prophylaxis regimen. Over time, and with continuing education, the committee anticipates increasing acceptance of the new guidelines among both provider and patient communities.

A multicenter randomized, controlled trial has never been performed to evaluate the efficacy of infective endocarditis prophylaxis in patients who undergo dental, GI, or GU procedures. On the basis of these new recommendations, fewer patients will receive infective endocarditis prophylaxis. It is hoped that the revised recommendations will stimulate properly designed prospective studies on the prevention of infective endocarditis.

Tables 5 and 8 of the 2006 Valvular Heart Disease Guideline (3) are now obsolete. Please disregard these tables.

3.1.4.4. AORTIC STENOSIS: MEDICAL THERAPY

Antibiotic prophylaxis is no longer indicated in patients with aortic stenosis for prevention of infective endocarditis.
3.4.3.1. MITRAL STENOSIS: MEDICAL THERAPY
Antibiotic prophylaxis is no longer indicated in patients with mitral stenosis for prevention of infective endocarditis.

3.5.2. Evaluation and Management of the Asymptomatic Patient With Mitral Valve Prolapse
Antibiotic prophylaxis is no longer indicated in all patients with mitral valve prolapse for prevention of infective endocarditis.

3.5.3. Evaluation and Management of the Symptomatic Patient With Mitral Valve Prolapse
Antibiotic prophylaxis is no longer indicated in all patients with mitral valve prolapse for prevention of infective endocarditis.

6. Management of Congenital Valvular Heart Disease in Adolescents and Young Adults
Antibiotic prophylaxis is no longer indicated in the adolescent and young adult with native heart valve disease for prevention of infective endocarditis.

6.6.3. Indications for Balloon Valvotomy in Pulmonic Stenosis
Antibiotic prophylaxis is no longer indicated in the adolescent and young adult with native heart valve disease for prevention of infective endocarditis.

Staff

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APPENDIX 1. AUTHOR RELATIONSHIPS WITH INDUSTRY—ACC/AHA 2008 GUIDELINE UPDATE ON VALVULAR HEART DISEASE: FOCUSED UPDATE ON INFECTIVE ENDOCARDITIS WRITING COMMITTEE

<table>
<thead>
<tr>
<th>Committee Member</th>
<th>Consultant</th>
<th>Speakers’ Bureau/Honoraria</th>
<th>Ownership/Partnership/Principal</th>
<th>Research</th>
<th>Institutional, Organizational, or Other Financial Benefit</th>
<th>Expert Witness</th>
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</thead>
<tbody>
<tr>
<td>Dr. Rick A. Nishimura</td>
<td>None</td>
<td>None</td>
<td>None</td>
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<td>Dr. Blase A. Carabello</td>
<td>None</td>
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<td>Dr. David P. Faxon</td>
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<td>Dr. Michael D. Freed</td>
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<td>Dr. Bruce W. Lytle</td>
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<td>None</td>
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<td>Dr. Patrick T. O’Gara</td>
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<tr>
<td>Dr. Robert A. O’Rourke</td>
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<tr>
<td>Dr. Pravin M. Shah</td>
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This table represents the relationships of committee members with industry 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 in this table are modest unless otherwise noted.
### APPENDIX 2. PEER REVIEWER RELATIONSHIPS WITH INDUSTRY—ACC/AHA 2008 GUIDELINE UPDATE ON VALVULAR HEART DISEASE: FOCUSED UPDATE ON INFECTIVE ENDOCARDITIS

<table>
<thead>
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<td>Dr. Ann F. Bolger</td>
<td>Official AHA Reviewer</td>
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<td>Dr. Paul L. Douglass</td>
<td>Official Reviewer—ACCF Board of Trustees</td>
<td>Aventis</td>
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### REFERENCES


**Key Words:** ACC/AHA practice guideline • focused update • valvular heart disease • infective endocarditis • prophylaxis.