

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.

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Preamble

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, and of other new data deemed to have an impact on patient care (see Section 1.1 “Evidence Review” for details regarding this focused update). It is important to note that this focused update is not intended to represent an update based on a full literature review from the date of the previous guideline publication. Specific criteria/considerations for inclusion of new data include:

- Publication in a peer-reviewed journal
- Large randomized, placebo-controlled trial(s)

- Nonrandomized data deemed important on the basis of results impacting current safety and efficacy assumptions
- Strength/weakness of research methodology and findings
- Likelihood of additional studies influencing current findings
- Impact on current performance measure(s) and/or likelihood of need to develop new performance measure(s)
- Requests and requirements for review and update from the practice community, key stakeholders, and other sources free of relationships with industry or other potential bias
- Number of previous trials showing consistent results
- 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

Table 1. Applying Classification of Recommendations and Level of Evidence

		SIZE OF TREATMENT EFFECT ➔			
		CLASS I <i>Benefit >>> Risk</i> Procedure/Treatment SHOULD be performed/administered	CLASS IIa <i>Benefit >> Risk</i> <i>Additional studies with focused objectives needed</i> IT IS REASONABLE to perform procedure/administer treatment	CLASS IIb <i>Benefit ≥ Risk</i> <i>Additional studies with broad objectives needed; additional registry data would be helpful</i> Procedure/Treatment MAY BE CONSIDERED	CLASS III <i>Risk ≥ Benefit</i> Procedure/Treatment should NOT be performed/administered SINCE IT IS NOT HELPFUL AND MAY BE HARMFUL
ESTIMATE OF CERTAINTY (PRECISION) OF TREATMENT EFFECT	LEVEL A Multiple populations evaluated* Data derived from multiple randomized clinical trials or meta-analyses	<ul style="list-style-type: none"> ■ Recommendation that procedure or treatment is useful/effective ■ Sufficient evidence from multiple randomized trials or meta-analyses 	<ul style="list-style-type: none"> ■ Recommendation in favor of treatment or procedure being useful/effective ■ Some conflicting evidence from multiple randomized trials or meta-analyses 	<ul style="list-style-type: none"> ■ Recommendation's usefulness/efficacy less well established ■ Greater conflicting evidence from multiple randomized trials or meta-analyses 	<ul style="list-style-type: none"> ■ Recommendation that procedure or treatment is not useful/effective and may be harmful ■ Sufficient evidence from multiple randomized trials or meta-analyses
	LEVEL B Limited populations evaluated* Data derived from a single randomized trial or nonrandomized studies	<ul style="list-style-type: none"> ■ Recommendation that procedure or treatment is useful/effective ■ Evidence from single randomized trial or nonrandomized studies 	<ul style="list-style-type: none"> ■ Recommendation in favor of treatment or procedure being useful/effective ■ Some conflicting evidence from single randomized trial or nonrandomized studies 	<ul style="list-style-type: none"> ■ Recommendation's usefulness/efficacy less well established ■ Greater conflicting evidence from single randomized trial or nonrandomized studies 	<ul style="list-style-type: none"> ■ Recommendation that procedure or treatment is not useful/effective and may be harmful ■ Evidence from single randomized trial or nonrandomized studies
	LEVEL C Very limited populations evaluated* Only consensus opinion of experts, case studies, or standard of care	<ul style="list-style-type: none"> ■ Recommendation that procedure or treatment is useful/effective ■ Only expert opinion, case studies, or standard of care 	<ul style="list-style-type: none"> ■ Recommendation in favor of treatment or procedure being useful/effective ■ Only diverging expert opinion, case studies, or standard of care 	<ul style="list-style-type: none"> ■ Recommendation's usefulness/efficacy less well established ■ Only diverging expert opinion, case studies, or standard of care 	<ul style="list-style-type: none"> ■ Recommendation that procedure or treatment is not useful/effective and may be harmful ■ Only expert opinion, case studies, or standard of care
Suggested phrases for writing recommendations [†]		should is recommended is indicated is useful/effective/beneficial	is reasonable can be useful/effective/beneficial is probably recommended or indicated	may/might be considered may/might be reasonable usefulness/effectiveness is unknown/unclear/uncertain or not well established	is not recommended is not indicated should not is not useful/effective/beneficial may be harmful

*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.

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.

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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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 ACC/AHA 2006 Guidelines for the Management of Patients With Valvular Heart Disease, With the 2008 Focused Update Incorporated.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 publications⁵ 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

2.3.1. Endocarditis Prophylaxis

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 AHA⁷ and European Society of Cardiology⁸ 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 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, esophagogastrosocopy, or colonoscopy, in the absence of active infection.

Table 2. Updates to Section 2.3.1. Endocarditis Prophylaxis

2006 VHD Guideline Recommendations	2008 VHD Focused Update Recommendations	Comments
Class I	Class IIa	
<p>1. Prophylaxis against infective endocarditis is recommended for the following patients:</p> <ul style="list-style-type: none"> • Patients with prosthetic heart valves and patients with a history of infective endocarditis. (<i>Level of Evidence: C</i>) • Patients who have complex cyanotic congenital heart disease (e.g., single-ventricle states, transposition of the great arteries, tetralogy of Fallot). (<i>Level of Evidence: C</i>) • Patients with surgically constructed systemic pulmonary shunts or conduits. (<i>Level of Evidence: C</i>) • Patients with congenital cardiac valve malformations, particularly those with bicuspid aortic valves, and patients with acquired valvular dysfunction (e.g., rheumatic heart disease). (<i>Level of Evidence: C</i>) • Patients who have undergone valve repair. (<i>Level of Evidence: C</i>) • Patients who have hypertrophic cardiomyopathy when there is latent or resting obstruction. (<i>Level of Evidence: C</i>) • Patients with MVP and auscultatory evidence of valvular regurgitation and/or thickened leaflets on echocardiography.* (<i>Level of Evidence: C</i>) 	<p>1. Prophylaxis against infective endocarditis is reasonable for the following patients at highest risk for adverse outcomes from infective endocarditis who undergo dental procedures that involve manipulation of either gingival tissue or the periapical region of teeth or perforation of the oral mucosa⁴:</p> <ul style="list-style-type: none"> • Patients with prosthetic cardiac valves or prosthetic material used for cardiac valve repair. (<i>Level of Evidence: B</i>) • Patients with previous infective endocarditis. (<i>Level of Evidence: B</i>) • Patients with CHD. (<i>Level of Evidence: B</i>) <ul style="list-style-type: none"> • Unrepaired cyanotic CHD, including palliative shunts and conduits. (<i>Level of Evidence: B</i>) • Completely repaired congenital heart defect repaired with prosthetic material or device, whether placed by surgery or by catheter intervention, during the first 6 months after the procedure. (<i>Level of Evidence: B</i>) • Repaired CHD with residual defects at the site or adjacent to the site of a prosthetic patch or prosthetic device (both of which inhibit endothelialization). (<i>Level of Evidence: B</i>) • Cardiac transplant recipients with valve regurgitation due to a structurally abnormal valve. (<i>Level of Evidence: C</i>) 	Modified recommendation (changed class of recommendation from I to IIa, changed text). There are no Class I recommendations for infective endocarditis prophylaxis.
	Class III	
<p>1. Prophylaxis against infective endocarditis is not recommended for the following patients:</p> <ul style="list-style-type: none"> • Patients with isolated secundum atrial septal defect. (<i>Level of Evidence: C</i>) • Patients 6 or more months after successful surgical or percutaneous repair of atrial septal defect, ventricular septal defect, or patent ductus arteriosus. (<i>Level of Evidence: C</i>) • Patients with MVP without MR or thickened leaflets on echocardiography.* (<i>Level of Evidence: C</i>) • Patients with physiological, functional, or innocent heart murmurs, including patients with aortic valve sclerosis as defined by focal areas of increased echogenicity and thickening of the leaflets without restriction of motion and a peak velocity less than 2.0 m per second. (<i>Level of Evidence: C</i>) • Patients with echocardiographic evidence of physiologic MR in the absence of a murmur and with structurally normal valves. (<i>Level of Evidence: C</i>) • Patients with echocardiographic evidence of physiological TR and/or pulmonary regurgitation in the absence of a murmur and with structurally normal valves. (<i>Level of Evidence: C</i>) 	<p>1. Prophylaxis against infective endocarditis is not recommended for nondental procedures (such as transesophageal echocardiogram, esophagogastroduodenoscopy, or colonoscopy) in the absence of active infection. (<i>Level of Evidence: B</i>)⁴</p>	Modified recommendation (changed text)

*This footnote is obsolete. Please see 2006 VHD Guideline³ for footnote text.
MR indicates mitral regurgitation; MVP, mitral valve prolapse; and TR, tricuspid regurgitation.

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

Table 3. Endocarditis Prophylaxis for Dental Procedures*

Reasonable	Not Recommended
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.	Endocarditis prophylaxis is not recommended for: <ul style="list-style-type: none"> • Routine anesthetic injections through noninfected tissue • Dental radiographs • Placement or removal of prosthodontic or orthodontic appliances • Adjustment of orthodontic appliances • Placement of orthodontic brackets • Shedding of deciduous teeth • Bleeding from trauma to the lips or oral mucosa

*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

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 Guideline³ 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.

Table 4. Regimens for a Dental Procedure*

Situation	Agent	Regimen: Single Dose 30 to 60 min Before Procedure	
		Adults	Children
Oral	Amoxicillin	2 g	50 mg/kg
Unable to take oral medication	Ampicillin	2 g IM or IV	50 mg/kg IM or IV
	OR		
	Cefazolin or ceftriaxone	1 g IM or IV	50 mg/kg IM or IV
Allergic to penicillins or ampicillin—oral	Cephalexin†‡	2 g	50 mg/kg
	OR		
	Clindamycin	600 mg	20 mg/kg
	OR		
	Azithromycin or clarithromycin	500 mg	15 mg/kg
Allergic to penicillins or ampicillin and unable to take oral medication	Cefazolin or ceftriaxone‡	1 g IM or IV	50 mg/kg IM or IV
	OR		
	Clindamycin	600 mg IM or IV	20 mg/kg IM or IV

IM indicates intramuscular; and IV, intravenous.

*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.

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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

Committee Member	Consultant	Speakers' Bureau/ Honoraria	Ownership/ Partnership/ Principal	Research	Institutional, Organizational, or Other Financial Benefit	Expert Witness
Dr. Rick A. Nishimura	None	None	None	None	None	None
Dr. Blase A. Carabello	None	None	None	None	None	None
Dr. David P. Faxon	<ul style="list-style-type: none"> • Boston Scientific • Bristol-Myers Squibb • GlaxoSmithKline • Johnson & Johnson 	None	None	None	None	None
Dr. Michael D. Freed	None	None	None	None	None	None
Dr. Bruce W. Lytle	None	None	None	None	None	None
Dr. Patrick T. O'Gara	None	None	None	None	None	None
Dr. Robert A. O'Rourke	None	None	None	None	None	None
Dr. Pravin M. Shah	<ul style="list-style-type: none"> • Edwards LifeSciences 	None	None	None	None	None

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

Peer Reviewer*	Representation	Consultant	Speakers' Bureau/ Honoraria	Ownership/ Partnership/ Principal	Research	Institutional, Organizational, or Other Financial Benefit	Expert Witness
Dr. Ann F. Bolger	• Official AHA Reviewer	None	None	None	None	None	None
Dr. Paul L. Douglass	• Official Reviewer— ACCF Board of Trustees	• Aventis • Merck • Novartis	• Bayer Healthcare • Bristol-Myers Squibb • Pfizer	None	None	None	None
Dr. Timothy J. Gardner	• Official AHA Reviewer	None	None	None	None	None	None
Dr. Chittur A. Sivaram	• Official Reviewer— ACCF Board of Governors	None	None	None	None	None	None
Dr. David Aguilar	• Content Reviewer— AHA Heart Failure & Transplant Committee	None	None	None	None	None	None
Dr. Larry M. Baddour	• Content Reviewer— AHA Rheumatic Fever, Endocarditis, & Kawasaki Disease Committee	• American College of Physicians • Enturia • UpToDate	None	None	None	None	None
Dr. Louis I. Bezold	• Content Reviewer— ACC Congenital Heart Disease & Pediatric Committee	None	None	None	None	None	None
Dr. Robert O. Bonow	• Content Reviewer— 2006 Writing Committee Chair	None	None	None	None	None	None
Dr. A. Michael Borkon	• Content Reviewer— ACC Cardiovascular Surgery Committee	None	None	None	None	None	None
Dr. Jeffrey A. Feinstein	• Content Reviewer— ACC Congenital Heart Disease & Pediatric Committee	None	None	None	None	None	None
Dr. Gary S. Francis	• Content Reviewer— AHA Heart Failure & Transplant Committee	• Boehringer Ingelheim • Johnson & Johnson • NitroMed • Novartis • Otsuka	None	None	• National Institutes of Health† • Pfizer†	None	None
Dr. Wayne L. Miller	• Content Reviewer— AHA Heart Failure & Transplant Committee	None	None	None	None	None	None
Dr. Judith E. Mitchell	• Content Reviewer— AHA Heart Failure & Transplant Committee	• Astellas • GlaxoSmithKline • NitroMed	None	None	None	None	None
Dr. John B. O'Connell	• Content Reviewer— AHA Heart Failure & Transplant Committee	None	None	None	None	None	None

(Continued)

Appendix 2. Continued

Peer Reviewer*	Representation	Consultant	Speakers' Bureau/Honoraria	Ownership/Partnership/Principal	Research	Institutional, Organizational, or Other Financial Benefit	Expert Witness
Dr. Geoffrey L. Rosenthal	• Content Reviewer—ACC Congenital Heart Disease & Pediatric Committee	None	None	None	None	None	None
Dr. Anne Rowley	• Content Reviewer—AHA Rheumatic Fever, Endocarditis, & Kawasaki Disease Committee	None	None	None	None	None	None
Dr. Hartzell V. Schaff	• Content Reviewer—ACC Cardiovascular Surgery Committee	None	None	None	<ul style="list-style-type: none"> • AtriCure • Bolton Medical • Jarvik Heart • Medtronic • Sorin Group/Carbomedics • St. Jude • Thoratec • W.L. Gore and Associates 	<ul style="list-style-type: none"> • Sorin Group† • St. Jude† 	None
Dr. Kathryn A. Taubert	• Content Reviewer—AHA Rheumatic Fever, Endocarditis, & Kawasaki Disease Committee	None	None	None	None	None	None

This table represents the relationships with industry that were disclosed at the time of peer review. It does not necessarily reflect relationships with industry at the time of publication. A person is deemed to have a significant interest in a business if the interest represents ownership of 5% or more of the voting stock or share of the business entity, or ownership of \$10 000 or more of the fair market value of the business entity; or if funds received by the person from the business entity exceed 5% of the person's gross income for the previous year. A relationship is considered to be modest if it is less than significant under the preceding definition. Relationships in this table are modest unless otherwise noted.

*Names are listed in alphabetical order within each category of review.

†Significant (greater than \$10 000) relationship.

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