AAOS
American Academy of Orthopaedic Surgeons

Prevention of Orthopaedic Implant Infection in Patients Undergoing Dental Procedues

Peer Review and Public Commentary with AAOS Responses

Peer Review: February 16, 2012 – March 15, 2012
Public Comment: July 27, 2012 – August 27, 2012

Changes Made to the Confidential Draft of the Guideline on the "Prevention of Orthopaedic Implant Infection in Patients Undergoing Dental Procedures"

Peer Review

February 16, 2012 – March 15, 2012

Line 66 (Summary of Recommendations)
Text was added to further stress that these recommendations should be thoroughly considered with all available patient information in mind.

Line 546 (Burden of Disease And Etiology)
Numbers were updated to be more current. Projections are now for 2020, not 2010.

Table 2 (IOM Systematic Review Standards)
Manage data collection information changed to reflect the data management process in this guideline. 2 independent reviewers were utilized to extract data and appraise the quality of the literature

Lines 826, 1128 (Methods)
Editorial changes made to text for clarity.

Table 10 (High and Low Risk Dental Procedures Defined by Berbari et al.)
Spelling error corrected.

Lines 1434, 1442, 1453, 1454 (Indirect Evidence: Background Microbiology)
Text italicized were appropriate.

Lines 1501-1505 (Recommendations)
Paragraph added before full recommendations to remind the practitioner that these recommendations are not intended to stand alone and that treatment decisions should be made in light of all circumstances presented by the patient.

Line 1572 and following figure and table titles (Results)
Editorial changes made to clarify what is being presented.

Lines 1575-1577 (Results)
Text added to define "network meta-analysis".

Line 1661 (Findings)
Grammatical error corrected.

Line 1674 and following figure and table titles (Results)
Editorial changes made to clarify what is being presented.

Lines 1813-1815 and 1826-1827 (Future Research)
Content added to recommend for future research on formal cost-benefit analysis of antimicrobial prophylaxis for patients with orthopaedic implants undergoing dental procedures.

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Reviewer Information:

Name of Reviewer: Not listed as requested

Address:
City: State: _____ Zip Code:

Phone: Fax: _____ E-mail:

Specialty Area/Discipline:

Work setting: Public Health _____ Credentials: PhD

May we list you as a Peer Reviewer in the final Guidelines? ☐ Yes X☐ No

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If yes, may we list your society as a reviewer of this guideline? ☐ Yes X☐ No

Society Name:

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Each item below requires an answer. Please report information for the last 12-months.

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Within the past twelve months, have you or a member of your immediate family served on the speakers bureau or have you been paid an honorarium to present by any pharmaceutical, biomaterial or orthopaedic product or device company? If YES, please identify company:	☐ Yes X☐ No
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Are you or a member of your immediate family an UNPAID CONSULTANT for any pharmaceutical, biomaterial or orthopaedic device or equipment company, or supplier? If YES, please identify company or supplier:	☐ Yes X☐ No
Do you or a member of your immediate family own stock or stock options in any pharmaceutical, biomaterial or orthopaedic device or equipment company, or supplier (excluding mutual funds) If YES, please identify company or supplier:	☐ Yes X☐ No
Do you or a member of your immediate family receive research or institutional support as a principal investigator from any pharmaceutical, biomaterial or orthopaedic device or equipment company, or supplier? If YES, please identify company or supplier:	☐ Yes X☐ No
Do you or a member of your immediate family receive any other financial or material support from any pharmaceutical, biomaterial or orthopaedic device and equipment company or supplier? If YES, please identify company or supplier:	☐ Yes X☐ No
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Please complete and return this form electronically in **WORD format** to boyer@aaos.org; please contact Kevin Boyer at (847) 384-4328 if you have any questions. Thank you in advance for your time in completing this form and giving us your feedback. We value your input and greatly appreciate your efforts. Please return the completed form in **WORD format** by end of day **March 15, 2012**.

Please indicate your level of agreement with each of the following statements by placing an "X" in the appropriate box.

	Disagree	Somewhat Disagree	Somewhat Agree	Agree
1. The recommendations are clearly stated	☐	☐	☐	X☐
2. There is an explicit link between the recommendations and the supporting evidence	☐	☐	X☐	☐
3. Given the nature of the topic and the data, all clinically important outcomes are considered	☐	☐	X☐	☐
4. The guideline's target audience is clearly described	☐	☐	☐	X☐
5. The patients to whom this guideline is meant to apply are specifically described	☐	☐	☐	X☐
6. The criteria used to select articles for inclusion are appropriate	☐	☐	☐	X☐
7. The reasons why some studies were excluded are clearly described	☐	☐	☐	X☐
8. All important studies that met the article inclusion criteria are included	☐	☐	☐	X☐
9. The validity of the studies is appropriately appraised	☐	☐	☐	X☐
10. The methods are described in such a way as to be reproducible.	☐	☐	☐	X☐
11. The statistical methods are appropriate to the material and the objectives of this guideline	☐	☐	☐	X☐
12. Important parameters (e.g., setting, study population, study design) that could affect study results are systematically addressed	☐	☐	☐	X ☐
13. Health benefits, side effects, and risks are adequately addressed	☐	☐	☐	X☐
14. The writing style is appropriate for health care professionals.	☐	☐	☐	X☐
15. The grades assigned to each recommendation are appropriate	☐	☐	☐	X☐

COMMENTS

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Please provide a brief explanation of both your positive and negative answers in the preceding section. If applicable, please specify the draft page and line numbers in your comments. Please feel free to also comment on the overall structure and content of the Guideline

Overall, the methods are well described and appropriate. Following, please find a few minor comments:

Line 824 – would suggest rewording term in parenthesis to randomized controlled trials. The Cochrane Group's Systematic Review of Sealants included both split mouth and parallel group studies..

Line 830 – Blinding protects against examiner bias as well as placebo effect.

Line 1125-1127 – Is this sentence correct?

Line 1539 – Could the review be more explicit on why there is a concern that reduced bacteremia could mask implant infection.

Doctor,

Thank you for your expert review of this clinical practice guideline. We have incorporated changes to clarify the content in the "Methods" section that you brought to our attention.

Our concern with surrogate outcomes is explained starting on line 1098 in the "Outcomes Considered" section of the "Methods" section. An intervention that improves a surrogate outcome does not necessarily improve a patient-oriented outcome. The opposite can occur and using a surrogate outcome as a study endpoint can make a harmful treatment look beneficial. This is the reason for our concern in regards to bacteremia reduction masking implant infection. Please review this section of the guideline for more details on our concerns with surrogate outcomes.

OVERALL ASSESSMENT

Would you recommend these guidelines for use in clinical practice? (Check one)

☐ Strongly recommend

☐ Recommend (with provisions or alterations)

☐ Would not recommend

X☐ Unsure

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Reviewer Information:

Name of Reviewer: Jamie Baisden MD FACS

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Specialty Area/Discipline: Neurosurgery/Complex Spine

Work setting: Academic Credentials: MD, Masters in Medical Management

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Are you reviewing this guideline as a representative of a professional society? **Xxx** Yes ☐ No

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Society Name: North American Spine Society

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Do you or a member of your immediate family own stock or stock options in any pharmaceutical, biomaterial or orthopaedic device or equipment company, or supplier (excluding mutual funds) If YES, please identify company or supplier:	☐ Yes xx No
Do you or a member of your immediate family receive research or institutional support as a principal investigator from any pharmaceutical, biomaterial or orthopaedic device or equipment company, or supplier? If YES, please identify company or supplier:	☐ Yes xx No
Do you or a member of your immediate family receive any other financial or material support from any pharmaceutical, biomaterial or orthopaedic device and equipment company or supplier? If YES, please identify company or supplier:	☐ Yes xx No
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Do you or a member of your immediate family serve on the editorial or governing board of any medical and/or orthopaedic publication? If YES, please identify: Surgical Neurology International	xx☐ Yes ☐ No
Do you or a member of your immediate family serve on the Board of Directors or a committee of any medical and/or orthopaedic professional society? If YES, please identify: EBM Guidelines Committee NASS, Performance Committee NASS, Patient Education Committee NASS, ETHICS Committee-AANS,	xx☐ Yes ☐ No

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	Disagree	Somewhat Disagree	Somewhat Agree	Agree
1. The recommendations are clearly stated	☐	☐	☐	xx
2. There is an explicit link between the recommendations and the supporting evidence	☐	☐	☐	xx
3. Given the nature of the topic and the data, all clinically important outcomes are considered	☐	☐	☐	xx
4. The guideline's target audience is clearly described	☐	☐	☐	xx
5. The patients to whom this guideline is meant to apply are specifically described	☐	☐	☐	xx
6. The criteria used to select articles for inclusion are appropriate	☐	☐	☐	xx
7. The reasons why some studies were excluded are clearly described	☐	☐	☐	xx
8. All important studies that met the article inclusion criteria are included	☐	☐	☐	xx
9. The validity of the studies is appropriately appraised	☐	☐	☐	xx
10. The methods are described in such a way as to be reproducible.	☐	☐	☐	xx
11. The statistical methods are appropriate to the material and the objectives of this guideline	☐	☐	☐	xx
12. Important parameters (e.g., setting, study population, study design) that could affect study results are systematically addressed	☐	☐	☐	xx
13. Health benefits, side effects, and risks are adequately addressed	☐	☐	☐	xx
14. The writing style is appropriate for health care professionals.	☐	☐	☐	xx
15. The grades assigned to each recommendation are appropriate	☐	☐	☐	xx

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System process well defined. Table and diagrams clean and clear.

724 Management of data collection- partially, did not use 2 independent researchers to extract data. Not sure what checks and balances were used to confirm the data as reviewers may come to differing conclusions given same data even using a computer system to quantitate flaws. How many people reviewed each article to determine consensus of flaws?

1316 Incidence and prevalence discussion good.

1369 Table 13. Risk factors and patient characteristics- patient nutritional status not included (albumin, prealbumin). Was this on purpose or an oversight?

1408 I like breaking the systemic and topical antibiotics/antiseptic apart. This could be potentially clinically more revealing and more cost savings in the end.

1454 Defining late infection criteria in the table as done prevented multiple subgroups.

1499 Giving Recommendation 1 a weak grade can be interpreted as almost favoring continued use of prophylactic antibiotics despite the lack of evidence. Wording the question differently ie Is the use of prophylactic antibiotics in patients who have undergone joint arthroplasty beneficial in preventing subsequent prosthetic joint infections. Giving this a weak recommendation reads somewhat differently - more like prophylaxis is not encouraged. I realize that it is too late to change the question but this may need to be considered in future guideline revisions. Nothing was presented on the potential complications associated with the antibiotic prophylaxis.

1625 Recommendation 2 and analysis is straight forward. Statistics seem appropriate.

1735 Recommendation 3. Consensus statement is appropriate but does not address the purpose of the guidelines – to continue with prophylactic antibiotics or not. 3 was prognostic indirect evidence alone. This guideline may influence continued use of antibiotics being prescribed by practioner's but likely won't make patients alter their behavior effecting their oral hygiene.

Future guidelines need to address potential harm of antibiotic prophylactic use and costs associated with antibiotic prophylaxis.

Dr. Baisden,

Thank you for your expert review of this clinical practice guideline. The guideline may not have explicitly stated it, but multiple independent researchers were utilized to extract data and all information was reviewed to confirm accuracy. We will make changes to the draft to reflect this. The computer system makes it very difficult to come to differing conclusions although it is not impossible. All of the data and its computer appraisal were reviewed for errors. The one case-control study that is the primary source of data for this guideline was heavily scrutinized by the entire workgroup and critically appraised by multiple independent analysts.

The risk factors and patient characteristics presented in Table 13 were extracted directly from the included studies. We reported all of the available information which was determined by the studies' authors.

Much thought and deliberation went into the wordsmithing of Recommendation 1 and we believe it is the best possible option given the rules we agreed to strictly adhere to, current scope of practice, and past clinical recommendations/guidelines. Adverse effects from antibiotic prophylaxis were not discussed because we did not recommend for them in this guideline. We conducted a review on antibiotic prophylaxis and adverse effects

but ultimately decided it was contrary to the evidence to discuss these matters considering that antibiotic prophylaxis is not recommended for in this guideline.

The workgroup intends Recommendation 3 to be primarily received by the prescriber and disseminated to their patients. The general audience of this guideline is the professional practitioner. We feel this is a good opportunity to promote the practice of good oral hygiene.

AAOS does not perform cost/benefit analyses in their clinical practice guidelines. Although we agree this should be an area of focus for future research and will update the "future research" section in the revision.

OVERALL ASSESSMENT

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☒ Strongly recommend

☐ Recommend (with provisions or alterations)

☐ Would not recommend

☐ Unsure

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Reviewer Information:

Name of Reviewer: Denise Bowers, RDH, PhD

Address: 3710 Doe Ct.

City: Lima State: OH Zip Code: 45807

Phone: (419) 995-8385 Fax: 419-995-8162 E-mail: bowers.d@rhodesstate.edu

Specialty Area/Discipline: Dental Hygiene

Work setting: Education Credentials: RDH, PhD

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If yes, may we list your society as a reviewer of this guideline? x Yes ☐ No

Society Name: the American Dental Hygienists' Association (ADHA)

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9. The validity of the studies is appropriately appraised	☐	☐	☐	x
10. The methods are described in such a way as to be reproducible.	☐	☐	☐	x
11. The statistical methods are appropriate to the material and the objectives of this guideline	☐	☐	☐	x
12. Important parameters (e.g., setting, study population, study design) that could affect study results are systematically addressed	☐	☐	☐	x
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14. The writing style is appropriate for health care professionals.	☐	☐	☐	x
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COMMENTS

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During my review of the AAOS/ADA Antibiotic Prophylaxis for the Prevention of Orthopedic Implant Infection in Patients Undergoing Dental Procedures Evidence-Based Guideline and Evidence Report it was clearly evident that a comprehensive study was conducted and all limitations were addressed. The proposed recommendations demonstrate understanding and acceptance of the evidence-based research available.

Categorizing the information into direct and indirect evidence enables the reader to easily follow the line of thought and interpret the findings in a systematic manner.

The Guideline is a well written, comprehensive, and evidence-based document.

Dr. Bowers,

Thank you for your expert review of this clinical practice guideline. We are pleased to hear that you found the guideline to be satisfactory.

OVERALL ASSESSMENT

Would you recommend these guidelines for use in clinical practice? (Check one)

x Strongly recommend

☐ Recommend (with provisions or alterations)

☐ Would not recommend

☐ Unsure

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Reviewer Information:

Name of Reviewer: Mijin Choi, DDS, MS, FACP

Address: 425 Washington Blvd #3506

City: Jersey City State: NJ Zip Code: 07310

Phone: 646-257-9515 Fax: _____ E-mail: mchoidds@gmail.com or mc185@nyu.edu

Specialty Area/Discipline: _____

Work setting: _____ Credentials: _____

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Society Name: American College of Prosthodontists

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Do you or a member of your immediate family own stock or stock options in any pharmaceutical, biomaterial or orthopaedic device or equipment company, or supplier (excluding mutual funds) If YES, please identify company or supplier:	☐ Yes ☒ No
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Please complete and return this form electronically in **WORD format** to boyer@aaos.org; please contact Kevin Boyer at (847) 384-4328 if you have any questions. Thank you in advance for your time in completing this form and giving us your feedback. We value your input and greatly appreciate your efforts. Please return the completed form in **WORD format** by end of day **March 15, 2012**.

Please indicate your level of agreement with each of the following statements by placing an "X" in the appropriate box.

	Disagree	Somewhat Disagree	Somewhat Agree	Agree
1. The recommendations are clearly stated	☐	☐	☐	☒
2. There is an explicit link between the recommendations and the supporting evidence	☐	☐	☐	☒
3. Given the nature of the topic and the data, all clinically important outcomes are considered	☐	☐	☒	☐
4. The guideline's target audience is clearly described	☐	☐	☐	☒
5. The patients to whom this guideline is meant to apply are specifically described	☐	☐	☐	☒
6. The criteria used to select articles for inclusion are appropriate	☐	☐	☐	☒
7. The reasons why some studies were excluded are clearly described	☐	☐	☐	☒
8. All important studies that met the article inclusion criteria are included	☐	☐	☐	☒
9. The validity of the studies is appropriately appraised	☐	☐	☐	☒
10. The methods are described in such a way as to be reproducible.	☐	☐	☐	☒
11. The statistical methods are appropriate to the material and the objectives of this guideline	☐	☐	☐	☒
12. Important parameters (e.g., setting, study population, study design) that could affect study results are systematically addressed	☐	☐	☐	☒
13. Health benefits, side effects, and risks are adequately addressed	☐	☐	☒	☐
14. The writing style is appropriate for health care professionals.	☐	☐	☐	☒
15. The grades assigned to each recommendation are appropriate	☐	☐	☐	☒

COMMENTS

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1. **The presented analysis was very clear and comprehensive.**
2. **While the major aspects of dental treatments were considered, the potential risk of developing bacteremia from the dental implant therapy does not appeared to be sufficiently evaluated. This is an important area to be explored because the dental implant therapy, including dental implant retained complete denture is considered to be a standard of care for the population with complete edentulism. The extent of dental implant therapy varies widely, and the potential risks of bacteremia from the extensive dental implant therapy may have differing impact.**

Dr. Choi,

Thank you for your expert review of this clinical practice guideline. We conducted a thorough review of the literature and searched for all dental treatments including dental implant therapy in relation to bacteremia and orthopaedic implant infection. One study that addressed bacteremia post dental implant therapy was included in our guideline. It is referenced in Figures 3 and 11. The primary focus of this guideline is on prophylaxis and preventing orthopaedic implant infection in patients undergoing dental procedures. Thoroughly addressing the potential risk of bacteremia from dental implant therapy is not within the scope of this guideline. We included the incidence and prevalence data on bacteremia post dental procedures in an attempt to be as thorough and transparent as possible. Bacteremia is a surrogate outcome for orthopaedic implant infection and no evidence exists to support that association.

OVERALL ASSESSMENT

Would you recommend these guidelines for use in clinical practice? (Check one)

☒ Strongly recommend

☐ Recommend (with provisions or alterations)

☐ Would not recommend

☐ Unsure

Note: Your answer to this question does not constitute an endorsement of this guideline. We ask this question as a means of monitoring the clinical relevance of our guideline.

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Reviewer Information:

Name of Reviewer: Erika J. Ernst

Address: S415 Pharmacy Building

City: Iowa City State: IA Zip Code: 52242

Phone: (319) 335-8785 Fax: (319) 353-5646 E-mail: Erika-ernst@uiowa.edu

Specialty Area/Discipline: Infectious Diseases Pharmacist

Work setting: Academic Hospital Credentials: PharmD, BCPS

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If yes, may we list your society as a reviewer of this guideline? ☒ Yes ☐ No

Society Name: Society of Infectious Diseases Pharmacists

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Do you or a member of your immediate family serve on the Board of Directors or a committee of any medical and/or orthopaedic professional society? If YES, please identify: Society of Infectious Diseases Pharmacists President-elect	☒ Yes ☐ No

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	Disagree	Somewhat Disagree	Somewhat Agree	Agree
1. The recommendations are clearly stated	☐	☒	☐	☐
2. There is an explicit link between the recommendations and the supporting evidence	☐	☐	☐	☒
3. Given the nature of the topic and the data, all clinically important outcomes are considered	☐	☐	☐	☒
4. The guideline's target audience is clearly described	☐	☐	☐	☒
5. The patients to whom this guideline is meant to apply are specifically described	☐	☐	☒	☐
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8. All important studies that met the article inclusion criteria are included	☐	☐	☐	☒
9. The validity of the studies is appropriately appraised	☐	☐	☐	☒
10. The methods are described in such a way as to be reproducible.	☐	☐	☐	☒
11. The statistical methods are appropriate to the material and the objectives of this guideline	☐	☐	☐	☒
12. Important parameters (e.g., setting, study population, study design) that could affect study results are systematically addressed	☐	☐	☐	☒
13. Health benefits, side effects, and risks are adequately addressed	☐	☒	☐	☐
14. The writing style is appropriate for health care professionals.	☐	☐	☒	☐
15. The grades assigned to each recommendation are appropriate	☐	☐	☒	☐

COMMENTS

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Recommendation 1 is not as clear as it could be. The recommendation is directed at the practitioner and suggests discontinuing the practice of routine prescribing of prophylactic antibiotics. However the grade of this recommendation is WEAK. It seems unclear whether the initiation of routine prophylactic antibiotics is equally weak. From the way it is worded it read like prophylactic antibiotics should be started in everyone and the evidence for discontinuing them is weak. However reading the evidence it seems it is the routine initiation of prophylactic antibiotics that has weak evidence in support. This recommendation should be reworded to address the lack of support for the routine prescribing of prophylactic antibiotics for the prevention of joint infection in patients.

The risks of routine antimicrobial use are not described. Prescribing antimicrobials predisposes patients to infections with resistant pathogens and additional risks such at C. difficile infection and these weren't adequately addressed.

Recommendation 3 is aimed at patients to maintain good oral hygiene whereas recommendation 1 is aimed at prescribers to discontinue a practice for which there is weak evidence. This adds to the confusion surrounding recommendation 1.

Overall the review is very comprehensive, exhaustive and free of bias.

Dr. Ernst,

Thank you for your expert review of this clinical practice guideline. We recognize that the wording of Recommendation 1, "The practitioner might consider discontinuing the practice of routinely prescribing prophylactic antibiotics for patients with hip and knee prosthetic joint implants undergoing dental procedures", is not without fault. However we follow a rigorous methodology. These methods start with preliminary recommendations formulated at the workgroup's first meeting. These recommendations specify [what] should be done in [whom], [when], [where], and [how often or how long]. To avoid "wordsmithing" discussions at the initial work group meeting, the preliminary recommendations are always worded as recommending for something. Therefore the preliminary recommendation "positively" recommended for antibiotic prophylaxis for patients with orthopaedic implants undergoing dental procedures. Consequently when the best available evidence (1 "moderate" strength study) revealed that dental procedures are not related to subsequent orthopaedic (namely hip and knee) implant infection and furthermore that antibiotic prophylaxis did not reduce the risk of alleged subsequent infection we were required to use the respective guideline language, "The practitioner MIGHT", and give it a "Weak" grade according to AAOS rules of evidence. We agreed to strictly adhere to these rules at the inception of this guideline and therefore there were no other alternative options.

Beyond the required language and "weak" grade the workgroup chose the remaining words very carefully and ultimately agreed that "consider discontinuing the practice of routinely prescribing prophylactic antibiotics" was the best possible wording based on knowledge of current practice and past clinical recommendations/guidelines. An informal survey of dental schools found that approximately half instruct their students to recommend for antibiotic prophylaxis in these matters. The ADA also recommends that the dentist have a conversation with the patient and their respective orthopaedic surgeon about antibiotic prophylaxis. It was the impression of the orthopaedic surgeons in the workgroup that their colleagues routinely recommend for antibiotic prophylaxis and they themselves favored its use. Also, previous guidelines recommended for the routine use of antibiotic prophylaxis. While it may not be evidence-based we believe prescription of antibiotic prophylaxis is the community standard for patients with certain comorbidities and for the first 2 years after orthopaedic implant surgery if not longer.

The risk of routine antimicrobial use is not described because the guideline does not recommend for them. We conducted a review on antimicrobials and adverse effects but ultimately decided it was contrary to the evidence

to discuss these matters considering that neither antibiotic prophylaxis nor topical antimicrobials are recommended for in this guideline.

The workgroup intends Recommendation 3 to be primarily received by the prescriber and disseminated to their patients. The general audience of this guideline is the professional practitioner. We feel this is a good opportunity to promote the practice of good oral hygiene.

OVERALL ASSESSMENT

Would you recommend these guidelines for use in clinical practice? (Check one)

☐ Strongly recommend

☒ Recommend (with provisions or alterations)

☐ Would not recommend

☐ Unsure

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Reviewer Information:

Name of Reviewer: Paul S. Farsai, D.M.D., M.P.H.

Address: Boston University Goldman School of Dental Medicine
Department of General Dentistry,
72 East Concord Street, Robinson Building Rm-334

City: Boston State: MA. Zip Code: 02118-2526

Phone: 617-414-1146 Fax: 617-414-1061 E-mail: pfarsai@bu.edu

Specialty Area/Discipline: General Dentistry

Work setting: Dental School / Solo Private Practice Credentials: Associate Professor

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Society Name: Consultant to the ADA Council on Scientific Affairs

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1. The recommendations are clearly stated	☐	☐	X	☐
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3. Given the nature of the topic and the data, all clinically important outcomes are considered	☐	☐	X	☐
4. The guideline's target audience is clearly described	☐	☐	☐	X
5. The patients to whom this guideline is meant to apply are specifically described	☐	☐	X	☐
6. The criteria used to select articles for inclusion are appropriate	☐	☐	☐	X
7. The reasons why some studies were excluded are clearly described	☐	☐	☐	X
8. All important studies that met the article inclusion criteria are included	☐	☐	☐	X
9. The validity of the studies is appropriately appraised	☐	☐	☐	X
10. The methods are described in such a way as to be reproducible.	☐	☐	☐	X
11. The statistical methods are appropriate to the material and the objectives of this guideline	☐	☐	X	☐
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13. Health benefits, side effects, and risks are adequately addressed	☐	☐	X	☐
14. The writing style is appropriate for health care professionals.	☐	☐	☐	X
15. The grades assigned to each recommendation are appropriate	☐	☐	☐	X

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General comment for throughout the document (not saying to re-write, or it's right or wrong, just a comment) that Orthodontics is now routinely being called Orthodontics and Dentofacial Orthopaedics in the dental field—so references to Orthopaedic Implant infection might confuse the dental readers a bit unless a reference is made at the beginning of the guideline to mean prosthetic/orthopaedic…not a very substantive comment but meant to make the document read better for dentists.

Page 2, line 545: a reference to procedures performed in 2010 from a referenced article estimating projected rates from 2005-2030. It's 2012, is it possible to obtain incidence rates from 2010 at the very least, not projected rates? Is it possible to have 2011 rates?

Page 23, line 1281: at the beginning of the sentence doesn't the figure 339 have to be spelled out? Same with line 1282.

Page 24, Table 10: in the right hand column, under Low risk Dental procedures, the word "endodontic" is misspelled.

Page 74, line 1563: need to elaborate on the definition of a "network meta analysis", so subsequent tables representing network meta-analysis make sense., i,e, pages 78-82. State the downside of network analysis and why a network analysis why calculated. Same issue with page 83, line 1651.

Dr. Farsai,

Thank you for your expert review of this clinical practice guideline. Our recommendations are explicitly written for patients with "prosthetic joint implants" and Recommendation 1 only applies to patients with hip or knee implants as stated. We will monitor comments about confusion of "orthopaedic implant infection" during public commentary and address this issue in the guideline and/or accompanying publications if necessary.

Unfortunately it is very difficult to obtain incidence rates of arthroplasties because they are guarded by insurance companies. Medicare data is available but it's a special population and not generalizable to the overall U.S. population. However we have updated the projected numbers. We now have projections for 2020 (380,000 hip procedures and over 1,500,000 knee procedures) instead of the outdated 2010 ones.

According to American Medical Association language, numbers below ten should be spelled out and all other over ten should be written in numerical form.

The misspelling you found in Table 10 has been corrected. Thank you for your careful review.

Lastly, we've added a brief statement describing a network meta-analysis in the section which you highlighted and more importantly redirected the reader to the methods section which describes the procedure in detail.

OVERALL ASSESSMENT

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X Strongly recommend

☐ Recommend (with provisions or alterations)

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Reviewer Information:

Name of Reviewer: James M Horton, M.D.

Address: Chair, IDSA Standards and Practice Guidelines Committee

City: Charlotte State: NC Zip Code: 28232

Phone: _____ Fax: _____ E-mail: _____

Specialty Area/Discipline: Infectious Diseases

Work setting: _____ Credentials: MD

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Society Name: Infectious Diseases Society of America (IDSA)

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Do you or a member of your immediate family receive royalties for any pharmaceutical, biomaterial or orthopaedic product or device? If YES, please identify product or device:	☐ Yes ☒ No
Within the past twelve months, have you or a member of your immediate family served on the speakers bureau or have you been paid an honorarium to present by any pharmaceutical, biomaterial or orthopaedic product or device company? If YES, please identify company:	☐ Yes ☒ No
Are you or a member of your immediate family a PAID EMPLOYEE for any pharmaceutical, biomaterial or orthopaedic device or equipment company, or supplier? If YES, please identify company or supplier:	☐ Yes ☒ No
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Do you or a member of your immediate family own stock or stock options in any pharmaceutical, biomaterial or orthopaedic device or equipment company, or supplier (excluding mutual funds) If YES, please identify company or supplier:	☐ Yes ☒ No
Do you or a member of your immediate family receive research or institutional support as a principal investigator from any pharmaceutical, biomaterial or orthopaedic device or equipment company, or supplier? If YES, please identify company or supplier: In the past 2 years I have been PI on studies with Gilead and GSK.	☒ Yes ☐ No
Do you or a member of your immediate family receive any other financial or material support from any pharmaceutical, biomaterial or orthopaedic device and equipment company or supplier? If YES, please identify company or supplier:	☐ Yes ☒ No
Do you or a member of your immediate family receive any royalties, financial or material support from any medical and/or orthopaedic publishers? If YES, please identify publisher:	☐ Yes ☒ No
Do you or a member of your immediate family serve on the editorial or governing board of any medical and/or orthopaedic publication? If YES, please identify:	☐ Yes ☒ No
Do you or a member of your immediate family serve on the Board of Directors or a committee of any medical and/or orthopaedic professional society? If YES, please identify: IDSA Standards and Practice Guidelines Committee (SPGC)	☒ Yes ☐ No

Structured Peer Review Form Instructions

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Please indicate your level of agreement with each of the following statements by placing an "X" in the appropriate box.

	Disagree	Somewhat Disagree	Somewhat Agree	Agree
1. The recommendations are clearly stated	☒	☐	☐	☐
2. There is an explicit link between the recommendations and the supporting evidence	☒	☐	☐	☐
3. Given the nature of the topic and the data, all clinically important outcomes are considered	☐	☒	☐	☐
4. The guideline's target audience is clearly described	☐	☒	☐	☐
5. The patients to whom this guideline is meant to apply are specifically described	☐	☐	☒	☐
6. The criteria used to select articles for inclusion are appropriate	☐	☐	☒	☐
7. The reasons why some studies were excluded are clearly described	☐	☐	☒	☐
8. All important studies that met the article inclusion criteria are included	☐	☐	☒	☐
9. The validity of the studies is appropriately appraised	☐	☒	☐	☐
10. The methods are described in such a way as to be reproducible.	☐	☐	☒	☐
11. The statistical methods are appropriate to the material and the objectives of this guideline	☐	☒	☐	☐
12. Important parameters (e.g., setting, study population, study design) that could affect study results are systematically addressed	☐	☒	☐	☐
13. Health benefits, side effects, and risks are adequately addressed	☐	☒	☐	☐
14. The writing style is appropriate for health care professionals.	☐	☐	☒	☐
15. The grades assigned to each recommendation are appropriate	☒	☐	☐	☐

COMMENTS

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Please provide a brief explanation of both your positive and negative answers in the preceding section. If applicable, please specify the draft page and line numbers in your comments. Please feel free to also comment on the overall structure and content of the Guideline

The panel is to be congratulated for compiling a comprehensive review of the medical literature on dental procedures and prosthetic joint infections. That said, I have several concerns with the conclusions:

1. Most of the literature is weak. Only one article addresses the issue of the benefits versus the risks of prophylactic antibiotics with dental work, and it showed no benefit.
2. The most important issue is the extrapolation from all this literature to the conclusions. The first recommendation stating that the practitioner might consider discontinuing the use of antibiotics does not really reflect the review of the literature in that section. The statement that more correctly summarizes the medical literature is the first sentence of the rationale: "Moderate strength evidence finds that dental procedures are unrelated to implant infection and that antibiotic prophylaxis prior to dental procedures does not reduce the risk of subsequent implant infections." That statement would serve as the best recommendation for this guideline.
3. The one well-conducted case-control study does not account for high risk patients such as those who are immunocompromised. Future research should clarify if some subgroups might benefit from antibiotic prophylaxis.
4. The authors do not mention the literature on the risks of antibiotic prophylaxis. The rate of allergic reaction to the antibiotics might exceed the rate of joint infection.

James Horton

James M. Horton, M.D.
Chair, Standards and Practice Guidelines Committee
Infectious Diseases Society of America

Dr. Horton,

Thank you for your expert review of this clinical practice guideline. We agree that the available evidence for this guideline is weak. Unfortunately this is best available evidence. Hopefully future research will provide us with greater insight on this complex situation.

We follow rigorous AAOS methodology. These methods start with preliminary recommendations formulated at the workgroup's first meeting. These recommendations specify [what] should be done in [whom], [when], [where], and [how often or how long]. To avoid "wordsmithing" discussions at the initial work group meeting, the preliminary recommendations are always worded as recommending for something. Therefore the preliminary recommendation "positively" recommended for antibiotic prophylaxis for patients with orthopaedic implants undergoing dental procedures. Consequently when the best available evidence (1 "moderate" strength study) revealed that dental procedures are not related to subsequent orthopaedic (namely hip and knee) implant infection and furthermore that antibiotic prophylaxis did not reduce the risk of alleged subsequent infection we were required to use the respective guideline language, "The practitioner MIGHT", and give it a "Weak" grade according to AAOS rules of evidence. We agreed to strictly adhere to these rules at the inception of this guideline and feel that the current wording of the recommendation is the best possible option.

The case-control study by Berbari et al. did account for immunocompromised patients. Their regression model included many covariates one of which being immunocompromised hosts. The authors defined this as "The presence of any of the following conditions: rheumatoid arthritis, current use of systemic corticosteroids/immunosuppressive drugs, diabetes mellitus, presence of a malignancy, and a history of chronic kidney disease". However future research to confirm their findings is warranted.

We did not address risk of antibiotic prophylaxis in this guideline because we did not recommend for them. We conducted a review on antibiotic prophylaxis and adverse effects but ultimately decided it was contrary to the evidence to discuss these matters considering that antibiotic prophylaxis is not recommended for in this guideline.

OVERALL ASSESSMENT

Would you recommend these guidelines for use in clinical practice? (Check one)

☐ Strongly recommend

☐ Recommend (with provisions or alterations)

☒ Would not recommend

☐ Unsure

Note: Your answer to this question does not constitute an endorsement of this guideline. We ask this question as a means of monitoring the clinical relevance of our guideline.

ALL REVIEW COMMENTS, RESPONSES AND REVIEWER CONFLICTS OF INTEREST DISCLSOURE WILL BE AVAILABLE ON OUR WEBSITE FOLLOWING APPROVAL OF THIS DOCUMENT.

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- **Your conflicts of interest disclosures will be published on the AAOS website, and may be published on the ADA website, with your review comments.**

Reviewer Information:

Name of Reviewer: John S. Kirkpatrick, M.D.

Address: University of Florida College of Medicine Jacksonville; 655 West Eighth Street

City: Jacksonville State: FL Zip Code: 32209

Phone: 9042445942 Fax: 9042448580 E-mail: John.Kirkpatrick@jax.ufl.edu

Specialty Area/Discipline: Spine

Work setting: Academic Credentials: MD, MS

May we list you as a Peer Reviewer in the final Guidelines? ☒ Yes ☐ No

PLEASE READ: If you do not wish to be listed, your name will be removed for identification purposes. However, your review comments, our responses and your COI will still be available for public review on our website with the posted Guideline if you complete this review.

Are you reviewing this guideline as a representative of a professional society? ☐ Yes ☒ No

If yes, may we list your society as a reviewer of this guideline? ☐ Yes ☒ No

Society Name:

(Listing the specialty society as a reviewing society does not imply or otherwise indicate endorsement of this guideline.)

Conflicts of Interest (COI): All Reviewers must declare their conflicts of interest.

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Do you or a member of your immediate family own stock or stock options in any pharmaceutical, biomaterial or orthopaedic device or equipment company, or supplier (excluding mutual funds) If YES, please identify company or supplier: Bristol Myers Squibb, Zimmer, Pfizer, Johnson&Johnson	☒ Yes ☐ No
Do you or a member of your immediate family receive research or institutional support as a principal investigator from any pharmaceutical, biomaterial or orthopaedic device or equipment company, or supplier? If YES, please identify company or supplier: Amgen, Medtronic, Eli Lilly	☒ Yes ☐ No
Do you or a member of your immediate family receive any other financial or material support from any pharmaceutical, biomaterial or orthopaedic device and equipment company or supplier? If YES, please identify company or supplier:	☐ Yes ☒ No
Do you or a member of your immediate family receive any royalties, financial or material support from any medical and/or orthopaedic publishers? If YES, please identify publisher:	☐ Yes ☒ No
Do you or a member of your immediate family serve on the editorial or governing board of any medical and/or orthopaedic publication? If YES, please identify: Journal of Surgical Orthopaedic Advances	☒ Yes ☐ No
Do you or a member of your immediate family serve on the Board of Directors or a committee of any medical and/or orthopaedic professional society? If YES, please identify: Cervical Spine Research Society	☒ Yes ☐ No

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Please complete and return this form electronically in **WORD format** to boyer@aaos.org; please contact Kevin Boyer at (847) 384-4328 if you have any questions. Thank you in advance for your time in completing this form and giving us your feedback. We value your input and greatly appreciate your efforts. Please return the completed form in **WORD format** by end of day **March 15, 2012**.

Please indicate your level of agreement with each of the following statements by placing an "X" in the appropriate box.

	Disagree	Somewhat Disagree	Somewhat Agree	Agree
1. The recommendations are clearly stated	☐	☐	☒	☐
2. There is an explicit link between the recommendations and the supporting evidence	☐	☐	☐	☒
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10. The methods are described in such a way as to be reproducible.	☐	☐	☐	☒
11. The statistical methods are appropriate to the material and the objectives of this guideline	☐	☐	☐	☒
12. Important parameters (e.g., setting, study population, study design) that could affect study results are systematically addressed	☐	☐	☐	☒
13. Health benefits, side effects, and risks are adequately addressed	☐	☐	☒	☐
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COMMENTS

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line 53-79: The "Overview of evidence" description 1264-1275) is excelent and would be helpful if possible to include in the summary of recommendations section. There is evidence that bacteremia occurs following dental procedures and that prophylaxis decreases this bacteremia. There is only one study that looked at joint infections after dental procedures and found no relationship to the procedres orthe prophylaxis. Summarizing this "up front" would be very helpful.

I think most clinicians would have asked the question of the evidence for prophylaxis rather than the evidence against it (recommendation 1). I expect this cannot be fixed due to methods and procedure, but this will likely be a source of criticism from membership.

Dr. Kirkpatrick,

Thank you for your expert review of this clinical practice guideline. When this guideline is disseminated through our associations' journals and media outlets we will present the recommendations along with the evidence upon which they are based. The "Overview of Evidence" and "Summary of Evidence" sections from the full guideline will be crucial in these publications. Some variation of the "Overview of Evidence" will surely be included in these.

Yes, the wording of Recommendation 1 will likely be criticized by some members. However we follow rigorous AAOS methodology which limits our options. These methods start with preliminary recommendations formulated at the workgroup's first meeting. These recommendations specify [what] should be done in [whom], [when], [where], and [how often or how long]. To avoid "wordsmithing" discussions at the initial work group meeting, the preliminary recommendations are always worded as recommending for something. Therefore the preliminary recommendation "positively" recommended for antibiotic prophylaxis for patients with orthopaedic implants undergoing dental procedures. Consequently when the best available evidence (1 "moderate" strength study) revealed that dental procedures are not related to subsequent orthopaedic (namely hip and knee) implant infection and furthermore that antibiotic prophylaxis did not reduce the risk of alleged subsequent infection we were required to use the respective guideline language, "The practitioner MIGHT", and give it a "Weak" grade according to AAOS rules of evidence. We agreed to strictly adhere to these rules at the inception of this guideline and feel that the current wording of the recommendation is the best possible option.

OVERALL ASSESSMENT

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☐ Strongly recommend

☒ Recommend (with provisions or alterations)

☐ Would not recommend

☐ Unsure

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Reviewer Information:

Name of Reviewer: Brian J. McGrory, MD

Address: 5 Bucknam Road

City: Falmouth State: Maine Zip Code: 04105

Phone: 207-781-1551 Fax: 207-781-1552 E-mail: mjri@yahoo.com

Specialty Area/Discipline: Adult Reconstruction/Orthopaedics

Work setting: AAHKS Committee Chair Credentials: MD, MS

May we list you as a Peer Reviewer in the final Guidelines? ☒ Yes ☐ No

PLEASE READ: If you do not wish to be listed, your name will be removed for identification purposes. However, your review comments, our responses and your COI will still be available for public review on our website with the posted Guideline if you complete this review.

Are you reviewing this guideline as a representative of a professional society? ☒ Yes ☐ No

If yes, may we list your society as a reviewer of this guideline? ☒ Yes ☐ No

Society Name: American Association of Hip and Knee Surgeons

(Listing the specialty society as a reviewing society does not imply or otherwise indicate endorsement of this guideline.)

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Do you or a member of your immediate family serve on the editorial or governing board of any medical and/or orthopaedic publication? If YES, please identify: Hospital Physician (Turner-White)	☒ Yes ☐ No
Do you or a member of your immediate family serve on the Board of Directors or a committee of any medical and/or orthopaedic professional society? If YES, please identify: American Association of Hip and Knee Surgeons	☒ Yes ☐ No

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Please complete and return this form electronically in **WORD format** to boyer@aaos.org; please contact Kevin Boyer at (847) 384-4328 if you have any questions. Thank you in advance for your time in completing this form and giving us your feedback. We value your input and greatly appreciate your efforts. Please return the completed form in **WORD format** by end of day **March 15, 2012**.

Please indicate your level of agreement with each of the following statements by placing an "X" in the appropriate box.

	Disagree	Somewhat Disagree	Somewhat Agree	Agree
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2. There is an explicit link between the recommendations and the supporting evidence	☐	☐	☐	☒
3. Given the nature of the topic and the data, all clinically important outcomes are considered	☐	☐	☐	☒
4. The guideline's target audience is clearly described	☐	☐	☐	☒
5. The patients to whom this guideline is meant to apply are specifically described	☐	☐	☐	☒
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9. The validity of the studies is appropriately appraised	☐	☐	☐	☒
10. The methods are described in such a way as to be reproducible.	☐	☐	☐	☒
11. The statistical methods are appropriate to the material and the objectives of this guideline	☐	☐	☒	☐
12. Important parameters (e.g., setting, study population, study design) that could affect study results are systematically addressed	☐	☐	☐	☒
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15. The grades assigned to each recommendation are appropriate	☐	☐	☐	☒

COMMENTS

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An AAHKS Evidence Based Medicine Committee review of the document was favorable, but the following question was brought up: Was the statistical power of the single reference supporting the first recommendation taken into account in the analysis? That is to say, with late infection being so uncommon after joint replacement, it seems that the study is underpowered to conclude that dental infections are not related to late PJI. Please comment.

Thank you for the opportunity to review this document.

Dr. McGrory,

> Thank you for presenting this clinical practice guideline to the AAHKS EBM Committee, we appreciate the committee's input.
>
> The work group had a substantial discussion regarding statistical power in the Berbari, et al. study (the single reference for Recommendation 1). The workgroup agreed that Berbari and colleagues took great care in reducing statistical bias in their study as illustrated by the power calculation reported in the methods section. Secondary analysis, by AAOS and ADA analysts, on the power of this study determined that the study could detect at least small effect sizes. Additionally, and perhaps more importantly, control of methodological biases (e.g. recall bias, detection bias) present in this case-control study coupled with the analyses of statistical power gave the work group confidence in the results of the study.

OVERALL ASSESSMENT

Would you recommend these guidelines for use in clinical practice? (Check one)

☒ Strongly recommend

☐ Recommend (with provisions or alterations)

☐ Would not recommend

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Reviewer Information:

Name of Reviewer: Louis G. Mercuri

Address:

City: State: IL Zip Code: 60305

Phone: 708-771-2770 Fax: _____ E-mail: lgm@tmjconcepts.com

Specialty Area/Discipline: Oral and Maxillofacial Surgery

Work setting: Clinical Consultant Credentials: DDS, MS

May we list you as a Peer Reviewer in the final Guidelines? X Yes ☐ No

PLEASE READ: If you do not wish to be listed, your name will be removed for identification purposes. However, your review comments, our responses and your COI will still be available for public review on our website with the posted Guideline if you complete this review.

Are you reviewing this guideline as a representative of a professional society? X Yes ☐ No

If yes, may we list your society as a reviewer of this guideline? X Yes ☐ No

Society Name: American Association of Oral and Maxillofacial Surgeons

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Do you or a member of your immediate family receive any royalties, financial or material support from any medical and/or orthopaedic publishers? If YES, please identify publisher:	☐ Yes X No
Do you or a member of your immediate family serve on the editorial or governing board of any medical and/or orthopaedic publication? If YES, please identify:	☐ Yes X No
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Structured Peer Review Form Instructions

Please read and review this Draft Clinical Practice Guideline with particular focus on your area of expertise. Your responses will be used to assess the validity, clarity and accuracy of the interpretation of the evidence. If applicable, **please specify the draft page and line numbers in your comments**. Please feel free to also comment on the overall structure and content of the document. If you need more space than is provided, please attach additional pages.

Please complete and return this form electronically in **WORD format** to boyer@aaos.org; please contact Kevin Boyer at (847) 384-4328 if you have any questions. Thank you in advance for your time in completing this form and giving us your feedback. We value your input and greatly appreciate your efforts. Please return the completed form in **WORD format** by end of day **March 15, 2012**.

Please indicate your level of agreement with each of the following statements by placing an "X" in the appropriate box.

	Disagree	Somewhat Disagree	Somewhat Agree	Agree
1. The recommendations are clearly stated	☐	☐	X	☐
2. There is an explicit link between the recommendations and the supporting evidence	☐	☐	X	☐
3. Given the nature of the topic and the data, all clinically important outcomes are considered	☐	X	☐	☐
4. The guideline's target audience is clearly described	☐	☐	X	☐
5. The patients to whom this guideline is meant to apply are specifically described	☐	☐	X	☐
6. The criteria used to select articles for inclusion are appropriate	☐	☐	X	☐
7. The reasons why some studies were excluded are clearly described	☐	☐	X	☐
8. All important studies that met the article inclusion criteria are included	☐	X	☐	☐
9. The validity of the studies is appropriately appraised	☐	☐	X	☐
10. The methods are described in such a way as to be reproducible.	☐	☐	☐	X
11. The statistical methods are appropriate to the material and the objectives of this guideline	☐	☐	☐	X
12. Important parameters (e.g., setting, study population, study design) that could affect study results are systematically addressed	☐	☐	X	☐
13. Health benefits, side effects, and risks are adequately addressed	☐	☐	X	☐
14. The writing style is appropriate for health care professionals.	☐	☐	X	☐
15. The grades assigned to each recommendation are appropriate	☐	☐	X	☐

COMMENTS

PLEASE RETURN ALL COMMENTS IN WORD FORMAT

Please provide a brief explanation of both your positive and negative answers in the preceding section. If applicable, please specify the draft page and line numbers in your comments. Please feel free to also comment on the overall structure and content of the Guideline

My responses are linked to the following narrative:

The original February 2009 American Academy of Orthopaedic Surgeons Information Statement: Antibiotic Prophylaxis for Bacteremia in Patients with Joint Replacements statement[1] (Statement) cited studies describing bacteremias causing hematogenous seeding of joint implants, in both the early post-operative period and many years after implantation as well as from dental, urological, other medical procedures and from daily life activities.[2-5]

However, three of the citations[3-5] relate to bacteremias causing endocarditis. McGowen states "The analogy of late prosthetic joint infections with infective endocarditis is invalid as the anatomy, blood supply, microorganisms and mechanisms of infection are all different." [6]

The Statement cited data that "likely" provide evidence of the association of oral cavity, skin, respiratory, gastrointestinal and genitourinary systems involvement with late orthopaedic implant infection.[7, 8] It also provided "risk factors" and "the current" prophylactic antibiotic recommendations for different invasive procedures based on the activity against the endogenous organisms likely encountered, the drug's toxicity and cost taken from the 2006 Medical Letter. [9]

Further quoting: "this statement provides recommendations to supplement practitioners in their clinical judgment regarding antibiotic prophylaxis for patients with joint replacements" …and that ... "it is not intended as the standard of care nor a substitute for clinical judgment..." Additionally, "any perceived potential benefit of antibiotic prophylaxis must be weighed against the known risks of toxicity, allergy, and development, selection and transmission of microbial resistance. Practitioners must exercise their own clinical judgment in determining whether or not antibiotic prophylaxis is appropriate."

In 1997, an expert panel representing both the American Dental Association and the American Academy of Orthopaedic Surgeons issued a joint advisory statement regarding antibiotic prophylaxis for dental patients with total joint replacements.[10] This panel concluded that antibiotic prophylaxis was not indicted for dental patients with pins, plates and screws, nor routinely indicated for most dental patients with total joint replacements. However, they believed it was advisable to consider premedication in a small number of patients who may have potential for increased risk of hematogenous total joint infection.

In 2002, Kingston et al[11] polled orthopaedic surgeons, urologists and dentists on whether reports of prosthetic joint infections after urologic and dental procedures might suggest antibiotic prophylaxis should be employed prior to these procedures. Orthopaedic surgeons and urologists agreed that infection of a prosthetic joint could result from urological procedures while dentists didn't know whether dental procedures did or didn't. These authors concluded that a consensus should be developed in light of the potential consequences in such cases. In the same year, Curry and Phillips[12] reviewed and relevant literature and reported that despite the joint panel advisory, consensus on this subject was lacking and concluded that antibiotic prophylaxis should not be routinely given to all patients undergoing dental treatment, but should be reserved for those patients deemed at high risk.

In the same year, Seymour et al[13] concluded that the evidence on cost-risk benefit seems to demonstrate that antibiotic prophylaxis with either amoxicillin or penicillin is not cost effective compared with no prophylaxis. Further, they deduced that the case for prophylaxis after alloplastic total joint replacement and before dental treatment was weak or virtually non-existent. They reported after reviewing the published data that in their opinion, the risk from antibiotic prophylaxis was greater than the risk of prosthetic joint infection.

The expert panel reconvened in 2003, and modified the advisory. Since the greatest risk of hematogenous bacterial infection of a total joint prosthesis was considered to be highest within the 2 years after arthroplasty or when the patient was chronically ill or immunocompromised[14], they recommended at risk prosthetic joint patients who undergo dental procedures where the mucosa was breeched be provided antibiotic prophylaxis for 2 years after prosthetic joint implantation.[15]

Berbari et al[16] presented a prospective, single-center, case-control study of patients hospitalized with alloplastic total hip and knee infections. Control subjects were patients who underwent alloplastic total hip and knee replacement who were hospitalized during the same time and on the same orthopaedic floor. These investigators concluded that dental procedures were not risk factors for subsequent total hip or knee infection, and that antibiotic prophylaxis prior to high or low risk dental procedures was not associated with a statistically significant reduction of the risk of hip or knee infection. They conclude that current opinion-based policies for the administration of antibiotic prophylaxis to patients with prosthetic hip and knee replacements who undergo subsequent dental treatment should be reconsidered.

In light of the Statement, potential clinical consequences, and the fact that oral and maxillofacial surgeons world-wide are implanting alloplastic temporomandibular joint (TMJ) devices, a survey was conducted to obtain perioperative and

postoperative antibiotic usage data in these cases.[17] Twenty-six surgeons from 8 countries responded. A total of 2476 cases (3368 joints) were retrospectively surveyed.

The data revealed 51 infected joints (1.51%). Of these 32 (62.7%) (0.1% of all joints) required removal and/or replacement. When organisms were isolated, bacteria commonly associated with biofilm infections of TJR devices, *Staphylococcus aureus, Staphylococcus epidermidis, Peptostreptococcus, Pseudamonas aerugenosa* were reported cultured. In only 1 joint (1.96%) (0.003% of all joints) was there even a suggestion of an association with an invasive dental/aero-digestive, GU/GI procedure. An ipsilateral tooth with a root canal treated by apicoectomy and antibiotics resulted in facial swelling. The oral infection resolved with antibiotic therapy and so did the associated facial swelling over the alloplastic joint. The device was not removed. The organism was not identified as the patient never developed any purulence.

As for providing prophylaxis after total alloplastic TMJ replacement and before invasive dental/aero-digestive, GU, GI procedures, 14 surgeons (53.8%) reported providing prophylaxis. Of these 14, 1 (7.1%) recommends doing this for 6 months; 4 (16%) for 2 years (the 2003 Advisory Panel's recommendation); and 9 (76.9%) reported they believed these TMJ replacement patients should have life-time antibiotic prophylaxis before such invasive procedures. Their common rationale was that the one dose of prophylactic antibiotic presently recommended was a small price to pay considering the clinical and financial consequences of such infections.

One of the many conclusions from this study was that post-implantation prophylaxis after orthopaedic total joint replacement and prior to invasive dental, urologic, gastrointestinal and aero-digestive procedures while questioned in published studies, might be important in alloplastic TMJ total joint replacement since the tips of the condylar component ramus fixation screws lie in the pterygomandibular space and could potentially be contaminated during inferior alveolar nerve anesthesia administration techniques. Further study was recommended.

Perhaps, Marculescu and Osmon's conclusions on the subject best summarizes where medicine and dentistry presently stand this issue: "The problem of prophylaxis in orthopedic implant surgery will become increasingly important and complex as the population ages and requires more arthroplasty procedures, and the prevalence of antimicrobial-resistant bacteria meanwhile continues to rise. Energy spent preventing prosthetic joint infection is more effective than that expended in treating the infection of a prosthetic joint, once established. Prevention measures encompass a wide array of variables related to host response, wound environment, and microorganisms. Prophylaxis should address these areas in the preoperative, intra-operative and postoperative periods. Antibiotic prophylaxis remains the single most effective method of reducing the prevalence of infection after total joint arthroplasty. In the postoperative period, prophylaxis aims to protect the prosthetic joint against hematogenous seeding from oral, urologic, skin or gastrointestinal sources. Current dental and urological advisory statements provide recommendations for antibiotic prophylaxis for high risk procedures. Close collaboration between the orthopedic surgeon, urologist, dentist and infectious disease specialist is crucial for providing recommendations regarding prophylaxis in special circumstances. In these particular circumstances, individual decisions should be made based on clinical judgement."[18]

Unfortunately, this question may never be able to be definitively answered because it appears impossible to design a randomized clinical trial with large enough cohorts since prosthetic joint infections are rare[19] and are more often caused by bacteria others than members of the oral flora.[20] Moreover, prescribing antibiotics needlessly may result in hypersensitivity reactions or even death from anaphylaxis. Also, the growing problem of antibiotic resistance must be taken into serious consideration.

References

1. **American Academy of Orthopaedic Surgeons. Public Relations Department Information Statement 1033. February 2009. American Academy of Orthopaedic Surgeons, 6300 North River Road Rosemont, Illinois 60018.**
2. **Rubin R, Salvati EA, Lewis R: Infected total hip replacement after dental procedures. Oral Surg 41:13-23, 1976.**
3. **Guntheroth WG: How important are dental procedures as a cause of infective endocarditis? Amer J Cardiol 54:797-801, 1984.**
4. **Bender IB, Naidorf IJ, Garvey GJ: Bacterial endocarditis: A consideration for physicians and dentists. JADA 109:415-420, 1984.**
5. **Everett ED, Hisrchmann JV: Transient bacteremia and endocarditis prophylaxis: A review. Medicine 56:61-77, 1977.**
6. **McGowen DA: Dentistry and endocarditis. Br Dent J 169:69, 1990.**
7. **Bartzokas CA, Johnson R, Jane M, et al: Relation between mouth and hematogenous infections in total joint replacement. Br Med J 309:506-508, 1994.**
8. **Ching DW, Gould IM, Rennie JA, et al: Prevention of late hematogenous infection in major prosthetic joints. J Antimicrob Chemother 23:678-680, 1989.**
9. **Antibiotic prophylaxis for surgery. The Medical Letter 52: 83-88, 2006.**
10. **Advisory statement. Antibiotic prophylaxis for dental patients with total joint replacements. American Dental Association; American Academy of Orthopaedic Surgeons. JADA 128:1004-1008, 1997.**
11. **Kingston R, Kiely P, McElwain JP: Antibiotic prophylaxis for dental or urological procedures following hip or knee replacement. J Infect 4:243-245, 2002.**
12. **Curry S and Phillips H: Joint arthroplasty, dental treatment and antibiotics: a review. J Arthroplasty 17:111-113, 2002.**
13. **Seymour RA, Whitworth JM, Martin M: Antibiotic prophylaxis for patients with joint prostheses – still a dilemma for**

dental practitioners. Br Dent J 194:6490-653, 2003.
14. **Kaar TK, Bogoch ER, Devlin HR: Acute metastatic infection of a revision total hip arthroplasty with oral bacteria after non-invasive dental treatment. J Arthroplasty 15:675-678, 2000.**
15. **Antibiotic prophylaxis for dental patients with total joint replacements. American Dental Association; American Academy of Orthopaedic Surgeons. JADA 134:895-899, 2003.**
16. **Berbari EF, Osmon DR, Carr A, et al: Dental Procedures as Risk Factors for Prosthetic Hip or Knee Infections: A Hospital-Based Prospective Case-Control Study Clin Inf Dis 50:8-16, 2010.**
17. **Mercuri LG and Psutka D: Peri-operative, Post-operative and Prophylactic Use of Antibiotics in Alloplastic Total Temporomandibular Joint Replacement Surgery: A Survey and Preliminary Guidelines. J Oral Maxillofac Surg 69:2106 – 2111, 2011.**
18. **Marculescu CE and Osmon DR: Antibiotic prophylaxis in orthopedic prosthetic surgery. Infect Dis Clin North Am 19:931-046, 2005.**
19. **Peersman G, Laskin R, Davis J, et al: Infection in total knee replacement: a review of 6489 total knee replacements. Clin Orthop Relat Res 392: 15 – 23, 2001.**
20. **Whal MJ: Myths of dental-induced prosthetic joint infections. 20:1420-1425, 1995.**

Dr. Mercuri,

Thank you for your expert review of this clinical practice guideline. Your commentary seems to coincide with our rationale for Recommendation 1. There simply isn't any direct evidence to warrant the prescribing of antibiotic prophylaxis for patients with orthopaedic implants undergoing dental procedures. Hopefully future research will shed more light on this complex subject, but our systematic review of the existing literature found no evidence that bacteremia caused by dental procedures seed orthopaedic implant infections. Therefore we did not recommend for any antimicrobial prophylaxis prior to dental procedures.

OVERALL ASSESSMENT

Would you recommend these guidelines for use in clinical practice? (Check one)

☐ Strongly recommend

X Recommend (with provisions or alterations)

☐ Would not recommend

☐ Unsure

Note: Your answer to this question does not constitute an endorsement of this guideline. We ask this question as a means of monitoring the clinical relevance of our guideline.

ALL REVIEW COMMENTS, RESPONSES AND REVIEWER CONFLICTS OF INTEREST DISCLSOURE WILL BE AVAILABLE ON OUR WEBSITE FOLLOWING APPROVAL OF THIS DOCUMENT.

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Reviewer Information:

Name of Reviewer: Dr. Paul A. Moore

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City: Pittsburgh State: PA Zip Code: 15261

Phone: 412 648-8476 Fax: _____ E-mail: pam7@pitt.edu

Specialty Area/Discipline: Pharmacology

Work setting: Academic_____ Credentials: DMD, PhD MPH_____

May we list you as a Peer Reviewer in the final Guidelines? x☐ Yes ☐ No

PLEASE READ: If you do not wish to be listed, your name will be removed for identification purposes. However, your review comments, our responses and your COI will still be available for public review on our website with the posted Guideline if you complete this review.

Are you reviewing this guideline as a representative of a professional society? **x**☐ Yes ☐ No

If yes, may we list your society as a reviewer of this guideline? x☐ Yes ☐ No

Society Name: American Association of Public Health Dentistry_____

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Are you or a member of your immediate family a PAID EMPLOYEE for any pharmaceutical, biomaterial or orthopaedic device or equipment company, or supplier? If YES, please identify company or supplier:	☐ Yes x☐ No
Are you or a member of your immediate family a PAID CONSULTANT for any pharmaceutical, biomaterial or orthopaedic device or equipment company, or supplier? If YES, please identify company or supplier:	☐ Yes x☐ No
Are you or a member of your immediate family an UNPAID CONSULTANT for any pharmaceutical, biomaterial or orthopaedic device or equipment company, or supplier? If YES, please identify company or supplier:	☐ Yes x☐ No
Do you or a member of your immediate family own stock or stock options in any pharmaceutical, biomaterial or orthopaedic device or equipment company, or supplier (excluding mutual funds) If YES, please identify company or supplier:	☐ Yes x☐ No
Do you or a member of your immediate family receive research or institutional support as a principal investigator from any pharmaceutical, biomaterial or orthopaedic device or equipment company, or supplier? If YES, please identify company or supplier: Novocol of Canada; re. Instituttional support for OraVerse study	x☐ Yes ☐ No
Do you or a member of your immediate family receive any other financial or material support from any pharmaceutical, biomaterial or orthopaedic device and equipment company or supplier? If YES, please identify company or supplier:	☐ Yes x☐ No
Do you or a member of your immediate family receive any royalties, financial or material support from any medical and/or orthopaedic publishers? If YES, please identify publisher:	☐ Yes x☐ No
Do you or a member of your immediate family serve on the editorial or governing board of any medical and/or orthopaedic publication? If YES, please identify: Editorial Boards for Anesthesia Progress	x☐ Yes ☐ No
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Structured Peer Review Form Instructions

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Please complete and return this form electronically in **WORD format** to boyer@aaos.org; please contact Kevin Boyer at (847) 384-4328 if you have any questions. Thank you in advance for your time in completing this form and giving us your feedback. We value your input and greatly appreciate your efforts. Please return the completed form in **WORD format** by end of day **March 15, 2012**.

Please indicate your level of agreement with each of the following statements by placing an "X" in the appropriate box.

	Disagree	Somewhat Disagree	Somewhat Agree	Agree
1. The recommendations are clearly stated	x☐	☐	☐	☐
2. There is an explicit link between the recommendations and the supporting evidence	☐	☐	x☐	☐
3. Given the nature of the topic and the data, all clinically important outcomes are considered	☐	☐	☐	x☐
4. The guideline's target audience is clearly described	☐	☐	☐	x☐
5. The patients to whom this guideline is meant to apply are specifically described	☐	☐	☐	x ☐
6. The criteria used to select articles for inclusion are appropriate	☐	☐	☐	x☐
7. The reasons why some studies were excluded are clearly described	☐	☐	☐	x☐
8. All important studies that met the article inclusion criteria are included	☐	☐	☐	x☐
9. The validity of the studies is appropriately appraised	☐	☐	☐	x☐
10. The methods are described in such a way as to be reproducible.	☐	☐	☐	x☐
11. The statistical methods are appropriate to the material and the objectives of this guideline	☐	☐	☐	x ☐
12. Important parameters (e.g., setting, study population, study design) that could affect study results are systematically addressed	☐	☐	☐	x☐
13. Health benefits, side effects, and risks are adequately addressed	☐	x☐	☐	☐
14. The writing style is appropriate for health care professionals.	☐	☐	☐	x☐
15. The grades assigned to each recommendation are appropriate	☐	☐	☐	x☐

COMMENTS

PLEASE RETURN ALL COMMENTS IN WORD FORMAT

Please provide a brief explanation of both your positive and negative answers in the preceding section. If applicable, please specify the draft page and line numbers in your comments. Please feel free to also comment on the overall structure and content of the Guideline

Paul A. Moore
3/11/2012
Peer review of AAOS/ADA Draft entitled:

PREVENTION OF ORTHOPAEDIC IMPLANT INFECTION IN PATIENTS UNDERGOING DENTAL PROCEDURE

This draft report provides an evidence-based systematic review of research data regarding the potential for preventing implant infections by providing antibiotic prophylaxis when patients undergo dental procedures. The findings of the review were to be used to create guidelines for evidence based care when patients receive dental procedures.

The systemic review is very thorough, casting a wide net to assure a complete review of the literature. Care has been taken to limit bias and to assure validity and reproducibility. The authors of this review should be commended.

Critical Comment.

I find that the first of the recommendations is poorly written and make an assumption that is incorrect. The recommendation states "The practitioner might consider discontinuing the practice of routinely prescribing prophylactic antibiotics for patients with hip and knee prosthetic joint implants undergoing dental procedures". The Grade of the evidence for this recommendation is "Weak".

I have been teaching pharmacology at the University of Pittsburgh for 25 years and have provided my students and CE lectures with a different recommendation based on the recommendation of the Council of Dental Therapeutics (1990). I have not used the opinion guidelines published by the AAOS (2009) because they were written without input or consensus from our profession in any official manor in establishing their recommendations. Most importantly, the literature used in the AAOS guideline of 2009 was EXACTLY the same as used in the ADA guidelines published in 1990. As such, I have never believed that any new evidence had been sited to justify the AAOS change to "routinely prescribing of antibiotics" or any justification to change our standard of care from the 1990 ADA document. It has been my position that the AAOS guidelines published in 2009 were to be regarded as their opinion, and not standard of care in dentistry.

Secondly, the "weak" grade for the first recommendation is confusing and presumptuous. If the evidence is negative albeit "weak" for the administration of antibiotics, then the recommendation should not be to "consider discontinuing antibiotics"; it should follow the original ADA guidelines that state that there is "inadequate evidence to justify the use antibiotics". Given that the evidence-based review does not consider the risk of administering up to a million doses of antibiotics to dental patients, one must consider that current wording of the recommendation is telling our dental profession that there is weak evidence to discontinue it use. In fact, the recommendation should be more properly stated that there is inadequate evidence to justify antibiotic use during dental procedures to prevent prosthetic hip and nee prosthetics.

Sincerely yours,
Paul Moore

Dr. Moore,

Thank you for your expert review of this clinical practice guideline and for recognizing the efforts of the workgroup and commending us. Your feedback on this guideline is invaluable and we exhaustively considered all of your critical comments.

We recognize that the wording of Recommendation 1, "The practitioner might consider discontinuing the practice of routinely prescribing prophylactic antibiotics for patients with hip and knee prosthetic joint implants undergoing dental procedures", is not without fault. However we follow a rigorous methodology. These methods start with preliminary recommendations formulated at the workgroup's first meeting. These recommendations specify [what] should be done in [whom], [when], [where], and [how often or how long]. To avoid "wordsmithing" discussions at the initial work group meeting, the preliminary recommendations are always worded as recommending for something. Therefore the preliminary recommendation "positively" recommended for antibiotic prophylaxis for patients with orthopaedic implants undergoing dental procedures. Consequently when the best available evidence (1 "moderate" strength study) revealed that dental procedures are not related to subsequent orthopaedic (namely hip and knee) implant infection and furthermore that antibiotic prophylaxis did not reduce the risk of alleged subsequent infection we were required to use the respective guideline language, "The practitioner MIGHT", and give it a "Weak" grade according to AAOS rules of evidence. We agreed to strictly adhere to these rules at the inception of this guideline and feel that the current wording of the recommendation is the best possible option.

Beyond the required language and "weak" grade the workgroup chose the remaining words very carefully and ultimately agreed that "consider discontinuing the practice of routinely prescribing prophylactic antibiotics" was the best possible wording based on current knowledge of practice and past clinical recommendations/guidelines. An informal survey of dental schools found that approximately half instruct their students to recommend for antibiotic prophylaxis in these matters. The ADA also recommends that the dentist have a conversation with the patient and their respective orthopaedic surgeon about antibiotic prophylaxis. It was the impression of the orthopaedic surgeons in the workgroup that their colleagues routinely recommend for antibiotic prophylaxis and they themselves favored its use.

While your teaching position on this topic is against antibiotic prophylaxis, it may unfortunately not reflect common practice. The Council of Dental Therapeutics (1990) that you refer to concluded that "data are insufficient at the present time to support the need for, or the effectiveness of, antibiotic prophylaxis for the dental patient who has a prosthetic joint". Since then AAOS and ADA released joint statements in 1997 and 2003 which recommended antibiotic prophylaxis for 2 years post orthopaedic implant placement for all patients undergoing a high risk procedure which includes prophylactic teeth cleaning and furthermore for high risk patients, such as immunocompromised ones. In 2009, as you noted, AAOS released an independent information statement that inferred that all orthopaedic joint implant patients receive antibiotic prophylaxis before dental procedures for their lifetime. In retrospect, none of these may have been the best course of care, but they were the community standard and we believe that dentists and orthopaedic surgeons routinely prescribe antibiotics for patients with certain comorbidities and for the first 2 years if not longer.

Through a systematic review of the evidence and consideration of common practice, the workgroup meticulously constructed the recommendation in accordance with the rules of the guideline creation process. While the wording of the newly proposed recommendation may assume that practitioners currently prescribe antibiotic prophylaxis, which may not be entirely accurate or based on sound science, the end result is that we

discourage the use of antibiotic prophylaxis for this population which seems to be in accordance with your teaching.

OVERALL ASSESSMENT

Would you recommend these guidelines for use in clinical practice? (Check one)

☐ Strongly recommend

☒ Recommend (with provisions or alterations)

☐ Would not recommend

☐ Unsure

Note: Your answer to this question does not constitute an endorsement of this guideline. We ask this question as a means of monitoring the clinical relevance of our guideline.

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Reviewer Information:

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City: Mclean State: VA Zip Code: 22102

Phone: 571-278-4444 Fax: _____ E-mail: orthopod203@hotmail.com

Specialty Area/Discipline: spinal surgery

Work setting: _____ Credentials: _____

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Are you reviewing this guideline as a representative of a professional society? **X**☐ Yes ☐ No

If yes, may we list your society as a reviewer of this guideline? X☐ Yes ☐ No

Society Name: Lumbar Spine Research Society

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Within the past twelve months, have you or a member of your immediate family served on the speakers bureau or have you been paid an honorarium to present by any pharmaceutical, biomaterial or orthopaedic product or device company? If YES, please identify company:	☐ Yes ☐ No
Are you or a member of your immediate family a PAID EMPLOYEE for any pharmaceutical, biomaterial or orthopaedic device or equipment company, or supplier? If YES, please identify company or supplier:	☐ Yes ☐ No
Are you or a member of your immediate family a PAID CONSULTANT for any pharmaceutical, biomaterial or orthopaedic device or equipment company, or supplier? If YES, please identify company or supplier:	☐ Yes ☐ No
Are you or a member of your immediate family an UNPAID CONSULTANT for any pharmaceutical, biomaterial or orthopaedic device or equipment company, or supplier? If YES, please identify company or supplier:	☐ Yes ☐ No
Do you or a member of your immediate family own stock or stock options in any pharmaceutical, biomaterial or orthopaedic device or equipment company, or supplier (excluding mutual funds) If YES, please identify company or supplier:	☐ Yes ☐ No
Do you or a member of your immediate family receive research or institutional support as a principal investigator from any pharmaceutical, biomaterial or orthopaedic device or equipment company, or supplier? If YES, please identify company or supplier:	☐ Yes ☐ No
Do you or a member of your immediate family receive any other financial or material support from any pharmaceutical, biomaterial or orthopaedic device and equipment company or supplier? If YES, please identify company or supplier:	☐ Yes ☐ No
Do you or a member of your immediate family receive any royalties, financial or material support from any medical and/or orthopaedic publishers? If YES, please identify publisher:	☐ Yes ☐ No
Do you or a member of your immediate family serve on the editorial or governing board of any medical and/or orthopaedic publication? If YES, please identify:	☐ Yes ☐ No
Do you or a member of your immediate family serve on the Board of Directors or a committee of any medical and/or orthopaedic professional society? If YES, please identify:	☐ Yes ☐ No

Structured Peer Review Form Instructions

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Please complete and return this form electronically in **WORD format** to boyer@aaos.org; please contact Kevin Boyer at (847) 384-4328 if you have any questions. Thank you in advance for your time in completing this form and giving us your feedback. We value your input and greatly appreciate your efforts. Please return the completed form in **WORD format** by end of day **March 15, 2012**.

Please indicate your level of agreement with each of the following statements by placing an "X" in the appropriate box.

	Disagree	Somewhat Disagree	Somewhat Agree	Agree
1. The recommendations are clearly stated	☐	☐	☐	x☐
2. There is an explicit link between the recommendations and the supporting evidence	☐	☐	☐	x☐
3. Given the nature of the topic and the data, all clinically important outcomes are considered	☐	☐	x☐	☐
4. The guideline's target audience is clearly described	☐	☐	☐	x☐
5. The patients to whom this guideline is meant to apply are specifically described	☐	☐	x☐	☐
6. The criteria used to select articles for inclusion are appropriate	☐	☐	☐	x☐
7. The reasons why some studies were excluded are clearly described	☐	☐	x☐	☐
8. All important studies that met the article inclusion criteria are included	☐	☐	x☐	☐
9. The validity of the studies is appropriately appraised	☐	☐	☐	x☐
10. The methods are described in such a way as to be reproducible.	☐	☐	x☐	☐
11. The statistical methods are appropriate to the material and the objectives of this guideline	☐	☐	x☐	☐
12. Important parameters (e.g., setting, study population, study design) that could affect study results are systematically addressed	☐	☐	x☐	☐
13. Health benefits, side effects, and risks are adequately addressed	☐	☐	x☐	☐
14. The writing style is appropriate for health care professionals.	☐	☐	x☐	☐
15. The grades assigned to each recommendation are appropriate	☐	☐	☐	x☐

COMMENTS

PLEASE RETURN ALL COMMENTS IN WORD FORMAT

Please provide a brief explanation of both your positive and negative answers in the preceding section. If applicable, please specify the draft page and line numbers in your comments. Please feel free to also comment on the overall structure and content of the Guideline

page 83 line 1644 needs X"infection" inserted after "implant"

it would be ideal if the type of implant were stratified, e.g. spinal hardware vs. prosthetic joint vs. trauma plates/screws vs. trauma intra-medullary devices. I suspect that the rates of infection independent of dental interventions are different for each type of implant and that there may be a differential change in the infection rate associated with dental procedures in each category of implant. This stratification needs to be clarified in the supporting evidence cited for the recommendations

Dr. Patel,

Thank you for your expert review of this clinical practice guideline. We will correct the error you found on line 1644. Tables 25 and 26 of the guideline stratify orthopaedic implant infection data by type. These tables only summarize the studies that were included in our review and are not representative of all orthopaedic implant infections. Our data pertains primarily to prosthetic joints because the only direct evidence available for this guideline addresses prosthetic hip and knee implants only. No other evidence existed that attempted to explain the relationship between dental procedures and subsequent infection of other types of orthopaedic implants. Also, past guidelines and our guideline workgroup proposed that total prosthetic joints are at a higher risk of infection than other orthopaedic implants. Being that there was no evidence to support that dental procedures cause prosthetic joint infection it is unlikely that other types of implants would be any different. Furthermore we do not recommend for any antimicrobial prophylaxis before dental procedures because there is no direct evidence that suggests that these procedures are related to any type of orthopaedic implant infection. We agree that rates of implant infection independent of dental interventions are likely different by type but without any correlation to dental procedures this does not provide any direct evidence for our recommendations. Further research into this area was not within the scope of this guideline.

OVERALL ASSESSMENT

Would you recommend these guidelines for use in clinical practice? (Check one)

x☐ Strongly recommend

☐ Recommend (with provisions or alterations)

☐ Would not recommend

☐ Unsure

Note: Your answer to this question does not constitute an endorsement of this guideline. We ask this question as a means of monitoring the clinical relevance of our guideline.

ALL REVIEW COMMENTS, RESPONSES AND REVIEWER CONFLICTS OF INTEREST DISCLSOURE WILL BE AVAILABLE ON OUR WEBSITE FOLLOWING APPROVAL OF THIS DOCUMENT.

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- **Your conflicts of interest disclosures will be published on the AAOS website, and may be published on the ADA website, with your review comments.**

Reviewer Information:

Name of Reviewer: A. Charles Post DDS

Address: Children's Hospital of Wisconsin, PO Box 1997

City: Milwaukee State: WI Zip Code: 53201

Phone: 414-266-2040 Fax: 414-266-6189 E-mail: cpost@chw.org

Specialty Area/Discipline: Pediatric Dentistry

Work setting: Hospital Credentials: Director, Pediatric Dental Residency Program

---

May we list you as a Peer Reviewer in the final Guidelines? ☒ Yes ☐ No

PLEASE READ: If you do not wish to be listed, your name will be removed for identification purposes. However, your review comments, our responses and your COI will still be available for public review on our website with the posted Guideline if you complete this review.

Are you reviewing this guideline as a representative of a professional society? ☒ Yes ☐ No

If yes, may we list your society as a reviewer of this guideline? ☒ Yes ☐ No

Society Name: American Academy of Pediatric Dentistry

(Listing the specialty society as a reviewing society does not imply or otherwise indicate endorsement of this guideline.)

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Within the past twelve months, have you or a member of your immediate family served on the speakers bureau or have you been paid an honorarium to present by any pharmaceutical, biomaterial or orthopaedic product or device company? If YES, please identify company:	☐ Yes ☒ No
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Are you or a member of your immediate family a PAID CONSULTANT for any pharmaceutical, biomaterial or orthopaedic device or equipment company, or supplier? If YES, please identify company or supplier:	☐ Yes ☒ No
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Please complete and return this form electronically in **WORD format** to boyer@aaos.org; please contact Kevin Boyer at (847) 384-4328 if you have any questions. Thank you in advance for your time in completing this form and giving us your feedback. We value your input and greatly appreciate your efforts. Please return the completed form in **WORD format** by end of day **March 15, 2012**.

Please indicate your level of agreement with each of the following statements by placing an "X" in the appropriate box.

	Disagree	Somewhat Disagree	Somewhat Agree	Agree
1. The recommendations are clearly stated	☐	☐	☐	☒
2. There is an explicit link between the recommendations and the supporting evidence	☐	☐	☐	☒
3. Given the nature of the topic and the data, all clinically important outcomes are considered	☐	☐	☐	☒
4. The guideline's target audience is clearly described	☐	☐	☐	☒
5. The patients to whom this guideline is meant to apply are specifically described	☐	☐	☐	☒
6. The criteria used to select articles for inclusion are appropriate	☐	☐	☐	☒
7. The reasons why some studies were excluded are clearly described	☐	☐	☒	☐
8. All important studies that met the article inclusion criteria are included	☐	☐	☐	☒
9. The validity of the studies is appropriately appraised	☐	☐	☐	☒
10. The methods are described in such a way as to be reproducible.	☐	☐	☐	☒
11. The statistical methods are appropriate to the material and the objectives of this guideline	☐	☐	☐	☒
12. Important parameters (e.g., setting, study population, study design) that could affect study results are systematically addressed	☐	☐	☐	☒
13. Health benefits, side effects, and risks are adequately addressed	☐	☐	☐	☒
14. The writing style is appropriate for health care professionals.	☐	☐	☐	☒
15. The grades assigned to each recommendation are appropriate	☐	☐	☐	☒

COMMENTS

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Please provide a brief explanation of both your positive and negative answers in the preceding section. If applicable, please specify the draft page and line numbers in your comments. Please feel free to also comment on the overall structure and content of the Guideline

Overall, this document is very good and appears to fulfill the criteria of an evidence based guideline. Based on the evidence presented, the recommendations are appropriate. However, I do have some additional points that might be considered.

a. **Working in a hospital, I have a number of patients with implants. Many of our orthopedic surgeons ask that we give prophylactic antibiotics for the first 6 months to a year following the implant surgery. After this immediate post-surgical time, prophylactic antibiotics are no longer necessary.**
Has the issue of antibiotic prophylaxis and post surgical time frames been considered and does it need to be considered? Is there any evidence to suggest that the immediate post surgical time poses a higher infection risk that would make antibiotics a consideration?

b. **Starting on line 1298 (Table 10), reference is made to the 1997 *American Heart Association Guideline on Infective Endocarditis* (AHA) in regard to delineating high risk vs. low risk dental procedures.**
The procedure descriptions are ambiguous. As a pediatric dentist, I would have a difficult time deciding whether specific procedures are high or low risk. This should be improved.

c. **Is there any evidence that delineates high vs low infection risk implants? If there are various risk levels, should prophylactic antibiotics be based on the risk factors associated with the type of implant and the type of dental procedure, and, as a result, consider refining Recommendation 1 to include risk based considerations.**

Conclusion:

1) **If there is any evidence that supports a higher infection risk immediately post-surgery, this evidence should be considered in Recommendation 1.**
2) **If there is any evidence that supports various infection risks based on the type of implant, this evidence should be considered in Recommendation 1.**
3) **If there is no evidence that supports 1) or2), Recommendation 1 should stand as written.**
4) **The definitions of high and low risk dental procedures (Table 10) should be stated more clearly.**
5) **Recommendations 2 and 3 are appropriate and clearly stated.**

Dr. Post,

Thank you for your expert review of this clinical practice guideline. We conducted an extremely broad search of the literature and we were interested in the potential relationship between post-surgical orthopaedic implant time and infection related to dental procedures. However there was no evidence that met our inclusion criteria that provided any data in this regard. The one piece of direct evidence (Berbari 2010), which is the foundation for this guideline, found that dental procedures are not related to prosthetic joint implant infection. Perhaps the risk of orthopaedic implant infection is inversely related to time following the implant surgery, but we found no evidence that dental procedures are correlated. Berbari et al included joint age as a covariate in their regression model which concluded that dental procedures are not related to subsequent prosthetic joint infection. This study only addresses prosthetic hips and knees. There was no other included literature in our review that addressed other types of orthopaedic implants.

The stratification of dental procedures into high and low risk categories was defined by Berbari et al via the 1997 AHA IE guideline. This data is informational and not meant to be considered by the practitioner in regards to prescribing prophylaxis as we did not recommend for any antimicrobial prophylaxis in this guideline.

OVERALL ASSESSMENT

Would you recommend these guidelines for use in clinical practice? (Check one)

☐ Strongly recommend

☒ Recommend (with provisions or alterations)

☐ Would not recommend

☐ Unsure

Note: Your answer to this question does not constitute an endorsement of this guideline. We ask this question as a means of monitoring the clinical relevance of our guideline.

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- **Your conflicts of interest disclosures will be published on the AAOS website, and may be published on the ADA website, with your review comments.**

Reviewer Information:

Name of Reviewer: Charles A. Reitman, MD

Address: 6620 Main Street, Suite 1325

City: Houston State: Tx Zip Code: 77030

Phone: 713-986-7410 Fax: _____ E-mail: creitman@bcm.tmc.edu

Specialty Area/Discipline: Spine

Work setting: Academic medical center Credentials: MD

May we list you as a Peer Reviewer in the final Guidelines? ☒ Yes ☐ No

PLEASE READ: If you do not wish to be listed, your name will be removed for identification purposes. However, your review comments, our responses and your COI will still be available for public review on our website with the posted Guideline if you complete this review.

Are you reviewing this guideline as a representative of a professional society? ☐ Yes ☒ No

If yes, may we list your society as a reviewer of this guideline? ☐ Yes ☐ No

Society Name: _____

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☒ **I have declared my conflicts of interest on page 2 of this form.**
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Do you or a member of your immediate family receive royalties for any pharmaceutical, biomaterial or orthopaedic product or device? If YES, please identify product or device:	☐ Yes ☒ No
Within the past twelve months, have you or a member of your immediate family served on the speakers bureau or have you been paid an honorarium to present by any pharmaceutical, biomaterial or orthopaedic product or device company? If YES, please identify company:	☐ Yes ☒ No
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Do you or a member of your immediate family receive any other financial or material support from any pharmaceutical, biomaterial or orthopaedic device and equipment company or supplier? If YES, please identify company or supplier:	☐ Yes ☒ No
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Do you or a member of your immediate family serve on the Board of Directors or a committee of any medical and/or orthopaedic professional society? If YES, please identify: North American Spine Society	☒ Yes ☐ No

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Please complete and return this form electronically in **WORD format** to boyer@aaos.org; please contact Kevin Boyer at (847) 384-4328 if you have any questions. Thank you in advance for your time in completing this form and giving us your feedback. We value your input and greatly appreciate your efforts. Please return the completed form in **WORD format** by end of day **March 5, 2012**.

Please indicate your level of agreement with each of the following statements by placing an "X" in the appropriate box.

	Disagree	Somewhat Disagree	Somewhat Agree	Agree
1. The recommendations are clearly stated	☐	☐	☒	☐
2. There is an explicit link between the recommendations and the supporting evidence	☐	☐	☐	☒
3. Given the nature of the topic and the data, all clinically important outcomes are considered	☐	☐	☐	☒
4. The guideline's target audience is clearly described	☐	☐	☐	☒
5. The patients to whom this guideline is meant to apply are specifically described	☐	☐	☐	☒
6. The criteria used to select articles for inclusion are appropriate	☐	☐	☐	☒
7. The reasons why some studies were excluded are clearly described	☐	☐	☐	☒
8. All important studies that met the article inclusion criteria are included	☐	☐	☐	☒
9. The validity of the studies is appropriately appraised	☐	☐	☐	☒
10. The methods are described in such a way as to be reproducible.	☐	☐	☐	☒
11. The statistical methods are appropriate to the material and the objectives of this guideline	☐	☐	☐	☐
12. Important parameters (e.g., setting, study population, study design) that could affect study results are systematically addressed	☐	☐	☐	☒
13. Health benefits, side effects, and risks are adequately addressed	☐	☐	☒	☐
14. The writing style is appropriate for health care professionals.	☐	☐	☐	☒
15. The grades assigned to each recommendation are appropriate	☐	☐	☐	☒

COMMENTS

PLEASE RETURN ALL COMMENTS IN WORD FORMAT

Please provide a brief explanation of both your positive and negative answers in the preceding section. If applicable, please specify the draft page and line numbers in your comments. Please feel free to also comment on the overall structure and content of the Guideline

This is an impressive document. Huge amount of work, objectively presented. Recommendations carefully and appropriately crafted based on available clinical data. In my opinion, there was appropriate use of surrogate data to qualify recommendations. I don't have any specific corrections but have some conceptual questions.

There are three points of interest that may improve the stength of the document for the reader.

The first point is simple. You presented nice data regarding topical and oral (and IV) abx prophyllaxis. The recommendation was weak for use for topical, and consider no prophyllactic oral use. All the tables were presented, but no specific recommendations were made regarding the ideal medications if the provider chose to use them. The authors assume that the readers will interpret the tables and statistics appropriately. While many probably will, I think there will be a significant number of providers that would benefit from specific recommendations. If the authors feel it would be appropriate, I think it would strengthen the document in terms of translation to clinical practice to actually state the optimal medications. Something like surrogate data would suggest best choice for prophyllaxis would be drug A. In the event of drug allergy, alternate choice would be drug B.

Second and third points together. I think it would be helpful if there were a discussion about decision making, risk vs. harm. This is a very unusual guideline for orthopedics because outcome is harm. Its not like clinical outcome for distal radius fracture with plate vs. ex fix. The only other guideline that would be similar that I can think of would be pharmacologic DVT prophyllaxis. In this case of harm, the reader needs to understand that it could be very difficult to have enough power to show statistically significant increase in incidence of harm. Although it may not be statistically significant, a small increase in infection rate may not be acceptable considering the severity of complication. Its not death, but it's a pretty serious, life changing complication. If the treatment is very low risk, and short term abx use with these inexpensive drugs probably is (unfortunately would have to look at the data), then perhaps the consideration should be stronger. I don't know if this is statistically correct, but what if you looked at this as a non inferiority question. You say use of very short term abx is inexpensive and carries almost no risk. Harm of possible joint is catastrophic. Question are, "How much risk is there giving pre procedure abx?" and "Is there any evidence that use of antibiotics increase the risk of joint infection?" If they don't, you could make an argument that this would be a recommendation to use them. I know you can't completely change your methodology at this point, but if some statement elaborating these concepts could be included, it would seem appropriate and beneficial.

I would ask the group to consider these concepts, but would endorse the document regardless of final disposition.

Dr. Reitman,

Thank you for your time reviewing the guideline draft, we always appreciate it. There is definitely a wealth of surrogate data related to bacteremia outcomes that could be utilized to create the list you suggest. The workgroup (after a long debate at their meeting) decided that including such a list in conjunction with a recommendation **against the use** of antibiotic prophylaxis is not helpful and could undermine the recommendation. In regards to your second and third points, as our guideline process dictates, we do not consider the interactions between costs and risks or benefits to aide decision making. We have added a sentence to our summary of recommendations to make this point to readers.

OVERALL ASSESSMENT

Would you recommend these guidelines for use in clinical practice? (Check one)

☐ Strongly recommend

☒ Recommend (with provisions or alterations)

☐ Would not recommend

☐ Unsure

Note: Your answer to this question does not constitute an endorsement of this guideline. We ask this question as a means of monitoring the clinical relevance of our guideline.

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Reviewer Information:

Name of Reviewer: ROBERT RICH JR MD

Address: PO BOX 517

City: ELIZABETHTOWN State: NC Zip Code: 28337

Phone: Fax: E-mail:

Specialty Area/Discipline: FAMILY MEDICINE

Work setting: OFFICE Credentials: MEDICAL DIRECTOR

May we list you as a Peer Reviewer in the final Guidelines? ☒ Yes ☐ No

PLEASE READ: If you do not wish to be listed, your name will be removed for identification purposes. However, your review comments, our responses and your COI will still be available for public review on our website with the posted Guideline if you complete this review.

Are you reviewing this guideline as a representative of a professional society? ☒ Yes ☐ No

If yes, may we list your society as a reviewer of this guideline? ☒ Yes ☐ No

Society Name: AAFP

(Listing the specialty society as a reviewing society does not imply or otherwise indicate endorsement of this guideline.)

Conflicts of Interest (COI): All Reviewers must declare their conflicts of interest.

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Are you or a member of your immediate family a PAID CONSULTANT for any pharmaceutical, biomaterial or orthopaedic device or equipment company, or supplier? If YES, please identify company or supplier:	☐ Yes ☒ No
Are you or a member of your immediate family an UNPAID CONSULTANT for any pharmaceutical, biomaterial or orthopaedic device or equipment company, or supplier? If YES, please identify company or supplier:	☐ Yes ☒ No
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Do you or a member of your immediate family receive research or institutional support as a principal investigator from any pharmaceutical, biomaterial or orthopaedic device or equipment company, or supplier? If YES, please identify company or supplier:	☐ Yes ☒ No
Do you or a member of your immediate family receive any other financial or material support from any pharmaceutical, biomaterial or orthopaedic device and equipment company or supplier? If YES, please identify company or supplier:	☐ Yes ☒ No
Do you or a member of your immediate family receive any royalties, financial or material support from any medical and/or orthopaedic publishers? If YES, please identify publisher:	☐ Yes ☒ No
Do you or a member of your immediate family serve on the editorial or governing board of any medical and/or orthopaedic publication? If YES, please identify:	☐ Yes ☒ No
Do you or a member of your immediate family serve on the Board of Directors or a committee of any medical and/or orthopaedic professional society? If YES, please identify: AAFP COMMISION ON HEALTH OF THE PUBLIC	☒ Yes ☐ No

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Please indicate your level of agreement with each of the following statements by placing an "X" in the appropriate box.

	Disagree	Somewhat Disagree	Somewhat Agree	Agree
1. The recommendations are clearly stated	☐	☐	☒	☐
2. There is an explicit link between the recommendations and the supporting evidence	☐	☐	☒	☐
3. Given the nature of the topic and the data, all clinically important outcomes are considered	☐	☐	☐	☒
4. The guideline's target audience is clearly described	☐	☐	☒	☐
5. The patients to whom this guideline is meant to apply are specifically described	☐	☐	☒	☐
6. The criteria used to select articles for inclusion are appropriate	☐	☐	☒	☐
7. The reasons why some studies were excluded are clearly described	☐	☐	☐	☒
8. All important studies that met the article inclusion criteria are included	☐	☐	☒	☐
9. The validity of the studies is appropriately appraised	☐	☐	☒	☐
10. The methods are described in such a way as to be reproducible.	☐	☐	☒	☐
11. The statistical methods are appropriate to the material and the objectives of this guideline	☐	☐	☒	☐
12. Important parameters (e.g., setting, study population, study design) that could affect study results are systematically addressed	☐	☐	☐	☒
13. Health benefits, side effects, and risks are adequately addressed	☐	☐	☒	☐
14. The writing style is appropriate for health care professionals.	☐	☐	☒	☐
15. The grades assigned to each recommendation are appropriate	☐	☐	☒	☐

COMMENTS

PLEASE RETURN ALL COMMENTS IN WORD FORMAT

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OVERALL, GUIDELINE IS APPROPRIATELY WRITTEN, EXAMINING ALL AVAILABLE DOCUEMENTS. STRUCTURE OF GUIDELINE APPROPRIATE AND APPEARS TO ADDRESS CONCERNS, BOTH BY PRIMARY CARE AND SPECIALTY CARE PHYSICIANS. GUIDELINES MAY APPEAR ON FACE VALUE TO CONTRADICT CURRENT PRACTICE IN MOST OFFICES BUT WHEN THE AVAILABLE EVIDENCE IS EXAMINED, GUIDELINES APPEAR APPROPRIATE.

Dr. Rich,

Thank you for your thoughtful input on this clinical practice guideline. We are pleased that you found the methods and results of this evidence-based guideline appropriately address the concerns of primary care physicians and specialty care physicians.

OVERALL ASSESSMENT

Would you recommend these guidelines for use in clinical practice? (Check one)

☒ Strongly recommend

☐ Recommend (with provisions or alterations)

☐ Would not recommend

☐ Unsure

Note: Your answer to this question does not constitute an endorsement of this guideline. We ask this question as a means of monitoring the clinical relevance of our guideline.

ALL REVIEW COMMENTS, RESPONSES AND REVIEWER CONFLICTS OF INTEREST DISCLSOURE WILL BE AVAILABLE ON OUR WEBSITE FOLLOWING APPROVAL OF THIS DOCUMENT.

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- **Your conflicts of interest disclosures will be published on the AAOS website, and may be published on the ADA website, with your review comments.**

Reviewer Information:

Name of Reviewer: Frank Scannaapieco

Address: University at Buffalo School of Dental Medicine, 3435 Main St.

City: Buffalo State: NY Zip Code: 14214

Phone: 7168293373 Fax: _____ E-mail: fas1@buffalo.edu

Specialty Area/Discipline: Periodontics

Work setting: University Credentials: D.M.D., Ph.D

May we list you as a Peer Reviewer in the final Guidelines? ☒ Yes ☐ No

PLEASE READ: If you do not wish to be listed, your name will be removed for identification purposes. However, your review comments, our responses and your COI will still be available for public review on our website with the posted Guideline if you complete this review.

Are you reviewing this guideline as a representative of a professional society? ☒ Yes ☐ No

If yes, may we list your society as a reviewer of this guideline? ☒ Yes ☐ No

Society Name: American Academy of Periodontology

(Listing the specialty society as a reviewing society does not imply or otherwise indicate endorsement of this guideline.)

Conflicts of Interest (COI): All Reviewers must declare their conflicts of interest.

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Are you or a member of your immediate family a PAID CONSULTANT for any pharmaceutical, biomaterial or orthopaedic device or equipment company, or supplier? If YES, please identify company or supplier: Colgate	☒ Yes ☐ No
Are you or a member of your immediate family an UNPAID CONSULTANT for any pharmaceutical, biomaterial or orthopaedic device or equipment company, or supplier? If YES, please identify company or supplier:	☐ Yes ☒ No
Do you or a member of your immediate family own stock or stock options in any pharmaceutical, biomaterial or orthopaedic device or equipment company, or supplier (excluding mutual funds) If YES, please identify company or supplier:	☐ Yes ☒ No
Do you or a member of your immediate family receive research or institutional support as a principal investigator from any pharmaceutical, biomaterial or orthopaedic device or equipment company, or supplier? If YES, please identify company or supplier: Colgate	☒ Yes ☐ No
Do you or a member of your immediate family receive any other financial or material support from any pharmaceutical, biomaterial or orthopaedic device and equipment company or supplier? If YES, please identify company or supplier: Colgate	☒ Yes ☐ No
Do you or a member of your immediate family receive any royalties, financial or material support from any medical and/or orthopaedic publishers? If YES, please identify publisher:	☐ Yes ☒ No
Do you or a member of your immediate family serve on the editorial or governing board of any medical and/or orthopaedic publication? If YES, please identify: Journal of Periodontology	☒ Yes ☐ No
Do you or a member of your immediate family serve on the Board of Directors or a committee of any medical and/or orthopaedic professional society? If YES, please identify:	☐ Yes ☒ No

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Please indicate your level of agreement with each of the following statements by placing an "X" in the appropriate box.

	Disagree	Somewhat Disagree	Somewhat Agree	Agree
1. The recommendations are clearly stated	☐	☐	☒	☐
2. There is an explicit link between the recommendations and the supporting evidence	☐	☐	☐	☒
3. Given the nature of the topic and the data, all clinically important outcomes are considered	☐	☐	☐	☒
4. The guideline's target audience is clearly described	☐	☐	☐	☒
5. The patients to whom this guideline is meant to apply are specifically described	☐	☐	☐	☒
6. The criteria used to select articles for inclusion are appropriate	☐	☐	☐	☒
7. The reasons why some studies were excluded are clearly described	☐	☐	☐	☒
8. All important studies that met the article inclusion criteria are included	☐	☐	☐	☒
9. The validity of the studies is appropriately appraised	☐	☐	☐	☒
10. The methods are described in such a way as to be reproducible.	☐	☐	☐	☒
11. The statistical methods are appropriate to the material and the objectives of this guideline	☐	☐	☒	☐
12. Important parameters (e.g., setting, study population, study design) that could affect study results are systematically addressed	☐	☐	☐	☒
13. Health benefits, side effects, and risks are adequately addressed	☐	☐	☐	☒
14. The writing style is appropriate for health care professionals.	☐	☐	☒	☐
15. The grades assigned to each recommendation are appropriate	☐	☐	☒	☐

COMMENTS

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Please provide a brief explanation of both your positive and negative answers in the preceding section. If applicable, please specify the draft page and line numbers in your comments. Please feel free to also comment on the overall structure and content of the Guideline

I enjoyed reading this guidelne. It was well-conceived, well executed and well written. After reviewing the tables of evidence, I agreed with the main conclusions. The most important conclusion from this effort is the great need to perform well-designed clinical trials to test the efficacy of antibiotics or other anti-microbial strategies during dental procedures to prevent orthopedic implant infections.

I have a suggestion regarding the clarity of the presentation. Specifically, many of the figures and tables need more explanatory text.

For example: Figure 35, page 75. What is being tested here? The effect of antibiotics on bacteremia? This should be spelled out in the Figure legend.

Table 27-28-29-30 , page 76, 78. What is being tested here? The effect of antibiotics on bacteremia? This should be spelled out in the Table legend.

Figure 36, 37, page 77, 870. What is being tested here? The effect of antibiotics on bacteremia? This should be spelled out in the Figure legend.

This is true for most of the tables and figures throughout the document.

Dr. Scannapieco,

Thank you for your expert review of this clinical practice guideline. We will make the appropriate changes to better clarify what is being represented in the tables and figures. Thank you for bringing these matters to our attention.

OVERALL ASSESSMENT

Would you recommend these guidelines for use in clinical practice? (Check one)

☒ Strongly recommend

☐ Recommend (with provisions or alterations)

☐ Would not recommend

☐ Unsure

Note: Your answer to this question does not constitute an endorsement of this guideline. We ask this question as a means of monitoring the clinical relevance of our guideline.

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- **Your conflicts of interest disclosures will be published on the AAOS website, and may be published on the ADA website, with your review comments.**

Reviewer Information:

Name of Reviewer: Charles Shuler

Address: University of British Columbia Faculty of Dentistry

City: Vancouver State: BC Zip Code: V6T 1Z3

Phone: 604-822-5773 Fax: 604-822-4532 E-mail: cshuler@dentistry.ubc.ca

Specialty Area/Discipline: Dentistry Oral Pathology

Work setting: University Credentials: DMD PhD

May we list you as a Peer Reviewer in the final Guidelines? XX Yes ☐ No

PLEASE READ: If you do not wish to be listed, your name will be removed for identification purposes. However, your review comments, our responses and your COI will still be available for public review on our website with the posted Guideline if you complete this review.

Are you reviewing this guideline as a representative of a professional society? XX Yes ☐ No

If yes, may we list your society as a reviewer of thiis guideline? XX Yes ☐ No

Society Name: Canadian Dental Association

(Listing the specialty society as a reviewing society does not imply or otherwise indicate endorsement of this guideline.)

Conflicts of Interest (COI): All Reviewers must declare their conflicts of interest.

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REVIEWER CONFLICT OF INTEREST - The Orthopaedic Disclosure Program

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Are you or a member of your immediate family a PAID CONSULTANT for any pharmaceutical, biomaterial or orthopaedic device or equipment company, or supplier? If YES, please identify company or supplier:	☐ Yes XX No
Are you or a member of your immediate family an UNPAID CONSULTANT for any pharmaceutical, biomaterial or orthopaedic device or equipment company, or supplier? If YES, please identify company or supplier:	☐ Yes XX No
Do you or a member of your immediate family own stock or stock options in any pharmaceutical, biomaterial or orthopaedic device or equipment company, or supplier (excluding mutual funds) If YES, please identify company or supplier:	☐ Yes XX No
Do you or a member of your immediate family receive research or institutional support as a principal investigator from any pharmaceutical, biomaterial or orthopaedic device or equipment company, or supplier? If YES, please identify company or supplier:	☐ Yes XX No
Do you or a member of your immediate family receive any other financial or material support from any pharmaceutical, biomaterial or orthopaedic device and equipment company or supplier? If YES, please identify company or supplier:	☐ Yes XX No
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Please indicate your level of agreement with each of the following statements by placing an "X" in the appropriate box.

	Disagree	Somewhat Disagree	Somewhat Agree	Agree
1. The recommendations are clearly stated	☐	☐	XX	☐
2. There is an explicit link between the recommendations and the supporting evidence	☐	☐	☐	XX
3. Given the nature of the topic and the data, all clinically important outcomes are considered	☐	☐	☐	XX
4. The guideline's target audience is clearly described	☐	☐	☐	XX
5. The patients to whom this guideline is meant to apply are specifically described	☐	☐	☐	XX
6. The criteria used to select articles for inclusion are appropriate	☐	☐	☐	XX
7. The reasons why some studies were excluded are clearly described	☐	☐	☐	XX
8. All important studies that met the article inclusion criteria are included	☐	☐	☐	XX
9. The validity of the studies is appropriately appraised	☐	☐	☐	XX
10. The methods are described in such a way as to be reproducible.	☐	☐	☐	XX
11. The statistical methods are appropriate to the material and the objectives of this guideline	☐	☐	☐	XX
12. Important parameters (e.g., setting, study population, study design) that could affect study results are systematically addressed	☐	☐	☐	XX
13. Health benefits, side effects, and risks are adequately addressed	☐	☐	☐	XX
14. The writing style is appropriate for health care professionals.	☐	☐	☐	XX
15. The grades assigned to each recommendation are appropriate	☐	☐	☐	XX

COMMENTS

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Please provide a brief explanation of both your positive and negative answers in the preceding section. If applicable, please specify the draft page and line numbers in your comments. Please feel free to also comment on the overall structure and content of the Guideline

Overall this study is extremely well done. The material is reviewed in a thorough approach and analyzed in a highly reproducle manner. This guideline will be of great value to clinicians and their patients.

One minor comment is that Recommendation #1 is open to some interpretation. While the evidence is cited as "Weak" for antibiotic prophylaxis the Recommendation is not as definitive as it might be. A more definitive statement such as "Antibiotic prophylaxis is not recommended prior to dental procedures" would provide more guidance to clinicians than the current Recommendation that seems to leave open the potential use antibiotics prophylactically.

Dr. Shuler,

Thank you for your expert review of this clinical practice guideline. We recognize that the wording of Recommendation 1, "The practitioner might consider discontinuing the practice of routinely prescribing prophylactic antibiotics for patients with hip and knee prosthetic joint implants undergoing dental procedures", is not without fault. However we follow a rigorous methodology. These methods start with preliminary recommendations formulated at the workgroup's first meeting. These recommendations specify [what] should be done in [whom], [when], [where], and [how often or how long]. To avoid "wordsmithing" discussions at the initial work group meeting, the preliminary recommendations are always worded as recommending for something. Therefore the preliminary recommendation "positively" recommended for antibiotic prophylaxis for patients with orthopaedic implants undergoing dental procedures. Consequently when the best available evidence (1 "moderate" strength study) revealed that dental procedures are not related to subsequent orthopaedic (namely hip and knee) implant infection and furthermore that antibiotic prophylaxis did not reduce the risk of alleged subsequent infection we were required to use the respective guideline language, "The practitioner MIGHT", and give it a "Weak" grade according to AAOS rules of evidence. We agreed to strictly adhere to these rules at the inception of this guideline and feel that the current wording of the recommendation is the best possible option.

Beyond the required language and "weak" grade, the workgroup chose the remaining words very carefully and ultimately agreed that "consider discontinuing the practice of routinely prescribing prophylactic antibiotics" was the best possible wording based on knowledge of current practice and past clinical recommendations/guidelines. An informal survey of dental schools found that approximately half instruct their students to recommend for antibiotic prophylaxis in these matters. The ADA also recommends that the dentist have a conversation with the patient and their respective orthopaedic surgeon about antibiotic prophylaxis. It was the impression of the orthopaedic surgeons in the workgroup that their colleagues routinely recommend for antibiotic prophylaxis and they themselves favored its use. Also, previous guidelines recommended for the routine use of antibiotic prophylaxis. Therefore through a systematic review of the evidence and consideration of common practice, the workgroup meticulously constructed the recommendation in accordance with the rules of the guideline creation process.

OVERALL ASSESSMENT

Would you recommend these guidelines for use in clinical practice? (Check one)

XX Strongly recommend

☐ Recommend (with provisions or alterations)

☐ Would not recommend

☐ Unsure

Note: Your answer to this question does not constitute an endorsement of this guideline. We ask this question as a means of monitoring the clinical relevance of our guideline.

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Reviewer Information:

Name of Reviewer: John Steele

Address: Georgia Health Sciences University, 1120 15th Street

City: Augusta State: GA Zip Code: 30912

Phone: 706-721-2776 Fax: 706-721-7837 E-mail: jsteele@georgiahealth.edu

Specialty Area/Discipline: Clinical Microbiology

Work setting: Academic Medical Center Credentials: MD, PhD

May we list you as a Peer Reviewer in the final Guidelines? ☒ Yes ☐ No

PLEASE READ: If you do not wish to be listed, your name will be removed for identification purposes. However, your review comments, our responses and your COI will still be available for public review on our website with the posted Guideline if you complete this review.

Are you reviewing this guideline as a representative of a professional society? ☒ Yes ☐ No

If yes, may we list your society as a reviewer of this guideline? ☒ Yes ☐ No

Society Name: College of American Pathologists

(Listing the specialty society as a reviewing society does not imply or otherwise indicate endorsement of this guideline.)

Conflicts of Interest (COI): All Reviewers must declare their conflicts of interest.

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Do you or a member of your immediate family receive any other financial or material support from any pharmaceutical, biomaterial or orthopaedic device and equipment company or supplier? If YES, please identify company or supplier:	☐ Yes ☒ No
Do you or a member of your immediate family receive any royalties, financial or material support from any medical and/or orthopaedic publishers? If YES, please identify publisher:	☐ Yes ☒ No
Do you or a member of your immediate family serve on the editorial or governing board of any medical and/or orthopaedic publication? If YES, please identify: *American Journal of Clinical Pathology* (microbiology topics)	☒ Yes ☐ No
Do you or a member of your immediate family serve on the Board of Directors or a committee of any medical and/or orthopaedic professional society? If YES, please identify: College of American Pathologists Microbiology Resource Committee	☒ Yes ☐ No

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	Disagree	Somewhat Disagree	Somewhat Agree	Agree
1. The recommendations are clearly stated	☐	☐	☐	☒
2. There is an explicit link between the recommendations and the supporting evidence	☐	☐	☐	☒
3. Given the nature of the topic and the data, all clinically important outcomes are considered	☐	☐	☒	☐
4. The guideline's target audience is clearly described	☐	☐	☐	☒
5. The patients to whom this guideline is meant to apply are specifically described	☐	☐	☒	☐
6. The criteria used to select articles for inclusion are appropriate	☐	☐	☒	☐
7. The reasons why some studies were excluded are clearly described	☐	☒	☐	☐
8. All important studies that met the article inclusion criteria are included	☐	☐	☒	☐
9. The validity of the studies is appropriately appraised	☐	☐	☒	☐
10. The methods are described in such a way as to be reproducible.	☐	☐	☒	☐
11. The statistical methods are appropriate to the material and the objectives of this guideline	☐	☐	☒	☐
12. Important parameters (e.g., setting, study population, study design) that could affect study results are systematically addressed	☐	☐	☐	☒
13. Health benefits, side effects, and risks are adequately addressed	☐	☐	☐	☒
14. The writing style is appropriate for health care professionals.	☐	☐	☐	☒
15. The grades assigned to each recommendation are appropriate	☐	☐	☒	☐

COMMENTS

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1431	***Staphylococcus* should be italicized**
1435	**It appears words are missing at the end of the line**
1439	***Streptococcus* should be italicized**
1450	***Staphylococcus* should be capitalized and italicized or replaced with staphylococci**
1451	***Streptococcus* should be capitalized and italicized or replaced with streptococci**
Fig 6-34	**Not clear what is included in Staphylococcus, Streptococcus, Pseudomonas, etc., when no species is listed. If speciation was not reported, indicate for example *Staphylococcus* species, NOS where NOS indicates not otherwise specified. If what is meant is staphylococci other than *S. aureus* and *S. epidermidis*, this should be clearly stated.**
1516-21	**Would be helpful to indicate if these were early or late and the definition used.**
Table 56	**Not clear what "Insufficient data on bacteremia for background microbiology" means. Didn't see defined in Study Selection Criteria**

Dr. Steele,

Thank you for your expert review of this clinical practice guideline. Words have been italicized where necessary and other grammatical errors have been corrected per your comments. For Figures 6-34 when no species is listed either the authors only provided genus level culture information or the bug was not of the species category that is represented in our pie charts. The culture data was so diverse amongst the literature that it was difficult to categorize the data and represent all of the information down to the species level. Our charts are primarily informational because there is no established link between bacteremia and orthopaedic implant infection. The general conclusion that can be drawn for these figures is that no clear association between the organisms found in orthopaedic implant infections and bacteremia exists. However, the majority of the organisms found in implant infections are *Staphylococcus* and the majority of the organisms found as the cause of bacteremias are *Streptococcus.*

The one piece of direct evidence for this guideline didn't define early vs. late orthopaedic implant infection. The case-control study enrolled patients with implant infection and recorded the joint age and investigated/controlled for this variable in multiple statistical models for significance. Dental procedures were not found to be risk factors for any subsequent implant infection.

"Insufficient data on bacteremia for background microbiology" simply means that the authors of these studies did not provide the bacterial culture information necessary for our purposes.

OVERALL ASSESSMENT

Would you recommend these guidelines for use in clinical practice? (Check one)

☒ Strongly recommend

☐ Recommend (with provisions or alterations)

☐ Would not recommend

☐ Unsure

Note: Your answer to this question does not constitute an endorsement of this guideline. We ask this question as a

means of monitoring the clinical relevance of our guideline.

ALL REVIEW COMMENTS, RESPONSES AND REVIEWER CONFLICTS OF INTEREST DISCLSOURE WILL BE AVAILABLE ON OUR WEBSITE FOLLOWING APPROVAL OF THIS DOCUMENT.

Review of any AAOS confidential draft allows us to improve the overall guideline but does not imply endorsement by any given individual or any specialty society who participates in our review processes. The AAOS review process may result in changes to the documents; therefore, endorsement cannot occur until the AAOS Board of Directors officially approves the final guideline. The ADA will also employ a formal approval process.

Please note that if you return a review:

- **Your review comments will be published on the AAOS website, and may be published on the ADA website, with our explanation of why we did or did not change the draft document in response to your comments.**
- **Your conflicts of interest disclosures will be published on the AAOS website, and may be published on the ADA website, with your review comments.**

Reviewer Information:

Name of Reviewer: Susan Sutherland

Address: Sunnybrook Health Sciences Centre/University of Toronto Department of Dentistry 2075 Bayview Avenue

City: Toronto State: ON Zip Code: M4N 3M5

Phone: 416 480 4436 Fax: 416 480 5757 E-mail: susan.sutherland@sunnybrook.ca

Specialty Area/Discipline: Dentistry

Work setting: Hospital Credentials: DDS MSc (Clin Epi)

May we list you as a Peer Reviewer in the final Guidelines? x Yes ☐ No

PLEASE READ: If you do not wish to be listed, your name will be removed for identification purposes. However, your review comments, our responses and your COI will still be available for public review on our website with the posted Guideline if you complete this review.

Are you reviewing this guideline as a representative of a professional society? x Yes ☐ No

If yes, may we list your society as a reviewer of this guideline? x Yes ☐ No

Society Name: Canadian Dental Association

(Listing the specialty society as a reviewing society does not imply or otherwise indicate endorsement of this guideline.)

Conflicts of Interest (COI): All Reviewers must declare their conflicts of interest.

If the boxes below are not checked and/or the reviewer does not attach his/her conflicts of interest, the reviewer's comments will not be addressed by the AAOS nor will the reviewer's name or society be listed as a reviewer of this GL. If a committee reviews the guideline, only the chairperson or lead of the review must declare their relevant COI.

x **I have declared my conflicts of interest on page 2 of this form.** ☐ **I have declared my conflicts of interest in the AAOS database; my customer # is _____**
x **I understand that the AAOS will post my declared conflicts of interest with my comments concerning review of this guideline on the AAOS website.**

REVIEWER CONFLICT OF INTEREST - The Orthopaedic Disclosure Program

Each item below requires an answer. Please report information for the last 12-months.

Do you or a member of your immediate family receive royalties for any pharmaceutical, biomaterial or orthopaedic product or device? If YES, please identify product or device:	☐ Yes x No
Within the past twelve months, have you or a member of your immediate family served on the speakers bureau or have you been paid an honorarium to present by any pharmaceutical, biomaterial or orthopaedic product or device company? If YES, please identify company:	☐ Yes x No
Are you or a member of your immediate family a PAID EMPLOYEE for any pharmaceutical, biomaterial or orthopaedic device or equipment company, or supplier? If YES, please identify company or supplier:	☐ Yes x No
Are you or a member of your immediate family a PAID CONSULTANT for any pharmaceutical, biomaterial or orthopaedic device or equipment company, or supplier? If YES, please identify company or supplier:	☐ Yes x No
Are you or a member of your immediate family an UNPAID CONSULTANT for any pharmaceutical, biomaterial or orthopaedic device or equipment company, or supplier? If YES, please identify company or supplier:	☐ Yes x No
Do you or a member of your immediate family own stock or stock options in any pharmaceutical, biomaterial or orthopaedic device or equipment company, or supplier (excluding mutual funds) If YES, please identify company or supplier:	☐ Yes x No
Do you or a member of your immediate family receive research or institutional support as a principal investigator from any pharmaceutical, biomaterial or orthopaedic device or equipment company, or supplier? If YES, please identify company or supplier:	☐ Yes x No
Do you or a member of your immediate family receive any other financial or material support from any pharmaceutical, biomaterial or orthopaedic device and equipment company or supplier? If YES, please identify company or supplier:	☐ Yes x No
Do you or a member of your immediate family receive any royalties, financial or material support from any medical and/or orthopaedic publishers? If YES, please identify publisher:	☐ Yes x No
Do you or a member of your immediate family serve on the editorial or governing board of any medical and/or orthopaedic publication? If YES, please identify:	☐ Yes x No
Do you or a member of your immediate family serve on the Board of Directors or a committee of any medical and/or orthopaedic professional society? If YES, please identify:	☐ Yes x No

Structured Peer Review Form Instructions

Please read and review this Draft Clinical Practice Guideline with particular focus on your area of expertise. Your responses will be used to assess the validity, clarity and accuracy of the interpretation of the evidence. If applicable, **please specify the draft page and line numbers in your comments**. Please feel free to also comment on the overall structure and content of the document. If you need more space than is provided, please attach additional pages.

Please complete and return this form electronically in **WORD format** to boyer@aaos.org; please contact Kevin Boyer at (847) 384-4328 if you have any questions. Thank you in advance for your time in completing this form and giving us your feedback. We value your input and greatly appreciate your efforts. Please return the completed form in **WORD format** by end of day **March 15, 2012**.

Please indicate your level of agreement with each of the following statements by placing an "X" in the appropriate box.

	Disagree	Somewhat Disagree	Somewhat Agree	Agree
1. The recommendations are clearly stated	☐	☐	x	☐
2. There is an explicit link between the recommendations and the supporting evidence	☐	☐	☐	x
3. Given the nature of the topic and the data, all clinically important outcomes are considered	☐	x	☐	☐
4. The guideline's target audience is clearly described	☐	☐	☐	x
5. The patients to whom this guideline is meant to apply are specifically described	☐	☐	☐	x
6. The criteria used to select articles for inclusion are appropriate	☐	☐	☐	x
7. The reasons why some studies were excluded are clearly described	☐	☐	☐	x
8. All important studies that met the article inclusion criteria are included	☐	☐	☐	x
9. The validity of the studies is appropriately appraised	☐	☐	☐	x
10. The methods are described in such a way as to be reproducible.	☐	☐	☐	x
11. The statistical methods are appropriate to the material and the objectives of this guideline	☐	☐	☐	x
12. Important parameters (e.g., setting, study population, study design) that could affect study results are systematically addressed	☐	☐	☐	x
13. Health benefits, side effects, and risks are adequately addressed	☐	x	☐	☐
14. The writing style is appropriate for health care professionals.	☐	☐	☐	x
15. The grades assigned to each recommendation are appropriate	☐	☐	☐	x

COMMENTS

PLEASE RETURN ALL COMMENTS IN WORD FORMAT

Please provide a brief explanation of both your positive and negative answers in the preceding section. If applicable, please specify the draft page and line numbers in your comments. Please feel free to also comment on the overall structure and content of the Guideline

1. **"The recommendations are clearly stated."**

   The first recommendation, while clearly stated, will require interpretation for the members of the Canadian Dental Association (CDA). "The practitioner may consider discontinuing the practice of routinely prescribing prophylactic antibiotics …" is graded as "Weak". Based on the Grade of the Recommendation, it can be anticipated that practitioners might continue to prescribe antibiotic prophylaxis, but there is insufficient guidance as to what is appropriate. The CDA continues (to date) to support the 2003 AAOS/ADA Guideline, rather than the 2009 Information Statement of the AAOS Patient Safety Committee.

2. **"Given the nature of the topic and the data, all clinically important outcomes are considered."**

   It would be helpful to have a better understanding of the burden of disease related to infection of orthopedic implants. Table 25 (page 54) presents the findings of a number of studies and it is stated that the range of infection rates is 0.3 – 8.3%. However, the overall rate of infection is 0.9% (0.3% early; 0.6% late). Without understanding the severity and outcomes of these infections for patients and the proportionate etiologic contribution of factors such as infection at the time of surgery, hospital acquired wound infection, antecedent dental procedures or recurrence of sepsis, it is difficult to appreciate the nature and burden of disease as it relates to peri implant infection. Without this contextual understanding, it is challenging to determine the importance of antibiotic prophylaxis for these patients.

3. **"Health benefits, side effects, and risks are adequately addressed."**

   A discussion of potential risks of antibiotic prophylaxis, including consideration of the risk/benefit ratio for individuals and populations, would add value to the Guideline. This is especially important in view of the fact that "no studies exist that explain the microbiological relationship between bacteremia [secondary to dental procedures and chewing] and orthopaedic implant infection" (lines 1272-3). In order for practitioners to make an informed decision about whether or not to discontinue routinely prescribing prophylactic antibiotics for these patients, the issues of antibiotic resistance/stewardship and individual risk of antibiotic-related adverse events needs to be considered.

4. From a methodological perspective, this guideline was well done. Systematic methods were used to control bias and rigorous methods were used to search the literature, appraise the findings and report the results. The document is clearly written.

5. The recommendations for future research are excellent.

Dr. Sutherland,

Thank you for your expert review of this clinical practice guideline. We recognize that the wording of Recommendation 1, "The practitioner might consider discontinuing the practice of routinely prescribing prophylactic antibiotics for patients with hip and knee prosthetic joint implants undergoing dental procedures", is not without fault. However we follow a rigorous methodology. These methods start with preliminary recommendations formulated at the workgroup's first meeting. These recommendations specify [what] should be done in [whom], [when], [where], and [how often or how long]. To avoid "wordsmithing" discussions at the initial work group meeting, the preliminary recommendations are always worded as recommending for something. Therefore the preliminary recommendation "positively" recommended for antibiotic prophylaxis for patients with orthopaedic implants undergoing dental procedures. Consequently when the best available evidence (1 "moderate" strength study) revealed that dental procedures are not related to subsequent orthopaedic (namely hip and knee) implant infection and furthermore that antibiotic prophylaxis did not reduce the risk of alleged subsequent infection we were required to use the respective guideline language, "The

practitioner MIGHT", and give it a "Weak" grade according to AAOS rules of evidence. We agreed to strictly adhere to these rules at the inception of this guideline and feel that the current wording of the recommendation is the best possible option.

Beyond the required language and "weak" grade the workgroup chose the remaining words very carefully and ultimately agreed that "consider discontinuing the practice of routinely prescribing prophylactic antibiotics" was the best possible wording based on knowledge of current practice and past clinical recommendations/guidelines. An informal survey of dental schools found that approximately half instruct their students to recommend for antibiotic prophylaxis in these matters. The ADA also recommends that the dentist have a conversation with the patient and their respective orthopaedic surgeon about antibiotic prophylaxis. It was the impression of the orthopaedic surgeons in the workgroup that their colleagues routinely recommend for antibiotic prophylaxis and they themselves favored its use. Also, previous guidelines recommended for the routine use of antibiotic prophylaxis. Therefore through a systematic review of the evidence and consideration of common practice, the workgroup meticulously constructed the recommendation in accordance with the rules of the guideline creation process.

A small amount of additional information about disease burden can be found in the "Burden of Disease and Etiology" section on page 2. Better understanding of these matters could be beneficial, but provided that there was no evidence to suggest that dental procedures are related to subsequent orthopaedic implant infections or that antibiotic prophylaxis reduces the risk of aforementioned infection, we felt it was unnecessary to pursue this further.

In similar fashion the risk of antibiotic prophylaxis is not described because the guideline does not recommend for them. We conducted a review on antimicrobials and adverse effects but ultimately decided it was contrary to the evidence to discuss these matters considering that antibiotic prophylaxis is not recommended for in this guideline. Furthermore, AAOS does not perform cost/benefit analyses in their clinical practice guidelines and the ADA agreed to this.

OVERALL ASSESSMENT

Would you recommend these guidelines for use in clinical practice? (Check one)

☐ Strongly recommend

x Recommend (with provisions or alterations)

☐ Would not recommend

☐ Unsure

Note: Your answer to this question does not constitute an endorsement of this guideline. We ask this question as a means of monitoring the clinical relevance of our guideline.

Boyer, Kevin

From: Srinivasan Varadarajan [Srinivasan.Varadarajan@AGD.org]
Sent: Tuesday, March 06, 2012 10:33 AM
To: Boyer, Kevin
Cc: battagja@prodigy.net
Subject: Review of AAOS' Guideline on the Prevention of Orthopaedic Implant Infection

Dear Mr. Boyer,

I am providing this response on behalf of the AGD's peer-reviewer, Dr. Battaglia, and through shared review by the AGD's Dental Practice Council, of which Dr. Battaglia is chairman. While we have no specific non-editorial comments on the guidelines, the council has appreciated the opportunity to review the draft and provide input, and requests that the AAOS continue to provide the AGD opportunities to review this and other matters as a key stakeholder in oral health.

Thank you,

Srini

Srinivasan Varadarajan, Esq.
Director, Dental Practice Advocacy
Academy of General Dentistry
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312.440.4973 Direct
888.AGD.DENT. ext. 4973
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srini.varadarajan@agd.org

Mr. Varadarajan,

Please convey our gratitude to Dr. Battaglia and the Dental Practice Council for their expert review of our clinical practice guideline. We hope they found it to be satisfactory.

ALL REVIEW COMMENTS, RESPONSES AND REVIEWER CONFLICTS OF INTEREST DISCLSOURE WILL BE AVAILABLE ON OUR WEBSITE FOLLOWING APPROVAL OF THIS DOCUMENT.

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- **Your conflicts of interest disclosures will be published on the AAOS website, and may be published on the ADA website, with your review comments.**

Reviewer Information:

Name of Reviewer: Sook-Bin Woo DMD

Address: 1620 Tremont Street, Suite 3-028

City: Boston State: MA Zip Code: 02120

Phone: 617-525-6859 Fax: 617-232-8970 E-mail: swoo@rics.bwh.harvard.edu

Specialty Area/Discipline: Oral Medicine and Oral Pathology

Work setting: Attending Dentist Credentials: Diplomate in Oral Pathology and Oral Medicine

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May we list you as a Peer Reviewer in the final Guidelines? ☒ Yes ☐ No

PLEASE READ: If you do not wish to be listed, your name will be removed for identification purposes. However, your review comments, our responses and your COI will still be available for public review on our website with the posted Guideline if you complete this review.

Are you reviewing this guideline as a representative of a professional society? ☒ Yes ☐ No

If yes, may we list your society as a reviewer of this guideline? ☒ Yes ☐ No

Society Name: American Academy of Oral Pathology

(Listing the specialty society as a reviewing society does not imply or otherwise indicate endorsement of this guideline.)

Conflicts of Interest (COI): All Reviewers must declare their conflicts of interest.

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Do you or a member of your immediate family receive royalties for any pharmaceutical, biomaterial or orthopaedic product or device? If YES, please identify product or device:	☐ Yes ☒ No
Within the past twelve months, have you or a member of your immediate family served on the speakers bureau or have you been paid an honorarium to present by any pharmaceutical, biomaterial or orthopaedic product or device company? If YES, please identify company:	☐ Yes ☒ No
Are you or a member of your immediate family a PAID EMPLOYEE for any pharmaceutical, biomaterial or orthopaedic device or equipment company, or supplier? If YES, please identify company or supplier:	☐ Yes ☒ No
Are you or a member of your immediate family a PAID CONSULTANT for any pharmaceutical, biomaterial or orthopaedic device or equipment company, or supplier? If YES, please identify company or supplier:	☐ Yes ☒ No
Are you or a member of your immediate family an UNPAID CONSULTANT for any pharmaceutical, biomaterial or orthopaedic device or equipment company, or supplier? If YES, please identify company or supplier:	☐ Yes ☒ No
Do you or a member of your immediate family own stock or stock options in any pharmaceutical, biomaterial or orthopaedic device or equipment company, or supplier (excluding mutual funds) If YES, please identify company or supplier:	☐ Yes ☒ No
Do you or a member of your immediate family receive research or institutional support as a principal investigator from any pharmaceutical, biomaterial or orthopaedic device or equipment company, or supplier? If YES, please identify company or supplier:	☐ Yes ☒ No
Do you or a member of your immediate family receive any other financial or material support from any pharmaceutical, biomaterial or orthopaedic device and equipment company or supplier? If YES, please identify company or supplier:	☐ Yes ☒ No
Do you or a member of your immediate family receive any royalties, financial or material support from any medical and/or orthopaedic publishers? If YES, please identify publisher:	☐ Yes ☒ No
Do you or a member of your immediate family serve on the editorial or governing board of any medical and/or orthopaedic publication? If YES, please identify:	☐ Yes ☒ No
Do you or a member of your immediate family serve on the Board of Directors or a committee of any medical and/or orthopaedic professional society? If YES, please identify:	☐ Yes ☒ No

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Please complete and return this form electronically in **WORD format** to boyer@aaos.org; please contact Kevin Boyer at (847) 384-4328 if you have any questions. Thank you in advance for your time in completing this form and giving us your feedback. We value your input and greatly appreciate your efforts. Please return the completed form in **WORD format** by end of day **March 15, 2012**.

Please indicate your level of agreement with each of the following statements by placing an "X" in the appropriate box.

	Disagree	Somewhat Disagree	Somewhat Agree	Agree
1. The recommendations are clearly stated	☐	☐	☐	☒
2. There is an explicit link between the recommendations and the supporting evidence	☐	☐	☐	☒
3. Given the nature of the topic and the data, all clinically important outcomes are considered	☐	☐	☐	☒
4. The guideline's target audience is clearly described	☐	☐	☐	☒
5. The patients to whom this guideline is meant to apply are specifically described	☐	☐	☐	☒
6. The criteria used to select articles for inclusion are appropriate	☐	☐	☐	☒
7. The reasons why some studies were excluded are clearly described	☐	☐	☐	☒
8. All important studies that met the article inclusion criteria are included	☐	☐	☐	☒
9. The validity of the studies is appropriately appraised	☐	☐	☐	☒
10. The methods are described in such a way as to be reproducible.	☐	☐	☐	☒
11. The statistical methods are appropriate to the material and the objectives of this guideline	☐	☐	☐	☒
12. Important parameters (e.g., setting, study population, study design) that could affect study results are systematically addressed	☐	☐	☐	☒
13. Health benefits, side effects, and risks are adequately addressed	☐	☐	☒	☐
14. The writing style is appropriate for health care professionals.	☐	☐	☐	☒
15. The grades assigned to each recommendation are appropriate	☐	☐	☐	☒

COMMENTS

PLEASE RETURN ALL COMMENTS IN WORD FORMAT

Please provide a brief explanation of both your positive and negative answers in the preceding section. If applicable, please specify the draft page and line numbers in your comments. Please feel free to also comment on the overall structure and content of the Guideline

Re: point #13. The side effects of taking the antibiotics were not particularly discussed and it may be that this is beyond the realm of the objectives of this manuscript. This is particularly important in the light of the recent Br Med J publication on patient deaths from antibiotic prophylaxis for endocarditis, not from anaphylaxis, as is so often quoted, but from colits. The corollary to that is what is the morbidity of having to replace an infected hip or knee implant? Quite significant I would imagine.

I am wondering if Recommendation #1 can be restated in the positive, instead of the negative: the evidence for discontinuing antibiotics prophylaxis is weak. Is the evidence for continuing antibiotic therapy also weak? I suspect the methodology was not set up to answer the second question.

Dr. Sook-Bin Woo,

Thank you for your expert review of this clinical practice guideline. In response to your comment about adverse effects from antibiotics, we did not discuss this because we did not recommend for them. We conducted a review on antibiotic prophylaxis and adverse effects but ultimately decided it was contrary to the evidence to discuss these matters considering that antibiotic prophylaxis is not recommended for in this guideline.

We cannot restate Recommendation #1 in the positive form. We follow a rigorous methodology. These methods start with preliminary recommendations formulated at the workgroup's first meeting. These recommendations specify [what] should be done in [whom], [when], [where], and [how often or how long]. To avoid "wordsmithing" discussions at the initial work group meeting, the preliminary recommendations are always worded as recommending for something. Therefore the preliminary recommendation "positively" recommended for antibiotic prophylaxis for patients with orthopaedic implants undergoing dental procedures. Consequently when the best available evidence (1 "moderate" strength study) revealed that dental procedures are not related to subsequent orthopaedic (namely hip and knee) implant infection and furthermore that antibiotic prophylaxis did not reduce the risk of alleged subsequent infection we are obligated to use the respective guideline language, "The practitioner MIGHT", and give it a "Weak" grade according to AAOS rules of evidence. ADA and AAOS agreed to strictly adhere to these rules at the inception of this guideline and feel that the current wording of the recommendation is the best possible option. Lastly, we found no evidence for continuing antibiotic therapy.

OVERALL ASSESSMENT

Would you recommend these guidelines for use in clinical practice? (Check one)

☐ Strongly recommend

☒ Recommend (with provisions or alterations)

☐ Would not recommend

☐ Unsure

Note: Your answer to this question does not constitute an endorsement of this guideline. We ask this question as a means of monitoring the clinical relevance of our guideline.