



EASTERN DENTISTS INSURANCE COMPANY

Clinical Dentistry Advisor

Update 2011: Guidelines for the Prescription of Antibiotic Prophylaxis

NOTE FROM EDIC:

This Clinical Dentistry Advisor is a reprint of an article and of the charts first published by Eastern Dentists Insurance Company (EDIC) shortly after the revised American Heart Association's Recommendations for Prevention of Infective Endocarditis were published in the June 2007 edition of the Journal of the American Dental Association. These recommendations are still in effect today. EDIC has received numerous requests for reprints of this Clinical Dental Advisory, which is why we are re-publishing this piece.

Dentists should be aware, however, that in February 2009, the American Academy of Orthopedic Surgeons issued an Information Statement¹ slightly altering their antibiotic prophylaxis recommendations for patients with total joint replacements. The Orthopedic surgeons now recommend lifetime coverage for those patients with joint replacements.

EDIC would advise its dentists to discuss the need for antibiotics with a patient who has had a joint replacement, and then consult with the patient's Orthopedic surgeon to determine the correct guideline to follow.

¹ Information Statement 1033, February 2009 American Academy of Orthopedic Surgeons, Revised June 2010

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On March 7th, 2007, the American Heart Association Science Advisory and Coordinating Committee approved new guidelines for the prescription of antibiotic prophylaxis. The AHA appointed a writing group, comprising members of the Rheumatic Fever, Endocarditis and Kawasaki Disease Committee of the AHA, the Council on Cardiovascular Disease in the Young, the Council on Clinical Cardiology, the Council on Cardiovascular Surgery and Anesthesia and the Quality of Care and Outcomes Research Interdisciplinary Working Group. Liaison members from the ADA, the Infectious Diseases Society of America and the American Academy of Pediatrics contributed as well.

The last version of the guidelines was published in 1997. The new guidelines are a dramatic departure from the previous guidelines that have evolved since 1955. The writing group effected an extensive literature review spanning from 1950 to 2006. Evidence, or lack thereof, was assessed using classifications of recommendation and levels of evidence from the American College of Cardiology and the AHA. Finally, the paper was revised by an outside group of international experts not affiliated with the AHA committee. The review aimed to define more clearly when IE prophylaxis is or is not recommended and to provide more uniform and consistent global recommendations.

These changes do not affect the recommendations for the protection of patients at risk for hematogenous joint infection. That protocol remains unchanged and there are no plans to change the regimen at the time of this publication.

MAJOR CHANGES

The committee concluded that:

- Only an extremely small number of IE cases might be prevented by antibiotic prophylaxis, even if this therapy were 100% effective.
- Bacteremia resulting from daily activities is much more likely to cause IE than bacteremia associated to a dental procedure.
- IE prophylaxis for dental procedures should only be administered to patients with underlying cardiac conditions that have the highest risk of adverse outcome from IE.
- For those patients only, prophylaxis is recommended for all dental procedures that involve manipulation of the gingival tissue, the periapical region of the teeth, or the perforation of the oral mucosa.
- Prophylaxis is no longer recommended for the limited condition of an increased lifetime risk of acquiring IE.
- Antibiotics to prevent IE are no longer recommended for GU or GI procedures.

Rationale for Revising the 1997 Guidelines

The previous recommendations for antibiotic prophylaxis were mostly based on expert opinion, and "what seemed to be a prudent attempt to prevent a life threatening infection."

The principles that guided the previous recommendations were:

1. IE is not a common disease but is life threatening and prevention is better than treating an existing IE.

2. Certain cardiac conditions predispose acquiring IE.
3. Organisms known to cause IE are commonly found in bacteremia following invasive treatment, GI or GU tract procedures.
4. Antibiotic prophylaxis successfully prevented IE in animal studies.
5. Antibiotic prophylaxis "was thought" to be effective for the prevention of IE in those aforementioned procedures.

While the ADA sustains the first four principles, it states that the fifth principle is now questionable. The authors agree that the reasons for applying the previous guidelines remain valid, yet they state that "collectively, these reasons do not compensate for the lack of published data that demonstrated a benefit from prophylaxis."

INFECTIVE ENDOCARDITIS

Abnormal development, multiple diseases, foreign bodies and/or turbulent blood flow can give rise to disruptions in the endothelial lining of the heart. This facilitates the deposition of platelets and fibrin to produce non-bacterial thrombotic endocarditis (NBTE). Colonization of this lesion occurs once bacteria possessing the proper adherence capacity invade the bloodstream. These bacteria further stimulate the aggregation of platelets and fibrin, thus incorporating the bacteria in the lesion.

Bacteria most commonly implicated in IE are Viridans group Streptococci (VgS), Staphylococci, and Enterococci. Other bacteria classified as HACEK (acronym for Haemophilus, Actinobacillus, Cardiobacterium, Eikenella and Kingella) as well as occasional fungi have been implicated in past literature. Mediators of adherence for these bacteria serve as virulence factors in the development of IE. Adherence factors also interact with the matrix proteins deposited on implanted medical devices, effectively forming a biofilm on the devices. Location of adherence may affect the virulence depending also on host response.

The authors state that VgS cause at least 50% of cases of community acquired native valve IE (not associated with IV drug use). VgS populate about 30% of the oral flora of the gingival crevice and are also the most prevalent of the more than 100 oral bacteria species recovered from blood cultures following dental procedures. It is also later stated that VgS are antagonistic to periodontal pathogens and predominate in a clean, healthy mouth.

BACTEREMIA AND DENTAL PROCEDURES

The reported frequencies of bacteremia following a dental procedure vary widely from 9-32% for rubber dam or wedge placement to 10-100% for extractions. Daily activities have frequencies reported from 20-68% with brushing and flossing, to 7-51% with chewing food. There is no evidence-based study to confirm which procedures are more likely associated with a transient bacteremia or produce a bacteremia of greater magnitude, nor is there confirmation that the incidence, magnitude or duration of bacteremia post-procedure leads to IE.

Only a few studies have quantified the magnitude of

bacteremia, and most of those are said to be unreliable. Yet, it appears from at least three studies that the magnitude of the bacteremia following a dental procedure is similar to that following daily routine activities and less than that used to cause IE in animal experiments. The infective dose required to cause IE in humans is not known, however. The assertion is made nonetheless that: "Cases of IE caused by oral bacteria probably results from the exposures to low inocula of bacteria in the bloodstream resulting from daily activities and not from a dental procedure." This also takes into account that most individuals see their dentist on average twice a year and that most patients with IE had not had a dental procedure in more than 2 weeks.

The duration of the bacteremia in the studies is reported from anywhere between 10 minutes to over an hour. No study exists to demonstrate that a longer duration causes IE. The authors state: "There may not be a clinically significant difference in the frequency, nature, magnitude and duration of bacteremia associated with a dental procedure compared with that resulting from routine daily activities." Following the rationale that it would be impractical to cover all patients with antibiotics for routine activities, it is recommended to discontinue covering many categories of patients who were previously subject to antibiotic coverage.

The Need to Emphasize Good Dental Hygiene

The authors also question how poor oral hygiene and the extent of pre-existing oral disease relate to the type of procedure and to the frequency, nature, magnitude and duration of the bacteremia present afterward. It is stated that evidence supports emphasizing good oral hygiene habits and maintaining good oral health to decrease the frequency of bacteremia from routine daily activities. Moreover, the authors contend that the previous guidelines have led to "an over-emphasis on antibiotic prophylaxis and an under-emphasis on maintenance of good oral hygiene and access to routine dental care which are likely more important in reducing the lifetime risk of IE than is the administration of antibiotic prophylaxis for a dental procedure. However, there are no observational or controlled studies to support this contention."

The authors report that the yearly exposure to bacteremia from routine daily activities may be as much as 5.6 million times more than exposure resulting from a single dental extraction. They add that these exposure rates are estimates at best and infer that even the procedure most likely to produce the bacteremia of the greatest magnitude would not be adding much to the lifetime exposure of a given patient.

The Risk from Dental Procedures

A precise determination of the relative risk of bacteremia following specific dental procedures is not possible. While it was thought that bleeding was a determining factor in developing IE, there is no data confirming that visible bleeding during a dental procedure is a reliable predictor for bacteremia and IE.

Some recent studies have shown that amoxicillin was effective in reducing the incidence, nature and duration of the bacteremia, but did not eliminate it all together. Other studies

show no statistical difference in frequency or magnitude 10 minutes post-procedure with penicillin or ampicillin. No data confirms whether amoxicillin could avoid IE.

While the authors repeatedly mention the need for double-blind placebo controlled studies, it would be surprising that such a study model would be accepted as ethical. This may depend on who leads and funds the study. The lack of such study makes the evaluation and standardization of a regimen for a given procedure in the presence of a given pathology difficult.

The authors mention studies, many of them European, that corroborate the idea that dental procedures are not a risk factor in developing IE and that very few cases of IE would be prevented by prescribing prophylaxis. As a support to this statement, a study by Van der Meer is cited as estimating that up to 25% of cases of IE occurred despite prophylaxis in patients for whom prophylaxis was recommended. The same study however reports that 10-20% of patients with IE caused by oral flora had undergone a procedure within 30-180 days of onset of IE symptoms. This later statistic is dismissed as largely circumstantial and overestimated as most cases are reported to have an onset of 7-14 days. The longest onset time is not known but it is felt that many cases were over-reported as having been attributable to a dental procedure that occurred too remotely in the past.

Estimated risks from a dental procedure are listed per underlying cardiac condition:

- Mitral valve prolapse (MVP) - 1/1.1million procedures
- Congenital Heart Disease (CHD) - 1/475,000 procedures
- Rheumatic Heart Disease RHD - 1/142,000 procedures
- Prosthetic valve - 1/114,000 procedures
- Previous IE - 1/95,000 dental procedures

These risks are categorized as "exceedingly small, and given the fact that an antibiotic may not be 100% effective, prophylaxis may not prevent IE."

CARDIAC CONDITIONS AND ENDOCARDITIS

The 1997 recommendations according to risk levels no longer apply.

Antibiotic prophylaxis is now recommended for conditions with the highest risk of adverse outcome. In native valve IE, the disease can progress from relative benign infection, to valvular dysfunction, congestive heart failure, embolic events and death. In a patient with a prosthetic valve or with a previous episode of IE, there is an increased need for valve replacement surgery. A stated example is that the mortality rate for VgS IE in a patient with a prosthetic valve rises to 20%. The authors reiterate that the effectiveness of prophylaxis in those patients is not known but that such a precaution "may be reasonable."

MVP has supplanted RHD as the most common underlying pathology in patients with IE in developed countries. Both conditions can present with various degree of pathology thus affecting the risk of acquisition of IE. The same can be said for CHD, further complicated by the fact that treatments increasingly include various intracardiac valvular prostheses,

intravascular shunts, grafts and devices. Patients with CHD appear to have the highest risk for morbidity and mortality. Prophylaxis is recommended during the first 6 months postoperatively, to allow for endothelialization of the prosthetic material. No further prophylaxis is recommended provided there is no residual effect postoperatively.

While all these conditions are known to be associated with an increased lifetime risk of acquisition for IE, the assertion is made that "a growing body of evidence ... suggests that IE prophylaxis may prevent only an exceedingly small number of cases of IE.... Antibiotic prophylaxis is no longer recommended based solely on an increased lifetime risk of acquisition of IE." MVP patients are no longer listed as recommended for prescription of antibiotic prophylaxis, no matter if they present with abnormal leaflets or regurgitation.

Co-morbid factors such as immuno suppressive pathologies and treatments, age and diabetes to name a few, may increase the risk of adverse outcome (i.e. morbidity and mortality rates) for IE.

REGIMEN

The regimen still calls for a single dose administration of antibiotic before the procedure. Only if the dose is inadvertently not given prior a procedure, may the dose be given up to 2 hours post procedure.

A patient presenting with fever should have blood cultures drawn before any procedure to rule out the fact that the patient may have a coincidental endocarditis.

Please see the companion reference card to this article for a list of indications and non-indications for prophylaxis.

The new guidelines address one recurring and fundamental issue: The rate at which multi-drug resistant VgS and Enterococci have developed in the past 20 years is alarming. This makes IE more difficult to treat. One study reports that bacterial resistance for clindamycin has gone from 0% to 4%, for penicillin from 0% to 13% and for macrolides from 11% to 26%. Another study rated resistance to cephalexin at 96%. King reports that the percentage of resistance to erythromycin of Streptococci went from 41% to 82% after one course of azithromycin and 71% after clindamycin. These studies are considered as supporting the argument that antibiotic prophylaxis would be of little, if any, value.

Vancomycin and Fluoroquinolone are very active against VgS, but their use is to be avoided, lest we find ourselves without anything to treat IE.

Of interesting note, cephalexin has been maintained in the regimen "even though (it) was less active against VgS than other first generation oral cephalosporins in one study ...No data show superiority on one cephalosporin over another for prevention of IE and generic cephalexin is widely available and is relatively inexpensive."

SPECIAL CONSIDERATIONS

As in previous recommendations, patients already on antibiotics for other conditions should be administered another antibiotic from a different class rather than increasing the dose of the antibiotic they are taking, to avoid treating already resistant bacteria. A period of 10 days post-antibiotic administration is recommended between appointments.

Conversely, if a patient is being treated with parenteral antibiotics, it is stated that the same antibiotic should be continued with the dosage adjusted to be given 30–60 minutes before the dental procedure. It is asserted that in such high doses, "the concentration would overcome any possible low level resistance developed among mouth flora."

Patients who receive anticoagulo therapy should not receive intramuscular antibiotics.

Patients with coronary artery bypass surgery and patients with coronary artery stents are no longer covered by prophylaxis. Heart transplant patients are at higher risk for acquired valvular dysfunction, especially during episodes of rejection. Though no study confirms or negates the effectiveness of antibiotic prophylaxis coverage, it is prescribed for cardiac transplant patients, only once they have developed valvulopathy.

LEGAL AND RISK MANAGEMENT PERSPECTIVE

Some doctors and patients may react to these new guidelines with some insecurity and skepticism. The new guidelines have arisen not so much as a result of new studies proving the ineffectiveness of antibiotic prophylaxis but rather because of lack of evidence of its effectiveness. With no proof one way or another, the question remains that if VgS is the predominant bacteria in the healthy, clean mouth, and if the level of the bacteremia post dental procedure may resemble that of routine activity, would a doctor not want to at least make sure that this healthy patient not risk acquiring IE?

Countering that argument is the real and present threat of rapidly increasing multi-drug resistant bacteria. In stating that the risk of taking the antibiotics outweighs the benefit derived (i.e. protection against IE) from taking them, the reference may not be so much about one individual's risk of adverse reaction (there are no known case of anaphylactic death from the administration of antibiotic prophylaxis for the prevention of IE with dental procedures), but rather the ensuing lack of effectiveness of an antibiotic if it were needed in a life threatening event.

The doctor, in considering the well being of her or his patient, may not feel swayed by what she or he may perceive as a purely statistical or cost-effectiveness based argument. While

most doctors are sensitive to a patient's financial limitations, the decision on which antibiotic to use should be based more on the probability of maximum therapeutic benefit from the medication prescribed than on financial considerations.

The profuse use of words throughout the document such as "may, maybe, likely, probably and estimated" underscores the sense of uncertainty. The authors indeed urge for research to be "designed and instituted promptly," to track any change in incidence. They caution that because the incidence is low, it may take years to notice any change.

The ADA supports the principle of doctors' independent professional judgment in the application of this or any other guideline. Current guidelines are usually cited in litigation. Derogation from guidelines, which can effectively be considered as standard of care in a court of law, must be supported with a rationale reflecting accurate knowledge and interest of the patient.

A situation may arise where the dentist and the physician disagree on the regimen or its application for a given patient. In such situations, discussion of the case with the treating physician is paramount. The physician may indeed be aware of medical factors that may complicate a patient's risk. Also, a patient may have not disclosed her or his full medical history because of a lack of understanding of its relevance to dental treatment, because the patient may have simply forgotten or because the patient may be having difficulty accepting or facing a diagnosis. Documentation is crucial; calls and conversations must be noted in the patient record with time, date and content. Ideally, confirmation in writing (e-mail and fax are acceptable) should be obtained. If confirmations are obtained verbally, they should follow a conversation between both doctors. If disagreement persists, the dentist assumes the decision and the responsibility of its consequences. The dentist must inform the patient of this disagreement and encourage the patient to discuss the issue with the physician.

The patient has the right to autonomous decision making, although she or he should not direct the course of treatment. Informed consent can protect from liability as long as the doctor is acting within the standard of care and has explained the risks and benefits of all options available. The dentist is never obligated to render treatment that she or he deems not to be in the patient's best interest, no matter how strongly the patient may feel about it.

Signed refusals to follow the doctor's recommendations, such as not filling out a medical questionnaire, submitting to a dental examination, agreeing to a consultation or taking prescribed antibiotics will not absolve a dentist from responsibility in case of an adverse event.

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Prevention of Infective Endocarditis. Guidelines From the American Heart Association. A Guideline From the American Heart Association Rheumatic Fever, Endocarditis, and Kawasaki Disease Committee, Council on Cardiovascular Disease in the Young, and the Council on Clinical Cardiology, Council on Cardiovascular Surgery and Anesthesia, and the Quality of Care and Outcomes Research Interdisciplinary Working Group
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Same article adapted on the ADA website, published in JADA June 2007. CDA5/11

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