

# The Diagnosis and Treatment of Osteochondritis Dissecans

# Review Change Summary, Review Comments, and AAOS Responses

Peer Review: May 15 - June 18, 2010

Public Comment: October 15 - November 12, 2010

Change Summary 1

# Changes Made to the Confidential Draft of the

# Guideline on the

# **Diagnosis and Treatment of Osteochondritis Dissecans**

# **Peer Review**

# May 15, 2010 - June 18, 2010

# **Public Comment**

# October 15, 2010 – November 12, 2010

## Line 69

We have added a statement directing the reader to Table 1 in the guideline.

"\*To see the description of the evidence linked to the strength of the recommendations, please refer to Table 1; "Strength of Recommendation descriptions" in the guideline."

# Line 85, Line 1008

Recommendation 7 was edited from:

In the absence of reliable evidence, it is the opinion of the work group that **symptomatic** skeletally immature patients with salvageable unstable or displaced OCD lesions be offered the option of surgery which may include drilling and fixation, with or without bone grafting, to restore congruency.

To:

In the absence of reliable evidence, it is the opinion of the work group that **symptomatic** skeletally immature patients with salvageable unstable or displaced OCD lesions be offered the option of surgery.

# Line 96, Line 1171

Recommendation 10 was edited from:

We are unable to recommend for or against treating asymptomatic skeletally mature patients with progression of OCD on x-ray and/or MRI as symptomatic skeletally mature patients.

To:

We are unable to recommend for or against treating asymptomatic skeletally mature patients with OCD progression (as identified by X-ray or MRI) like symptomatic patients.

# Line 100, Line 1183

Recommendation 11 was edited from:

In the absence of reliable evidence, it is the opinion of the work group that **symptomatic** skeletally mature patients with salvageable unstable or displaced OCD lesions be offered the option of surgery which may include drilling and fixation, with or without bone grafting, to restore congruency.

To:

In the absence of reliable evidence, it is the opinion of the work group that **symptomatic** skeletally mature patients with salvageable unstable or displaced OCD lesions be offered the option of surgery.

# Line 115, Line 1422

Recommendation 15 was edited from:

In the absence of either reliable evidence or consensus among the work group, we are unable to recommend for or against physical therapy comprised of protective, restorative, and return to activities/sports phases for all patients who have had operative treatment for OCD.

Strength of Recommendation: Inconclusive

To:

In the absence of reliable evidence, it is the opinion of the work group that patients who have received surgical treatment of OCD be offered the option of post-operative physical therapy.

Strength of Recommendation: Consensus

# Line 374 Goals and Rationale

Additional text was added stating: *Treatments and procedures applicable to the individual patient rely on mutual communication between the patient, physician and other healthcare practitioners.*"

# Line 376 Goals and Rationale

For clarification, the following sentence has been added:

"Providers unfamiliar with the treatment of patients with OCD should be referred to qualified physicians and surgeons."

# Line 392, Incidence

Additional text has been added to this section as follows:

One study<sup>1</sup> reported that the mean age of JOCD has decreased from 12.9 years (1983) to 11.3 years (1992) in children. This study<sup>1</sup> also suggests that the incidence of JOCD is due to children being introduced to sports at an earlier age and "cumulative exercise is increasing annually due to the demands of competition." Adults typically experience vague, chronic or non-specific knee pain.<sup>12, 13</sup>

# Line 393, Burden of Disease

This section has been edited from:

Adults typically experience vague, chronic or non-specific knee pain.<sup>12, 13</sup> One study<sup>1</sup> reported that the mean age of JOCD has decreased from 12.9 years (1983) to 11.3 years (1992) in children. This study<sup>1</sup> also suggests that the incidence of JOCD is due to children being introduced to sports at an earlier age and "cumulative exercise is increasing annually due to the demands of competition." Individuals affected by OCD limit activity and decrease sports participation to limit pain.<sup>14</sup>

To Read as follows:

*The burden of disease from juvenile and adult Osteochondritis Dissecans is not known. Individuals affected by OCD limit activity and decrease sports participation to limit pain.*<sup>14</sup>

# Line 405, Potential Harms and Benefits

#### Text has been edited from:

The aim of treatment is pain relief, improved knee function, and prevention of degenerative joint disease. Surgical treatments are associated with some known risks such as infection, bleeding, venous thromboembolic events and persistent pain, although arthroscopic approaches have relatively low risk compared to more invasive surgeries.<sup>18</sup> Also, some surgical treatments cannot be performed arthroscopically; many require arthroscopic evaluation followed by open reduction and internal fixation of the fragment with bone grafting. Non-operative treatment may be associated with poor knee function, and early progression to osteoarthritis.<sup>13</sup> "If untreated (OCD), this may ultimately jeopardize the integrity of the joint and lead to the development of osteoarthritis."<sup>13</sup>

#### <u>To:</u>

The aim of treatment is pain relief, improved knee function, and prevention of degenerative joint disease. Surgical treatments are associated with some known risks such as infection, bleeding, venous thromboembolic events and persistent pain, although arthroscopic approaches have relatively low risk compared to more invasive surgeries.<sup>18</sup> Also, some surgical treatments cannot be performed arthroscopically; many require arthroscopic evaluation followed by open reduction and internal fixation of the fragment with bone grafting. Non operative treatment also presents with challenges because "it is difficult to predict which stable juvenile Osteochondritis Dissecans lesions will heal and the patient and family, at the advice of the treating physician, may wait to see if non-operative treatment allows the lesions to heal."{105}

Most treatments are associated with some known risks and contraindications vary widely based on the treatment administered. Therefore, discussion of available treatments and procedures applicable to the individual patient rely on mutual communication between the patient and physician, weighing the potential risks and benefits for that patient.

### Line 415

For clarification, Line 415 was changed from:

"The aim of treatment is pain relief, improved knee function, and prevention of degenerative joint disease."

#### To:

"The aim of treatment is pain relief, improved knee function, and potentially altering the degenerative joint process."

# Line 426

The wording "Treatment of Symptomatic Osteoporotic Spinal Compression Fractures" was replaced with "Osteochondritis Dissecans".

### Lines 434-439 Methods

The following lines were edited for clarity from:

The resulting draft guidelines were then peer-reviewed, subsequently sent for public commentary, and then sequentially approved by the AAOS Evidence Based Practice Committee, AAOS Guidelines and Technology Oversight Committee, AAOS Council on Research, Quality Assessment, and Technology, and the AAOS Board of Directors (see Appendix II for a description of the AAOS bodies involved in the approval process).

To:

To develop this guideline, the work group held an introductory meeting to develop the scope of the guideline on April 19<sup>th</sup> 2009. Upon completion of the systematic review, the work group met again on April 10<sup>th</sup> and 11<sup>th</sup>, 2010 to write and vote on the final recommendations and **associated** rationales for each recommendation **based on the evidence**.

The resulting draft guidelines are then peer reviewed, edited in response to that review, and then sent for public commentary where after additional edits are made. Thereafter, the draft guideline is sequentially sent for approval by the AAOS Evidence Based Practice Committee, AAOS Guidelines and Technology Oversight Committee, the AAOS Council on Research, Quality Assessment, and Technology, and the AAOS Board of Directors (Appendix II provides a description of the AAOS bodies involved in the approval process). All AAOS guidelines are reviewed and updated or retired every five years in accordance with the criteria of the National Guideline Clearinghouse.

# Line 522

Text was added for clarification:

"We did not include systematic reviews compiled by others or guidelines developed by other organizations. These documents are developed using different inclusion criteria than those specified by the AAOS work group. Therefore they may include studies that do not meet our inclusion criteria. We recalled these documents, if the abstract suggested they might provide an answer to one of our recommendations, and searched their bibliographies for additional studies to supplement our systematic review."

# Line 550

Text was added for clarification:

"Similarly, throughout the guideline we refer to Level I evidence as reliable, Level II and III evidence as moderately reliable, and Level IV and V evidence as not reliable."

# Line 621

Text was added for clarification concerning consensus based recommendations.

\*Consensus based recommendations are made according to specific criteria. These criteria can be found in Appendix VI.

## Line 801

The word "by" was removed.

## Line 1026

The word "theorized" was added to the sentence for clarification.

## Line 1014 to 1034, Recommendation 7 Rationale

The rationale has been edited to:

Children who are skeletally immature (i.e., those with open physes) who exhibit continued or progressing symptoms and signs of loosening (usually detected by MRI) are unlikely to heal without treatment. This is also true of skeletally mature patients with OCD lesions who have a history of not healing and/or there are already signs of loosening. Further, these skeletally immature and mature patients, because of loss of bone and cartilage, may be at higher risk of developing severe osteoarthritis (osteoarthrosis) at an early age. Although the exact degree of risk is not known, the work group deemed that it was imprudent to ignore it.

In issuing this consensus recommendation, the work group is issuing a recommendation consistent with current medical practice. However, the work group also acknowledges the paucity of evidence on the effectiveness of fixation of unstable OCD lesions, and that surgery entails risks. These risks include, but are not limited to, bleeding, infection, damage to nerves and blood vessels, venous thromboembolic events, anesthesia complications, and surgical failure. Again, however, not performing surgery also carries a risk, irreversible osteoarthritis/osteoarthrosis. This latter risk is of particular concern since effective treatments for young patients with severe osteoarthritis (osteoarthrosis) are limited. It is, therefore, the opinion of the work group that symptomatic patients with salvageable unstable or displaced OCD lesions (the work group defines "salvageable, unstable or displaced OCD lesions", either unstable but in situ or displaced, as those that may be restored, using the patient's native tissue from the osteochondritis region) be given the option of balancing the risks of performing or not performing surgery against the benefits of performing or not performing it. One potential benefit of surgery is the prevention or delay of severe osteoarthritis (osteoarthrosis). Another potential benefit is that these patients will be relieved of their existing symptoms.

The work group stresses that the choice to proceed with surgery is part of a shared decision making process between the patient, family, and physician. Offering patients the option of surgery is not a mandate that they have it. Patients can, and sometimes do, decline surgery.

Offering patients surgery requires informed consent. Failure to inform patients concerning the possible risks of surgical treatment is unethical and precludes them from surgery. Informed

consent should provide patients with enough information about surgery to make a sound judgment about whether they wish to proceed to surgery given their individual situation.

The present recommendation does not apply to all patients with OCD. In many skeletal immature children (i.e., those with open physes), these lesions heal without treatment. This is particularly true in children who have incidentally discovered lesions and have minimal symptoms. Accordingly, the work group makes no recommendations about surgery or physical therapy for such patients.

# Line 1170 Recommendation 10

This recommendation was edited from:

We are unable to recommend for or against treating **asymptomatic** skeletally mature patients with progression of OCD on x-ray and/or MRI as symptomatic skeletally mature patients.

To:

We are unable to recommend for or against treating asymptomatic skeletally mature patients with OCD progression (as identified by X-ray or MRI) like symptomatic patients.

# Line 1188- 1207 Recommendation 11Rationale

The rationale has been edited to:

Skeletally mature patients with OCD lesions who have a history of not healing and/or have signs of loosening (usually detected by MRI) are unlikely to heal without treatment. Further, these skeletally mature patients, because of loss of bone and cartilage, may be at higher risk of developing severe osteoarthritis (osteoarthrosis) at an early age. Although the exact degree of risk is not known, the work group deemed that it was imprudent to ignore it.

In issuing this consensus recommendation, the work group is issuing a recommendation consistent with current medical practice. However, the work group also acknowledges the paucity of evidence on the effectiveness of fixation of unstable OCD lesions, and that surgery entails risks. These risks include, but are not limited to, bleeding, infection, damage to nerves and blood vessels, venous thromboembolic events, anesthesia complications, and surgical failure. Again, however, not performing surgery also carries a risk, irreversible osteoarthritis/osteoarthrosis. This latter risk is of particular concern since effective treatments for young patients with severe osteoarthritis (osteoarthrosis) are limited. It is, therefore, the opinion of the work group that symptomatic patients with salvageable unstable or displaced OCD lesions (the work group defines "salvageable, unstable or displaced OCD lesions", either unstable but in situ or displaced, as those that may be restored, using the patient's native tissue from the osteochondritis region) be given the option of balancing the risks of performing or not performing surgery against the benefits of performing or not performing it. One potential benefit of surgery is the prevention or delay of severe osteoarthritis (osteoarthrosis). Another potential benefit is that these patients will be relieved of their existing symptoms. The work group stresses that the choice to proceed with surgery is part of a shared decision making process between the patient, family, and physician. Offering patients the option of surgery is not a mandate that they have it. Patients can, and sometimes do, decline surgery.

Offering patients surgery requires informed consent. Failure to inform patients concerning the possible risks of surgical treatment is unethical and precludes them from surgery. Informed consent should provide patients with enough information about surgery to make a sound judgment about whether they wish to proceed to surgery given their individual situation.

The present recommendation does not apply to all patients with OCD. In many skeletal immature children (i.e., those with open physes), these lesions heal without treatment. This is particularly true in children who have incidentally discovered lesions and minimal symptoms. Accordingly, the work group makes no recommendations about surgery or physical therapy for such patients.

## Line 1421 Recommendation 15

This recommendation was edited from:

"In the absence of either reliable evidence or consensus among the work group, we are unable to recommend for or against physical therapy comprised of protective, restorative, and return to activities/sports phases for all patients who have had operative treatment for OCD."

#### To:

"In the absence of reliable evidence, it is the opinion of the work group that post-operative OCD patients be offered the option of physical therapy."

#### The accompanying rationale was also edited to:

Patients who receive surgical interventions for OCD of the knee may experience impairments such as loss of motion, strength deficits, altered movement patterns, and post-operative effusion. Although we could not locate any rigorously collected evidence about how common these impairments are, or their degree of severity, the work group deemed that it was imprudent to ignore them.

In making this consensus recommendation, the work group is issuing a recommendation consistent with current practice. However, the work group also acknowledges the paucity of evidence on the effectiveness of physical therapy, including its effects on either the duration or severity of these impairments (none of the eight studies included in this guideline that reported that their patients received post-operative physical therapy.<sup>41, 43-45, 51, 52, 56, 57</sup> (check and insert correct references) evaluated the effects of that therapy), or whether supervised therapy and unsupervised therapy yield different outcomes. Accordingly, it is not possible to determine whether patients should be offered supervised or unsupervised therapy.

The work group also notes that there are minimal risks associated with physical therapy, which, given its potential benefits, also argues for offering it to patients. These patients should be offered sufficient information to allow them to choose between supervised and unsupervised therapy, given their own, unique circumstances.

# Line 1457 Future Research

Additional text was added:

"The available classification systems should be reviewed, compare, evaluated and validated according to the most important criteria for the diagnosis of Osteochondritis Dissecans. Identifying a reliable classification system could help standardize diagnoses, corresponding treatment and the true incidence and prevalence of this disease in children and adults."

# Line 1733, Appendix VI

Text was added to include the rules the work group used to make opinion-based recommendations.

# Line 1803

The wording "Treatment of Symptomatic Osteoporotic Spinal Compression Fractures" was replaced with "Osteochondritis Dissecans".

# **Overall Guideline Change**

Throughout the guideline, where osteoarthritis is noted "(osteoarthrosis)" was added for clarification.

Review Comments and Responses 2

# ALL REVIEW COMMENTS, OUR RESPONSES AND REVIEWER COI WILL BE AVAILABLE FOR REVIEW ON OUR WEBSITE FOLLOWING BOD APPROVAL OF THIS DOCUMENT.

Review of any AAOS confidential draft allows us to improve the overall guideline but <u>does not imply endorsement</u> 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 be solicited until the AAOS Board of Directors officially approves the final guideline.

Please note that if you return a review:

- Your review will be published on the AAOS website with our explanation of why we did nor did not change the draft document in response to your comments
- Your conflicts of interest will be published on the AAOS website with your review

Reviewer Information:	
Name of ReviewerKurt T. Hegmann, MD, MPH	
AddressRMCOEH, U of Utah, 391 Chipeta Way, Suite C	
CitySLCStateUTZip Code8410	08
Phone801-581-4800Fax801-581-7224	E-mailkurt.hegmann@hsc.utah.edu
Specialty Area/Discipline:Occupational Medicine	
Work setting:AcademicsCredentials:MD, MPH	
<u>May we list you as a Peer Reviewer in the final Guidelines (GL)?</u> PLEASE READ: If you do not wish to be listed, your name will be removed for ident However, your review comments, our responses and your COI will still be available public review on our website with the posted Guideline if you complete this review.	tification purposes. 9 for
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 this guideline?	XX Yes 🔲 No
Society Name:American College of Occupational and Environmental Medicine (Listing the specialty society as a reviewing society does not imply or otherwise indicate e	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.

☐ I have declared my conflicts of interest on page 2 of this form. X I have declared my conflicts of interest in the AAOS database; my customer # is00391758
XX I understand that the AAOS will post my declared conflicts of interest with my comments concerning review of this guideline or technology overview 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 as required by the Accreditation Council for Continuing Medical Education (ACCME) guidelines.

Do you or a member of your immediate family receive royalties for any pharmaceutical, biomaterial or	🗌 Yes 🛛 XX No
orthopaedic product or device?	
If YES, please identify product or device:	
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?	☐ Yes XX No
If YES, please identify company:	
Are you or a member of your immediate family a PAID EMPLOYEE for any pharmaceutical, biomaterial or orthopaedic device or equipment company, or supplier?	🗌 Yes 🛛 XX No
If YES, please identify company or supplier:	
Are you or a member of your immediate family a PAID CONSULTANT for any pharmaceutical, biomaterial or orthopaedic device or equipment company, or supplier?	☐ Yes XX No
If YES, please identify company or supplier:	
Are you or a member of your immediate family an UNPAID CONSULTANT for any pharmaceutical, biomaterial or orthopaedic device or equipment company, or supplier?	🗌 Yes XX No
If YES, please identify company or supplier:	
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)	🗌 Yes XX No
If YES, please identify company or supplier:	
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?	🗌 Yes XX No
If YES, please identify company or supplier:	
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?	🗌 Yes XX No
If YES, please identify company or supplier:	ļ
Do you or a member of your immediate family receive any royalties, financial or material support from any medical and/or orthopaedic publishers?	🗌 Yes 🛛 XX No
If YES, please identify publisher:	
Do you or a member of your immediate family serve on the editorial or governing board of any medical and/or orthopaedic publication?	🗌 Yes XX No
If YES, please identify:	L
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?	XX Yes 🗌 No
If YES, please identify: ACOEM's Ergonomics Committee. Am Board of Preventive Medicine's Board of Trustees	

#### **Reviewer Instructions**

Please read and review this Draft Clinical Practice Guideline and its associated Technical Report with particular focus on your area of expertise. Your responses are confidential and will be used only 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 guideline and Technical Report. If you need more space than is provided, please attach additional pages.

Please complete and return this form electronically in WORD format to <u>wies@aaos.org</u>; please contact Jan Wies at (847) 823-9769 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 send the completed form and comments <u>in WORD format</u> by end of day <u>June 18, 2010</u>.

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

#### COMMENTS

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 and Technical Report

#### Dear Dr. Hegemenn,

We appreciate your thoughtful input. In order to address your concerns, please find below a point-by-point response that has been edited and approved by the AAOS Chair and Vice-Chair of the physician work group that developed this guideline.

The AAOS and the panel of experts are to be congratulated for producing a draft evidence review on the important topic of osteochondritis dissecans. This review is meant to be supportive, constructive and helpful. Overall, the guideline demonstrates good capture of the relevant literature and analyses.

#### Thank you for your kind comments.

It should not be surprising that there is no substantive, quality literature on treatments and conclusions are at best tepid. This is a frequent occurrence for all disorders that are not common. This does raise a considerable issue that includes this guideline but also is beyond the scope of this guideline: Is there a place for more consensus recommendations? I believe the answer is yes. The problem with not pushing further into consensus recommendations in important areas is that the typical clinician is very busy. At best, most will probably only read the conclusions/main recommendations. I suggest there should be a few more important points included to at least address some of these issues that are frequently faced by these clinicians. I noted a few of these below with specific suggestions. A possible consideration for the future is to be sure the major questions clinicians are confronted with are adequately captured initially, then assuring they are subsequently addressed in the final product.

When we write evidence-based guidelines and we limit opinion-based recommendations to critical issues that are catastrophic to the patient if not addressed. The AAOS is currently considering other vehicles for making statements that are more opinion-based. Given your comments, as well as others, we realized we inadvertently left out of the Appendices the rules we use for constructing opinion-based recommendations. We have added these rules into Appendix VI at line 1733 for clarification and transparency. AAOS "opinion-based" recommendations must conform to specific criteria in order to be included in the guideline. For your convenience, I have listed the additional text below.

#### **Opinion-Based Recommendations**

A guideline can contain recommendations that are backed by little or no data. Under such circumstances, work groups often issue opinion-based recommendations. Although doing so is sometimes acceptable in an evidence-based guideline (expert opinion is a form of evidence), it is also important to avoid constructing a guideline that liberally uses expert opinion; research shows that expert opinion is often incorrect.

Opinion-based recommendations are developed only if they address a vitally important aspect of patient care. For example, constructing an opinion-based recommendation in favor of taking a history and physical is warranted. Constructing an opinion-based recommendation in favor of a specific modification of a surgical technique is seldom warranted. To ensure that an opinion-based recommendation is absolutely necessary, the

4

AAOS has adopted rules to guide the content of the rationales that underpin such recommendations. These rules are based on those outlined by the US Preventive Services Task Force (USPSTF). {786} Specifically, rationales based on expert opinion must:

- Not contain references to or citations from articles not included in the systematic review that underpins the recommendation.
- Not contain the AAOS guideline language "We Recommend", "We suggest" or "treatment x is an option".
- Contain an explanation of the potential preventable burden of disease. This involves considering both the incidence and/or prevalence of the disease, disorder, or condition and considering the associated burden of suffering. To paraphrase the USPSTF, when evidence is insufficient, provision of a treatment (or diagnostic) for a serious condition might be viewed more favorably than provision of a treatment (or diagnostic) for a condition that does not cause as much suffering. The AAOS (like the USPSTF) understand that evaluating the "burden of suffering" is subjective and involves judgment. This evaluation should be informed by patient values and concerns. The considerations outlined in this bullet make it difficult to recommend new technologies. It is not appropriate for a guideline to recommend widespread use of a technology backed by little data and for which there is limited experience. Such technologies are addressed in the AAOS' Technology Overviews.
- Address potential harms. In general, "When the evidence is insufficient, an intervention with a large potential for harm (such as major surgery) might be viewed less favorably than an intervention with a small potential for harm (such as advice to watch less television)." {786}
- Address apparent discrepancies in the logic of different recommendations. Accordingly, if there are no relevant data for several recommendations and the work group chooses to issue an opinion-based recommendation in some cases but chooses not to make a recommendation in other cases, the rationales for the opinion-based recommendations must explain why this difference exists. Information garnered from the previous bullet points will be helpful in this regard.
- Consider current practice. The USPSTF specifically states that clinicians justifiably fear that not doing something that is done on a widespread basis will lead to litigation. {786} The consequences of not providing a service that is neither widely available nor widely used are less serious than the consequences of not providing a treatment accepted by the medical profession and thus expected by patients. Discussions of available treatments and procedures rely on mutual communication between the patient's guardian and physician, and on weighing the potential risks and benefits for a given patient. The patient's "expectation of treatment" must be tempered by the treating physician's guidance about the reasonable outcomes that the patient can expect.
- Justify, why a more costly device, drug, or procedure is being recommended over a less costly one whenever such an opinion-based recommendation is made.

Work group members write the rationales for opinion based recommendations on the first day of the final work group meeting. When the work group re-convenes on the second day of its meeting, it will vote on the rationales. The typical voting rules will apply. If the work group cannot adopt a rationale after three votes, the rationale and the opinion-based recommendation will be withdrawn, and a "recommendation" stating that the group can neither recommend for or against the recommendation in question will appear in the guideline.

Discussions of opinion-based rationales may cause some members to change their minds about whether to issue an opinion-based recommendation. Accordingly, at any time during the discussion of the rationale for an opinion-based recommendation, any member of the work group can make a motion to withdraw that recommendation and have the guideline state that the work group can neither recommend for or against the recommendation in question.

### **Checklist for Voting on Opinion-Based Recommendations**

When voting on the rationale, please consider the following:

- 1. Does the recommendation affect a substantial number of patients or address treatment (or diagnosis) of a condition that causes death and/or considerable suffering?
- 2. Does the recommendation address the potential harms that will be incurred if it is implemented and, if these harms are serious, does the recommendation justify;
  - a. why the potential benefits outweigh the potential harms and/or
  - b. why an alternative course of treatment (or diagnostic workup) that involves less serious or fewer harms is not being recommended?
- 3. Does the rationale explain why the work group chose to make a recommendation in the face of minimal evidence while, in other instances, it chose to make no recommendation in the face of a similar amount of evidence?
- 4. Does the rationale explain that the recommendation is consistent with current practice?
- 5. If relevant, does the rationale justify why a more costly device, drug, or procedure is being recommended over a less costly one?

Below are specific comments and suggestions.

 Regarding etiology/risks (lines 378-82; 400-404). There are not quality epidemiological studies (if there are, the literature review is incomplete, but I am not aware of any). The available evidence is largely anecdote, which may be sufficient for acute onset painful OD lesions occurring from discrete, high-force, contact sports injuries. However, it is particularly speculative when it comes to "microtrauma" which is a theory. It is suggested either to delete "microtrauma" or at least note it as a theory without supporting quality data. Also suggest a sentence noting that "The quality of the epidemiological literature is sparse and aside from discrete traumatic events for which cause is non-controversial, there is no quality epidemiological literature."

As indicated in Lines 378 – 382 below we state in the guideline that the etiology is unknown and the suspected factors are based on theory:

"The etiology of Osteochondritis Dissecans of the Knee is unknown. Family history, growth disorders, ischemia, trauma and repetitive microtrauma due to high levels of participation in sports in juveniles have been theorized as possible etiologic factors of Osteochondritis Dissecans of the Knee.1-12"

6

We also note that the risk factors for this disease are also based on theory in Lines 400 – 404

Osteochondritis dissecans can occur in different joints, including the knee, elbow, hip and ankle.<sup>15</sup> The knee is most commonly affected. <u>Risk factors are theorized</u> to include repetitive stress to the joint, trauma or joint injuries, age between 10 and 20 years and participation in sports.<sup>15-17</sup>

When possible, we use information from the studies that meet our inclusion criteria to address the introductory sections of the guidelines. If these studies do not offer quality evidence concerning the incidence, prevalence, etiology and/or other introductory sections of the guideline we seek quality studies that address these questions. This is why there is a reference section and an included studies section in the Appendices. References 1 through 17 are cited as support for these sections. The Schindler (2006) reference specifically discusses micro trauma as a theory. Other references, for example Cahill (1995) and Aichroth (1968) discuss "repetitive" trauma; hence we believe the information is accurately reflected in the guideline.

2. Lines 434-439. Suggest deleting in future requests for reviews, as it inaccurately suggests the Academy is not open to changes to the document.

These lines are found in the "Methods" section of the document. We are explaining to the reviewer the AAOS' review and approval processes to enhance transparency. Based on your comments, we have edited these lines to the present tense to avoid confusion and misinterpretation.

#### Lines 434 – 439:

The resulting draft guidelines were then peer-reviewed, subsequently sent for public commentary, and then sequentially approved by the AAOS Evidence Based Practice Committee, AAOS Guidelines and Technology Oversight Committee, AAOS Council on Research, Quality Assessment, and Technology, and the AAOS Board of Directors (see Appendix II for a description of the AAOS bodies involved in the approval process).

#### Edited to:

The resulting draft guidelines are then peer-reviewed, edited in response to that review, and then sent for public commentary where after additional edits are made. Thereafter, the draft guideline is sequentially sent for approval by the AAOS Evidence Based Practice Committee, the AAOS Guidelines and Technology Oversight Committee, the AAOS Council on Research, Quality Assessment, and Technology, and the AAOS Board of Directors (Appendix II provides a description of the AAOS bodies involved in the approval process). All AAOS guidelines are reviewed and updated or retired every five years in accordance with the criteria of the National Guideline Clearinghouse.

3. Recommendation #4. What would a group of experts do? It seems like most would operate, especially on larger lesions. It seems as though most would treat non-operatively if asymptomatic and smaller lesions. Isn't it better to get a consensus of the experts, rather than leave it as a blank?

We have specific criteria for writing opinion-based recommendations. The work group did not believe that making a recommendation for asymptomatic patients met these criteria and hence, issued an "inconclusive" recommendation. Please refer to the rules for making opinion-based recommendations listed above.

4. Recommendation #4. Is there also no consensus amongst the panel that playing football is contraindicated? I realize this is not what is written, but it seems as though that could be implied from reading this

recommendation. That also is a major decision point for many teenagers and their physicians, thus if there is a consensus on very high impact sports, then it would make a better guideline to note that.

Unfortunately, there is no evidence to support Recommendation 4, so the work group is reluctant to make any statements. In addition, the specific etiology for OCD is unknown. We believe our disclaimer sufficiently addresses individuals and the activities they wish to participate in. Accordingly, Lines 58 – 61 state:

"Treatment decisions should be made in light of all circumstances presented by the patient. Treatments and procedures applicable to the individual patient rely on mutual communication between patient, physician and other healthcare practitioners."

5. Similar to above, but with Recommendation #5. Is there no recommendation against playing high-level contact sports such as football if they are symptomatic? I would think the panel actually would have a consensus if the current position with regards to specific high-torque sports.

#### Please see our response to your previous comment.

6. Recommendation #16. I suggest this should be modified. I would think there is consensus that obesity will accelerate the development of osteoarthrosis. At minimum, suggest noting "However, obesity is a well documented risk factor for osteoarthrosis," because a casual clinician could be otherwise misled by the document.

This recommendation does not prohibit the physician from advising patients to loose weight. It states that we did not find evidence to support the statement that weight loss and activity modification <u>prevents recurrence or</u> <u>progression to osteoarthritis in patients with OCD</u>. We also did not find evidence of a correlation between the incidence of OCD and specific activities. We specifically looked for evidence to identify the natural history of OCD and to show that OCD progresses to osteoarthritis but, once again, could not find evidence to support or refute this.

#### The recommendation states the following:

"We are unable to recommend for or against counseling patients about whether activity modification and weight control prevents onset and progression of OCD to osteoarthritis."

We do however sincerely hope that the absence of evidence found concerning the natural progression of OCD to osteoarthritis will spur quality research so that this question can be answered for future patients afflicted with OCD. The overall lack of quality evidence in this guideline suggests that research is sorely needed to define future treatment.

7. Also, it is suggested to change the term to osteoarthrosis from osteoarthritis due to the lack of cardinal signs of inflammation.

Based on your comments, we have edited the guideline to include reference to "osteoarthrosis" where applicable.

I hope this is helpful to you and wish you the very best. Please do not hesitate to contact me should you have any questions or need further information.

Your comments are always helpful and we also appreciate the time and expertise you generously give to the Academy. Thank you.

Kurt Hegmann

Dear Dr. Hegemann,

We sincerely appreciate your comments and the time you took to review this guideline. Your comments help us to clarify the intent of the work group through edits in the document. We believe your comments also help strengthen the final document we ultimately present to the AAOS Board of Directors. Thank you.

#### OVERALL ASSESSMENT

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

Strongly recommend

X Recommend (with provisions or alterations)

U Would not recommend

Unsure

# ALL REVIEW COMMENTS, OUR RESPONSES AND REVIEWER COI WILL BE AVAILABLE FOR REVIEW ON OUR WEBSITE FOLLOWING BOD APPROVAL OF THIS DOCUMENT.

Review of any AAOS confidential draft allows us to improve the overall guideline but <u>does not imply endorsement</u> 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 be solicited until the AAOS Board of Directors officially approves the final guideline.

Please note that if you return a review:

- Your review will be published on the AAOS website with our explanation of why we did nor did not change the draft document in response to your comments
- Your conflicts of interest will be published on the AAOS website with your review

Reviewer Information:			
Name of Reviewer Terese Chm	ielewski		
Address_University of Florida, Depart	tment of Physical Therapy; P	2.O. Box 100154, HSC	
City_Gainesville	State	_Zip Code <u>32610</u>	
Phone 352-273-6104	_Fax <u>352-273-6109</u>	E-mail <u>tchm@ufl.edu</u>	
Specialty Area/Discipline: _Orthopedi	cs and Sports Physical Thera	a <u>py</u>	
Work setting: _Academic	Credentials:	PT, PhD, SCS	
May we list you as a Peer Reviewer in the final Guidelines (GL)? ⊠ 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	s a representative of a profe	essional society? 🛛 Yes 🗌 No	
If yes, may we list your society as a	a reviewer of this guideline?	? 🛛 Yes 🗌 No	
Society Name:American Physical (Listing the specialty society as a revi		confirm with them) or otherwise indicate endorsement of this guideline	<i>э.)</i>

#### 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.

⊠ 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
⊠ I understand that the AAOS will post my declared conflicts of interest with my comments concerning review of this guideline or technology overview 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 as required by the Accreditation Council for Continuing Medical Education (ACCME) guidelines.

Do you or a member of your immediate family receive royalties for any pharmaceutical, biomaterial or orthopaedic product or device?	🗌 Yes 🛛 No
If YES, please identify product or device:	
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?	🗌 Yes 🖾 No
If YES, please identify company:	
Are you or a member of your immediate family a PAID EMPLOYEE for any pharmaceutical, biomaterial or orthopaedic device or equipment company, or supplier?	🗌 Yes 🛛 No
If YES, please identify company or supplier:	
Are you or a member of your immediate family a PAID CONSULTANT for any pharmaceutical, biomaterial or orthopaedic device or equipment company, or supplier?	🗌 Yes 🛛 No
If YES, please identify company or supplier:	
Are you or a member of your immediate family an UNPAID CONSULTANT for any pharmaceutical, biomaterial or orthopaedic device or equipment company, or supplier?	🗌 Yes 🛛 No
If YES, please identify company or supplier:	
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)	🗌 Yes 🛛 No
If YES, please identify company or supplier:	
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?	🗌 Yes 🛛 No
If YES, please identify company or supplier:	
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?	🗌 Yes 🛛 No
If YES, please identify company or supplier:	
Do you or a member of your immediate family receive any royalties, financial or material support from any medical and/or orthopaedic publishers?	🗌 Yes 🛛 No
If YES, please identify publisher:	
Do you or a member of your immediate family serve on the editorial or governing board of any medical and/or orthopaedic publication?	🛛 Yes 🗌 No
If YES, please identify: Journal of Orthopaedic & Sports Physical Therapy	
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?	🗌 Yes 🛛 No
If VES plagas identify	

If YES, please identify:

#### **Reviewer Instructions**

Please read and review this Draft Clinical Practice Guideline and its associated Technical Report with particular focus on your area of expertise. Your responses are confidential and will be used only 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 guideline and Technical Report. If you need more space than is provided, please attach additional pages.

Please complete and return this form electronically in WORD format to <u>wies@aaos.org</u>; please contact Jan Wies at (847) 823-9769 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 send the completed form and comments <u>in WORD format</u> by end of day <u>June 18, 2010</u>.

#### 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	t Agree
1. The recommendations are clearly stated		Ū	Ď	X
2. There is an explicit link between the recommendations and the supporting evidence				$\boxtimes$
3. Given the nature of the topic and the data, all clinically important outcomes are considered				$\boxtimes$
4. The guideline's target audience is clearly described				$\boxtimes$
5. The patients to whom this guideline is meant to apply are specifically described				$\boxtimes$
6. The criteria used to select articles for inclusion are appropriate				$\boxtimes$
7. The reasons why some studies were excluded are clearly described				$\boxtimes$
8. All important studies that met the article inclusion criteria are included				$\boxtimes$
9. The validity of the studies is appropriately appraised				$\boxtimes$
10. The methods are described in such a way as to be reproducible.				$\boxtimes$
11. The statistical methods are appropriate to the material and the objectives of this guideline				$\boxtimes$
12. Important parameters (e.g., setting, study population, study design) that could affect study results are systematically addressed				$\boxtimes$
13. Health benefits, side effects, and risks are adequately addressed				$\boxtimes$
14. The writing style is appropriate for health care professionals.				$\boxtimes$
15. The grades assigned to each recommendation are appropriate		Based on cu	rrent format	$\boxtimes$

#### COMMENTS

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 and Technical Report

Dear Dr. Chmielewski,

We appreciate your thoughtful input. In order to address your concerns, please find below a point-by-point response that has been edited and approved by the AAOS Chair and Vice-Chair of the physician work group that developed this guideline.

Thank you for the opportunity to review the practice guideline on The Diagnosis & Treatment of Osteochondritis Dissecans.

We appreciate your kind comment, the time and support of the American Physical Therapy Association and we strongly believe your input strengthens our guidelines. Thank you for the time, effort and expertise that you contributed to this process.

First and foremost, this practice guideline will serve an important role in alerting clinicians and researchers about the paucity of evidence for OCD diagnosis and treatment, and the need for high-quality research. It is surprising that only 16 articles met quality standards.

The work group appropriately identified key factors in OCD around which to create the recommendations (e.g. presence/absence of knee symptoms, skeletal maturity, lesion stability, and course of management). The recommendations are easy to read, and procedures used to arrive at the recommendations are clearly documented.

#### Thank you for your kind comments.

From my perspective, the format of Recommendations 14 and 15 stand in contrast to the other recommendations.

**First**, the wording of Recommendation 15 (i.e. "physical therapy comprised of protective, restorative, and return to activities/sports phases") is more specific than the wording of Recommendation 14 (i.e. "physical therapy"), and the main difference between the two recommendations is non-operative treatment (Recommendation 14) vs post-operative treatment (Rehabilitation 15). For other recommendations that differed by group (e.g. Recommendation 4 vs 5 or Recommendation 7 vs 11), a similar wording format was used in both; thus, it is unclear why a more specific wording was used in Recommendation 15.

Based on your comments, as well as those of others, the work group reconsidered Recommendation 15 and its corresponding rationale. The work group made a consensus based recommendation for physical therapy. The recommendation and its accompanying rationale now read as follows:

In the absence of reliable evidence, it is the opinion of the work group that patients who have received surgical treatment of OCD be offered the option of post-operative physical therapy.

**Strength of Recommendation: Consensus** 02 10

Rev 3

#### Rationale

Patients who receive surgical interventions for OCD of the knee may experience impairments such as loss of motion, strength deficits, altered movement patterns, and post-operative effusion. Although we could not locate any rigorously collected evidence about how common these impairments are, or their degree of severity, the work group deemed that it was imprudent to ignore them.

In making this consensus recommendation, the work group is issuing a recommendation consistent with current practice. However, the work group also acknowledges the paucity of evidence on the effectiveness of physical therapy, including its effects on either the duration or severity of these impairments (none of the seven studies included in this guideline that reported that their patients received post-operative physical therapy.<sup>41, 43-45, 51, 52, 56, 57</sup> (check and insert correct references) evaluated the effects of that therapy), or whether supervised therapy and unsupervised therapy yield different outcomes. Accordingly, it is not possible to determine whether patients should be offered supervised or unsupervised therapy.

# The work group also notes that there are minimal risks associated with physical therapy, which, given its potential benefits, also argues for offering it to patients. These patients should be offered sufficient information to allow them to choose between supervised and unsupervised therapy, given their own, unique circumstances.

**Second**, Recommendations 14 and 15 both state "We are unable to recommend for or against physical therapy...", but the Rationale sections (page 93 and 94) each include a statement referring to the efficacy of physical therapy for treating impairments in the AAOS Clinical Guideline on the Treatment of Osteoarthritis of the Knee. Although the literature does not provide conclusive evidence of efficacy for physical therapy in OCD, it would seem there is potential to build consensus to "...offer the option of..." physical therapy to address impairments (such as loss of motion and strength deficits) that can occur with OCD, based on the efficacy of physical therapy for addressing impairments in other populations. The risk/benefit ratio would seem to be in favor of physical therapy since the impairments can lead to reduced function, and the work group similarly used consensus for Recommendations 7, 11, and 13 based on risk/benefit ratio. It appears that the work group already tried and was unable to reach a consensus in Recommendation 15, and I wonder if the wording of the recommendation would permit high impact loading, and as mentioned in the Risk Factors section (page 2), repetitive stress is theorized to lead to the onset of OCD.

Based on reviews' comments we reconsidered Recommendation 15 and made a consensus based statement. The recommendation and its accompanying rationale now read as written in the previous reply.

We do however, limit opinion-based recommendations to critical issues that are catastrophic to the patient if not addressed. AAOS "opinion-based" recommendations must conform to specific criteria in order to be included in the guideline. Based on your comments, as well as others, we realized we inadvertently left out of the Appendices the rules we use for constructing opinion-based recommendations. We have added these rules into Appendix VI at line 1733 for clarification and transparency. For your convenience, I have listed these rules for your review following our responses to your comments below.

**In summary,** I ask the work group to consider1) removing the wording "comprised of protective, restorative and return to activities/sports phases" from Recommendation 15, and 2) exploring whether consensus is possible for Recommendations 14 and/or 15 with a revised wording such as "…offer the option of physical therapy to address impairments …" OR exploring separate recommendations for aspects of physical therapy for which there is consensus and aspects of physical therapy for which there is no consensus.

Please see the response to your previous comments.

Editorial Comments

- 1. The wording "Treatment of Symptomatic Osteoporotic Spinal Compression Fractures" is found on page 3, lines 425-426 and page117, line 1803.
- 2. There are other places for minor editorial changes, but these will likely be found by a copy editor. I am willing to detail these minor editorial changes if requested.

Thank you! These edits attest to the thoroughness of your review and we sincerely appreciate your input. These editorial errors have been corrected.

#### OVERALL ASSESSMENT

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

- Strongly recommend
- Recommend (with provisions or alterations)
- U Would not recommend
- Unsure

#### Dear Dr. Chmielewski,

We sincerely appreciate your comments and the time you took to review this guideline. Your comments help us to clarify the intent of the work group through edits in the document. We believe your comments also help strengthen the final document we ultimately present to the AAOS Board of Directors. Thank you.

#### **Rules for Creating Opinion-Based Recommendations**

A guideline can contain recommendations that are backed by little or no data. Under such circumstances, work groups often issue opinion-based recommendations. Although doing so is sometimes acceptable in an evidence-based guideline (expert opinion is a form of evidence), it is also important to avoid constructing a guideline that liberally uses expert opinion; research shows that expert opinion is often incorrect.

Opinion-based recommendations are developed only if they address a vitally important aspect of patient care. For example, constructing an opinion-based recommendation in favor of taking a history and physical is warranted. Constructing an opinion-based recommendation in favor of a specific modification of a surgical technique is seldom warranted. To ensure that an opinion-based recommendation is absolutely necessary, the AAOS has adopted rules to guide the content of the rationales that underpin such recommendations. These rules are based on those outlined by the US Preventive Services Task Force (USPSTF). {786} Specifically, rationales based on expert opinion must:

- Not contain references to or citations from articles not included in the systematic review that underpins the recommendation.
- Not contain the AAOS guideline language "We Recommend", "We suggest" or "treatment x is an option".

- Contain an explanation of the potential preventable burden of disease. This involves considering both the incidence and/or prevalence of the disease, disorder, or condition and considering the associated burden of suffering. To paraphrase the USPSTF, when evidence is insufficient, provision of a treatment (or diagnostic) for a serious condition might be viewed more favorably than provision of a treatment (or diagnostic) for a condition that does not cause as much suffering. The AAOS (like the USPSTF) understand that evaluating the "burden of suffering" is subjective and involves judgment. This evaluation should be informed by patient values and concerns. The considerations outlined in this bullet make it difficult to recommend new technologies. It is not appropriate for a guideline to recommend widespread use of a technology backed by little data and for which there is limited experience. Such technologies are addressed in the AAOS' Technology Overviews.
- Address potential harms. In general, "When the evidence is insufficient, an intervention with a large potential for harm (such as major surgery) might be viewed less favorably than an intervention with a small potential for harm (such as advice to watch less television)." {786}
- Address apparent discrepancies in the logic of different recommendations. Accordingly, if there are no relevant data for several recommendations and the work group chooses to issue an opinion-based recommendation in some cases but chooses not to make a recommendation in other cases, the rationales for the opinion-based recommendations must explain why this difference exists. Information garnered from the previous bullet points will be helpful in this regard.
- Consider current practice. The USPSTF specifically states that clinicians justifiably fear that not doing something that is done on a widespread basis will lead to litigation. {786} The consequences of not providing a service that is neither widely available nor widely used are less serious than the consequences of not providing a treatment accepted by the medical profession and thus expected by patients. Discussions of available treatments and procedures rely on mutual communication between the patient's guardian and physician, and on weighing the potential risks and benefits for a given patient. The patient's "expectation of treatment" must be tempered by the treating physician's guidance about the reasonable outcomes that the patient can expect.
- Justify, why a more costly device, drug, or procedure is being recommended over a less costly one whenever such an opinion-based recommendation is made.

Work group members write the rationales for opinion based recommendations on the first day of the final work group meeting. When the work group re-convenes on the second day of its meeting, it will vote on the rationales. The typical voting rules will apply. If the work group cannot adopt a rationale after three votes, the rationale and the opinion-based recommendation will be withdrawn, and a "recommendation" stating that the group can neither recommend for or against the recommendation in question will appear in the guideline.

Discussions of opinion-based rationales may cause some members to change their minds about whether to issue an opinion-based recommendation. Accordingly, at any time during the discussion of the rationale for an opinion-based recommendation, any member of the work group can make a motion to withdraw that recommendation and have the guideline state that the work group can neither recommend for or against the recommendation in question.

7

### **Checklist for Voting on Opinion-Based Recommendations**

When voting on the rationale, please consider the following:

- 1. Does the recommendation affect a substantial number of patients or address treatment (or diagnosis) of a condition that causes death and/or considerable suffering?
- 2. Does the recommendation address the potential harms that will be incurred if it is implemented and, if these harms are serious, does the recommendation justify;
  - a. why the potential benefits outweigh the potential harms and/or
  - b. why an alternative course of treatment (or diagnostic workup) that involves less serious or fewer harms is not being recommended?
- 3. Does the rationale explain why the work group chose to make a recommendation in the face of minimal evidence while, in other instances, it chose to make no recommendation in the face of a similar amount of evidence?
- 4. Does the rationale explain that the recommendation is consistent with current practice?

If relevant, does the rationale justify why a more costly device, drug, or procedure is being recommended over a less costly one?

# ALL REVIEW COMMENTS, OUR RESPONSES AND REVIEWER COI WILL BE AVAILABLE FOR REVIEW ON OUR WEBSITE FOLLOWING BOD APPROVAL OF THIS DOCUMENT.

Review of any AAOS confidential draft allows us to improve the overall guideline but <u>does not imply endorsement</u> 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 be solicited until the AAOS Board of Directors officially approves the final guideline.

Please note that if you return a review:

- Your review will be published on the AAOS website with our explanation of why we did nor did not change the draft document in response to your comments
- Your conflicts of interest will be published on the AAOS website with your review

Reviewer Information:
Name of Reviewer: Jeffrey R Dugas/Brian J Ludwig
Address 805 ST. VINCENT'S DR STE 100
City BIRMINGHAM State ALABAMA Zip Code 35205
Phone 205-939-3699 Fax 205-314-2539 E-mail KELSEY.MCLEMORE@ANDREWSCENTERS.COM
Specialty Area/Discipline: SPORTS MEDICINE
Work setting:PRIVATE GROUP W/ FELLOWSHIP PROGRAMCredentials:
May we list you as a Peer Reviewer in the final Guidelines (GL)?       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.       Yes       Yes         Are you reviewing this guideline as a representative of a professional society?       Yes       Yes       No
If yes, may we list your society as a reviewer of this guideline?
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.

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 or technology overview 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 as required by the Accreditation Council for Continuing Medical Education (ACCME) guidelines.

Do you or a member of your immediate family receive royalties for any pharmaceutical, biomaterial or orthopaedic product or device?	X 🗌 Yes 🗌 No
If YES, please identify product or device: MICROMAX SUTURE ANCHORS	
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?	☐ Yes X☐ No
If YES, please identify company:	
Are you or a member of your immediate family a PAID EMPLOYEE for any pharmaceutical, biomaterial or orthopaedic device or equipment company, or supplier?	☐ Yes X☐ No
If YES, please identify company or supplier:	
Are you or a member of your immediate family a PAID CONSULTANT for any pharmaceutical, biomaterial or orthopaedic device or equipment company, or supplier?	□ Yes X□ No
If YES, please identify company or supplier:	
Are you or a member of your immediate family an UNPAID CONSULTANT for any pharmaceutical, biomaterial or orthopaedic device or equipment company, or supplier?	🗌 Yes X🗌 No
If YES, please identify company or supplier:	
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)	☐ Yes X☐ No
If YES, please identify company or supplier:	
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?	X 🗌 Yes 🗌 No
If YES, please identify company or supplier: SMITH & NEPHEW, BIOMET, MITEK, ARTHREX, TORNIER, DONJOY, STRYKER	
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?	☐ Yes X☐ No
If YES, please identify company or supplier:	
Do you or a member of your immediate family receive any royalties, financial or material support from any medical and/or orthopaedic publishers?	☐ Yes X☐ No
If YES, please identify publisher:	
Do you or a member of your immediate family serve on the editorial or governing board of any medical and/or orthopaedic publication?	X 🗌 Yes 🗌 No
If YES, please identify: AJSM, AJO	
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?	X 🗌 Yes 🗌 No
If YES, please identify: AOSSM- RESEARCH COMMITTEE AND COULCIL OF DELEGATES	

#### **Reviewer Instructions**

Please read and review this Draft Clinical Practice Guideline and its associated Technical Report with particular focus on your area of expertise. Your responses are confidential and will be used only 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 guideline and Technical Report. If you need more space than is provided, please attach additional pages.

Please complete and return this form electronically in WORD format to <u>wies@aaos.org</u>; please contact Jan Wies at (847) 823-9769 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 send the completed form and comments <u>in WORD format</u> by end of day <u>June 18, 2010</u>.

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

	Disagree	Somewhat Disagree	Somewha Agree	t Agree
1. The recommendations are clearly stated				ХŪ
2. There is an explicit link between the recommendations and the supporting evidence				ХП
3. Given the nature of the topic and the data, all clinically important outcomes are considered				ХП
4. The guideline's target audience is clearly described				Х□
5. The patients to whom this guideline is meant to apply are specifically described				Х□
6. The criteria used to select articles for inclusion are appropriate				Х□
7. The reasons why some studies were excluded are clearly described				ХП
8. All important studies that met the article inclusion criteria are included				ХП
9. The validity of the studies is appropriately appraised				Х□
10. The methods are described in such a way as to be reproducible.				ХП
11. The statistical methods are appropriate to the material and the objectives of this guideline				ХП
12. Important parameters (e.g., setting, study population, study design) that could affect study results are systematically addressed				ХП
13. Health benefits, side effects, and risks are adequately addressed				ХП
14. The writing style is appropriate for health care professionals.				X
15. The grades assigned to each recommendation are appropriate				X

#### COMMENTS

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 and Technical Report

#### Dear Drs. Dugas and Ludwig,

We appreciate your thoughtful input. In order to address your concerns, please find below a point-by-point response that has been edited and approved by the AAOS Chair and Vice-Chair of the physician work group that developed this guideline.

First off, I would like to congratulate Osteochondritis Dissecans Workgroup on the outstanding job done on preparing the AAOS Guidelines for The Diagnosis and Treatment of Osteochondritis Dissecans. The group has done an exemplary job of looking critically at the available literature and determining the guidelines outlined based on highest quality literature available. The exhaustive review of the literature is a remarkable accomplishment of this group.

#### Thank you for your kind comments.

There are a couple of comments that I would like to make about some of the specific recommendations.

#### Recommendation 1

I think that x-rays are mandatory in a patient with knee pain and/or mechanical symptoms. Although the radiographs may not show an OCD lesion, they may demonstrate an occult fracture, neoplasm or other cause to pain and mechanical symptoms. Radiographs are a good place to rule in, or out, a significant number of disorders on the differential diagnosis of knee pain. There may not be evidence to support radiographs as the diagnostic modality of choice for OCD, it is generally good practice to obtain radiographs in these patients and should not be discouraged by this manuscript.

We found weak evidence to support Recommendation 1 and the associated guideline language is, therefore, that radiographs are an option for physicians. Radiographs are a better "rule in" test than a "rule out" test. The rationale states:

"Analysis of likelihood ratios (LR) and associated confidence intervals indicates clinical exam by a pediatric orthopaedic surgeon with consideration of radiographs is a good or moderately good rule in test for OCD and a moderately good, weak, or poor rule out test for OCD (Table 4)."

If radiographs are indeed the diagnostic modality of choice for OCD, we hope that this document will, at the very least, encourage better high quality research be performed to illustrate the clear diagnostic benefit of radiographs in diagnosing OCD lesions.

#### Recommendation 3

I believe that an MRI of the knee in a patient with the radiographic diagnosis of an OCD lesion is necessary for a couple of reasons. Although, the data on stability of the lesion based on MRI findings in nicely outlined in the review, there is information to be gleaned from this test. First, it helps to determine if there is other pathology in the knee (meniscal, ligamentous, neoplastic). Second, it can give information on the stability of the lesion (as defined quite nicely in the review of the literature). The MRI can also provide information on the amount of edema present in the surrounding subchondral bone to give an indication as to the age of the lesion. 02.10 4Rev 3

The work group does not disagree that this modality *may* provide additional information when diagnosing an OCD lesion. However, quality evidence to support a strong recommendation for the diagnostic value of MRI is lacking. Use of this modality as an adjunct to clinical examination with radiographs is supported by three studies that correlated findings with arthroscopic results. We hope this guideline will spur high quality research to provide evidence to support your beliefs that MRIs are "necessary".

The work group identified the evidence that supports Recommendation 3 as "weak" evidence however. As indicated in our response to your comments above, weak evidence supports the use of this modality as "an option" for the physician. The rationale states:

"These Level II studies, when considered together, may have supported a moderate strength of recommendation. However, these studies found that both x-ray and MRI are good rule in tests and <u>do not address the incremental diagnostic</u> value of an MRI in the setting of known OCD determined by x-ray. That is, these studies do not compare the diagnostic performance of clinical examination with standard radiographs to clinical examination with standard radiographs and an MRI; therefore we downgraded the strength of this recommendation to weak."

The rationale also states:

"this modality may be used as an adjunct to clinical examination with radiographs to provide additional information that will guide therapeutic decision-making".(see line 815).

The rationale also states:

*Of note, three studies*<sup>47-49</sup> *correlated MRI findings with arthroscopic findings in patients with OCD of the knee.* <u>*The evidence for assessment of stability of an OCD lesion was inconsistent.*</u>

#### Recommendation 7

I strongly agree with this recommendation. Any OCD lesion in a skeletally immature individual that may be salvageable should have every attempt at fixation and healing. The downside of these articular cartilage lesions in skeletally immature patients can be devastating without good treatment options. Every attempt should be made to fix these lesions.

#### Thank you.

#### Recommendation 15

I feel that although physical therapy may not have level one and level two studies showing the benefits in the post-operative period for treatment of OCD lesions, it is absolutely a necessary post-operative protocol. The beneficial effects of physical therapy include: strengthening, ROM, edema control and pain relief. As these individuals return to normal activities of daily living, physical therapy can be used to bring the patient back to functioning levels more quickly. For the athlete, physical therapy can not only return the athlete back to pre-op level of functioning it can also be protective of further injury to the knee by strengthening the musculature around the knee.

Based on your comments as well as those of others, we reconsidered Recommendation 15 and its rationale. The recommendation and rationale now state the following:

In the absence of reliable evidence, it is the opinion of the work group that patients who have received surgical treatment of OCD be offered the option of post-operative physical therapy.

#### Strength of Recommendation: Consensus

#### Rationale

Patients who receive surgical interventions for OCD of the knee may experience impairments such as loss of motion, strength deficits, altered movement patterns, and post-operative effusion. Although we could not locate any rigorously collected evidence about how common these impairments are, or their degree of severity, the work group deemed that it was imprudent to ignore them.

In making this consensus recommendation, the work group is issuing a recommendation consistent with current practice. However, the work group also acknowledges the paucity of evidence on the effectiveness of physical therapy, including its effects on either the duration or severity of these impairments (none of the seven studies included in this guideline that reported that their patients received post-operative physical therapy.<sup>41, 43-45, 51, 52, 56, 57</sup> (check and insert correct references) evaluated the effects of that therapy), or whether supervised therapy and unsupervised therapy yield different outcomes. Accordingly, it is not possible to determine whether patients should be offered supervised or unsupervised therapy.

The work group also notes that there are minimal risks associated with physical therapy, which, given its potential benefits, also argues for offering it to patients. These patients should be offered sufficient information to allow them to choose between supervised and unsupervised therapy, given their own, unique circumstances.

Additional Response to Comments:

The work group does not necessarily disagree with your sentiments. Further, this guideline could include evidence evaluated as level III, IV as well as V (please see Table 1, "Strength of the Recommendations"), but <u>no studies</u> were found to support physical therapy for post operative OCD patients.

We hope that this guideline will spur those who share your feelings, that physical therapy following operative treatment is "absolutely a necessary post-operative protocol", to demonstrate the benefit of physical therapy in high quality research.

Additionally, I feel that an inconclusive recommendation by the AAOS as to the usage of physical therapy after surgical intervention for OCD lesions would open the door for insurance companies to deny reimbursement for physical therapy services.

6

We hope that this guideline will spur those who share your feelings, that physical therapy following operative treatment is "absolutely a necessary post-operative protocol" in this patient population, to demonstrate the benefits of physical therapy **and** define the appropriate protocols to use. It is incumbent on insurance companies, as well as all users of this guideline, to read the full guideline including the accompanying rationales that explain why the work group reached the conclusions that they did *based on the evidence*.

#### Recommendation 16

Weight control should be addressed in all of our patients. Although, specifically as it relates to OCD this may not be a literature backed argument, as physicians it is our job to take care of our patients. This means taking care of the entire person. Obesity is an epidemic causing numerous ill-effects: diabetes, HTN, hypercholestolemia to name a few. If we can help to counsel our patients about weight control, it may not specifically address OCD, but can absolutely affect the long-term health of our patients. In regards to this recommendation, the absence of literature does not mean that we as physicians should not keep the best interest of our patients in mind.

This recommendation does not prohibit the physician from advising patients to loose weight or to modify their activities, per se. Our recommendation is about advising patients that weight loss and activity modification *prevents* recurrence or progression to osteoarthritis. Despite our exhaustive searches, we were unable to find any studies. Accordingly, the recommendation states:

"We are unable to recommend for or against counseling patients about whether activity modification and weight control <u>prevents onset and progression of OCD to osteoarthritis</u>."

We do however sincerely hope that the absence of evidence found concerning the natural progression of OCD to osteoarthritis will spur quality research so that this question can be answered for future patients afflicted with OCD. The overall lack of quality evidence in this guideline suggests that research is sorely needed to define future treatment.

Overall, I feel this is an extraordinarily strong body of work. Please feel free to contact me at any time to discuss my above noted comments.

#### Dear Drs. Dugas and Ludwig,

We sincerely appreciate your comments and the time you took to review this guideline. Your comments help us to clarify the intent of the work group through edits in the document. We believe your comments also help strengthen the final document we ultimately present to the AAOS Board of Directors. Thank you.

#### **OVERALL ASSESSMENT**

#### Would you recommend these guidelines for use in practice? (check one)

- Strongly recommend
- X Recommend (with provisions or alterations)
- U Would not recommend
- Unsure

#### ALL REVIEW COMMENTS, OUR RESPONSES AND REVIEWER COI WILL BE AVAILABLE FOR REVIEW ON OUR WEBSITE FOLLOWING BOD APPROVAL OF THIS DOCUMENT.

Review of any AAOS confidential draft allows us to improve the overall guideline but <u>does not imply</u> <u>endorsement</u> 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 be solicited until the AAOS Board of Directors officially approves the final guideline.

Please note that if you return a review:

- Your review will be published on the AAOS website with our explanation of why we did nor did not change the draft document in response to your comments
- Your conflicts of interest will be published on the AAOS website with your review

#### **Reviewer Information:** Name of Reviewer POSNA EBM Committee Address 6300 North River Road\_\_\_Suite 727\_\_\_\_\_ City\_\_\_\_\_Rosemont\_\_\_\_\_State\_\_\_IL\_\_\_\_Zip Code\_\_60018\_\_\_\_\_ Phone \_\_\_\_\_ Fax \_\_\_\_E-mail\_\_\_\_\_ Specialty Area/Discipline: \_Pediatric Surgeons\_\_\_\_\_ Work setting: \_\_\_\_\_Credentials: May we list you as a Peer Reviewer in the final Guidelines (GL)? Yes 🕅 $\square$ 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: Pediatric Orthopaedic Society of North America (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.

☐ 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 \_

□ I understand that the AAOS will post my declared conflicts of interest with my comments concerning review of this guideline or technology overview on the AAOS website.

#### Kishore Mulpuri, MD:

Submitted on: 09/23/2010 at 03:35 PM Last confirmed as accurate on: 09/23/2010 at 03:50 PM Item 1 Royalties from a company or supplier: No Conflict Reported Item 2 Speakers bureau/paid presentations for a company or supplier: • No Conflict Reported Paid employee for a company or supplier: Item • No Conflict Reported 3A Paid consultant for a company or supplier: Item 3B • No Conflict Reported Item Unpaid consultant for a company or supplier: 3C No Conflict Reported Item 4 Stock or stock options in a company or supplier: • No Conflict Reported Item 5 Research support from a company or supplier as a PI: No Conflict Reported Item 6 Other financial or material support from a company or supplier: No Conflict Reported

- Item 7Royalties, financial or material support from publishers:• No Conflict Reported
- Item 8 Medical/Orthopaedic publications editorial/governing board: • No Conflict Reported
- Item 9 Board member/committee appointments for a society:
  - Pediatric Orthopaedic Society of North America

## **COMPILED ANSWERS – OCD**

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

XXX denotes all respondents responded in this category

XX denotes that some respondents responded in this category

X denotes that few respondents responded in this category

Dear Members of the POSNA EBM Committee,

We appreciate your thoughtful input. In order to address your concerns, please find below a point-by-point response that has been edited and approved by the AAOS Chair and Vice-Chair of the physician work group that developed this guideline.

## COMMENTS

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 and Technical Report

## **General Comments:**

This was a good review of a complicated topic. These guidelines represent a great deal of work by the group. Unfortunately, there is not much evidence to support specific treatment for OCD.

Thank you for your kind comments. We agree that quality evidence concerning the treatment of Osteochondritis Dissecans is lacking.

We understand that topics for recommendations are based on the questions generated at the initial guideline development meeting. Where Level I and II evidence is lacking, instead of making it a guideline, the topic should be recommended as an area for further research. The review of the literature is valid for future research, since "evidence of absence is not absence of evidence" (DG Altman and JM Bland. *BMJ* 1995;311:485)

Please refer to "Judging the Quality of the Evidence", Line 539, and "Defining the strength of the recommendations), Line 596. Ideally, every evidence-based guideline would be based only on high quality evidence with a strong strength of recommendation. Unfortunately, high quality evidence is currently not available to answer the majority of recommendations in this guideline. We hope that this paucity of quality data will at the very least spur additional quality research concerning the treatment of Osteochondritis Dissecans.

We also include Level III, IV and V (Consensus) evidence because we believe some information can be gleaned from these studies and that they do provide some information albeit "weak" evidence. Recommendations with no evidence or conflicting evidence and an "inconclusive" strength of recommendation are regularly addressed in the "Future Research" section of our guidelines. Please see other published AAOS guidelines at https://www.aaos.org/.

Finally, we agree that absence of evidence is not evidence of ineffectiveness. When we are unable to make a recommendation, we are very careful to say we can neither recommend *for nor against*.

Most of the reviewers will likely agree that OCD's that fail non-operative therapy should be offered surgical intervention even though it is currently unclear which surgical procedure produces the best outcomes. It is important that this document is not used as a reason for payors to deny treatment of these patients.

Third party payors may indeed access these materials as will patients and other healthcare professionals; it is incumbent upon the reader to glean the appropriate information from the document and this includes reading the supporting documentation and all rationales that explain why the work group made a recommendation.

This comment appears to be in reference to Recommendation 7, Line 1007, and Recommendation 11, Line 1182 in the guideline. Both of these recommendations, listed below for your convenience, were made on the basis of the opinion of the work group with no supporting evidence. We limit opinion-based recommendations to critical issues that are catastrophic to the patient if not addressed. AAOS "opinion-based" recommendations must conform to specific criteria in order to be included in the guideline. Based on your comments, as well as others, we realized we inadvertently left out of the Appendices the rules we use for constructing opinion-based recommendations. We have added these rules into Appendix VI at line 1733 for clarification and transparency. For your convenience, I have listed these rules for your convenience following the recommendations below.

Further, we agree that it is absolutely essential for orthopaedic surgeons to do better highquality research to determine the efficacy of all treatments. This is the only way to sustain treatment options in the future. We believe that this is in the best interest of the patient.

#### **RECOMMENDATION 7**

In the absence of reliable evidence, it is the opinion of the work group that **symptomatic** skeletally immature patients with salvageable unstable or displaced OCD lesions be offered the option of surgery, which may include drilling and fixation, with or without bone grafting, to restore congruency.

#### **Strength of Recommendation: Consensus**

#### **RECOMMENDATION 11**

In the absence of reliable evidence, it is the opinion of the work group that **symptomatic** skeletally mature patients with salvageable unstable or displaced OCD lesions be offered the option of surgery, which may include drilling and fixation, with or without bone grafting to restore congruency.

#### **Strength of Recommendation: Consensus**

## Rules for creating Opinion-Based Recommendations

A guideline can contain recommendations that are backed by little or no data. Under such circumstances, work groups often issue opinion-based recommendations. Although doing so is sometimes acceptable in an evidence-based guideline (expert opinion is a form of evidence), it is also important to avoid constructing a guideline that liberally uses expert opinion; research shows that expert opinion is often incorrect.

Opinion-based recommendations are developed only if they address a vitally important aspect of patient care. For example, constructing an opinion-based recommendation in favor of taking a history and physical is warranted. Constructing an opinion-based recommendation in favor of a specific modification of a surgical technique is seldom warranted. To ensure that an opinion-based recommendation is absolutely necessary, the AAOS has adopted rules to guide the content of the rationales that underpin such recommendations. These rules are based on those outlined by the US Preventive Services Task Force (USPSTF). {786} Specifically, rationales based on expert opinion must:

- Not contain references to or citations from articles not included in the systematic review that underpins the recommendation.
- Not contain the AAOS guideline language "We Recommend", "We suggest" or "treatment x is an option".
- Contain an explanation of the potential preventable burden of disease. This involves considering both the incidence and/or prevalence of the disease, disorder, or condition and considering the associated burden of suffering. To paraphrase the USPSTF, when evidence is insufficient, provision of a treatment (or diagnostic) for a serious condition might be viewed more favorably than provision of a treatment (or diagnostic) for a condition that does not cause as much suffering. The AAOS (like the USPSTF) understand that evaluating the "burden of suffering" is subjective and involves judgment. This evaluation should be informed by patient values and concerns. The considerations outlined in this bullet make it difficult to recommend new technologies. It is not appropriate for a guideline to recommend widespread use of a technology backed by little data and for which there is limited experience. Such technologies are addressed in the AAOS' Technology Overviews.
- Address potential harms. In general, "When the evidence is insufficient, an intervention with a large potential for harm (such as major surgery) might be viewed less favorably than an intervention with a small potential for harm (such as advice to watch less television)." {786}
- Address apparent discrepancies in the logic of different recommendations. Accordingly, if there are no relevant data for several recommendations and the work group chooses to issue an opinion-based recommendation in some cases but chooses not to make a recommendation in other cases, the rationales for the opinion-based recommendations must explain why this difference exists. Information garnered from the previous bullet points will be helpful in this regard.
- Consider current practice. The USPSTF specifically states that clinicians justifiably fear that not doing something that is done on a widespread basis will lead to litigation. {786} The consequences of not providing a service that

is neither widely available nor widely used are less serious than the consequences of not providing a treatment accepted by the medical profession and thus expected by patients. Discussions of available treatments and procedures rely on mutual communication between the patient's guardian and physician, and on weighing the potential risks and benefits for a given patient. The patient's "expectation of treatment" must be tempered by the treating physician's guidance about the reasonable outcomes that the patient can expect.

• Justify, why a more costly device, drug, or procedure is being recommended over a less costly one whenever such an opinion-based recommendation is made.

Work group members write the rationales for opinion based recommendations on the first day of the final work group meeting. When the work group re-convenes on the second day of its meeting, it will vote on the rationales. The typical voting rules will apply. If the work group cannot adopt a rationale after three votes, the rationale and the opinion-based recommendation will be withdrawn, and a "recommendation" stating that the group can neither recommend for or against the recommendation in question will appear in the guideline.

Discussions of opinion-based rationales may cause some members to change their minds about whether to issue an opinion-based recommendation. Accordingly, at any time during the discussion of the rationale for an opinion-based recommendation, any member of the work group can make a motion to withdraw that recommendation and have the guideline state that the work group can neither recommend for or against the recommendation in question.

## **Checklist for Voting on Opinion-Based Recommendations**

When voting on the rationale, please consider the following:

- 1. Does the recommendation affect a substantial number of patients or address treatment (or diagnosis) of a condition that causes death and/or considerable suffering?
- 2. Does the recommendation address the potential harms that will be incurred if it is implemented and, if these harms are serious, does the recommendation justify;
  - a. why the potential benefits outweigh the potential harms and/or
  - b. why an alternative course of treatment (or diagnostic workup) that involves less serious or fewer harms is not being recommended?
- 3. Does the rationale explain why the work group chose to make a recommendation in the face of minimal evidence while, in other instances, it chose to make no recommendation in the face of a similar amount of evidence?

- 4. Does the rationale explain that the recommendation is consistent with current practice?
- 5. If relevant, does the rationale justify why a more costly device, drug, or procedure is being recommended over a less costly one?

## **POSNA Specific Comments:**

- Summary point 3: In a patient with a known OCD lesion, MRI is an option to characterize the OCD lesion..." "Strength of recommendation: WEAK"
  - This may be construed by HMO/Insurance companies to deny MRI's in symptomatic OCD patients.
  - Most current published OCD treatment protocols and retrospective papers about OCD recommend MRI in symptomatic patients; however, the guidelines recommend this as "an option." This needs to be clarified for the reader.

We believe you are referring to Recommendation 3. Third party payors may access these materials. Patients and other healthcare professionals will also have access to them. If these groups do review the guideline, it will be incumbent upon them to read and understand the full document, including the rationales that accompany each recommendation describing the evidence (in this case Lines 790 to 827), as well as the explicit link between the strength of the body of evidence and the language of a recommendation (see Table 1, line 617). We agree that it is absolutely essential for orthopaedic surgeons to do better high quality research to determine the efficacy of all treatments in order to sustain treatment options in the future. We believe that this is in the best interest of the patient.

We do not consider the "most current published OCD treatment protocols" or "retrospective papers" as evidence unless they meet the inclusion criteria for this guideline and answer the applicable diagnostic recommendation. We also tie the language of the recommendation to the strength of the overall body of evidence that supports it. Again, please see Table 1, Line 617, and Table 2, Line 620, in the guideline. The body of evidence supporting Recommendation 3 consists of five level II studies. The quality of each of these studies is described in detail in Table 6, Line 858.

The work group downgraded the body of evidence from moderate, which corresponds to language of "we suggest" in a recommendation, to weak, which corresponds to language of "option". This downgrade was explained in the rationale, Line 807; "<u>the authors of</u> <u>these studies do not compare the diagnostic performance of clinical examination with</u> <u>standard radiographs to clinical examination with standard radiographs and an MRI;</u> <u>therefore, the incremental diagnostic value of an MRI is unknown.</u>" As a result, the work group downgraded the strength of this recommendation to weak and the corresponding language in the recommendation is that an MRI is an *option*.

This language also reflects the confidence the work group has in the evidence. Recommendations supported by strong evidence are unlikely to be overturned by future quality trials; the work group is not as confident in recommendations supported by a body of evidence that is only weak.

The work group recognizes that additional information may be gleaned from an MRI; hence the recommendation states "to characterize the OCD lesion or when concomitant knee pathology is suspected". The work group discusses this in the rationale at line 814 in the guideline. Please see below.

## **RECOMMENDATION 3**

In a patient with a known OCD lesion on x-ray, an MRI of the knee is an option to characterize the OCD lesion or when concomitant knee pathology is suspected such as meniscal pathology, ACL injury, or articular cartilage injury.

## Strength of Recommendation: Weak

## Rationale Line 807:

These Level II studies, when considered together, may have supported a moderate strength of recommendation. However, these studies found that both x-ray and MRI are good rule in tests and do not address the incremental diagnostic value of an MRI in the setting of known OCD determined by x-ray. That is, these studies do not compare the diagnostic performance of clinical examination with standard radiographs to clinical examination with standard radiographs to the strength of this recommendation to weak.

## Rationale Line 814:

In addition to identifying the presence of OCD lesions and distinguishing OCD lesions from other intra-articular pathology, an MRI may be used as an adjunct to clinical examination with radiographs to provide additional information that will guide therapeutic decision-making. Of the 5 therapeutic studies<sup>41-45</sup> that were included in the development of this guideline, three studies <sup>41-43</sup> report the acquisition of an MRI at enrollment and three studies<sup>41, 43, 44</sup> report the acquisition of an MRI at follow-up evaluation. Further, one prognostic study<sup>46</sup> predicts the healing potential of stable OCD lesions, utilizing a multivariable logistic regression model. Of all of the variables that were considered (including sex, side, location, symptoms, knee dimensions, and lesion dimensions), only knee symptoms as well as normalized length and normalized width of the OCD lesion as measured on MRI were found to be predictive of healing potential.

*Of note, three studies*<sup>47-49</sup> *correlated MRI findings with arthroscopic findings in patients with OCD of the knee. The evidence for assessment of stability of an OCD lesion was inconsistent.* 

In Summary Section – Page 2. Incidence: The workgroup identified that the major problem in determining the incidence of OCD is the plethora of classification systems. Can they either propose or support 1 classification system that POSNA will stand by to eliminate this problem? This should be listed as the 1<sup>st</sup> future research proposal – to identify, or construct a new system if a current system is deemed inadequate, a classification system that meets consensus of the group. Without this tool, we will be discussing the same problems when these guidelines are revised/updated 5 to 10 years from now.

## Lines 385 to 392 state the following:

"The exact incidence of Osteochondritis Dissecans of the Knee is unknown due to a variety of classification systems, studies with small numbers of patients and inconsistencies within the literature regarding the diagnosis, treatment, and prognosis of patients with the disease. One study<sup>2</sup> reported the incidence as 29 per 100,000 in males and 18 per 100,000 in females between 1965-1974. This study reported males were at higher risk than females but a later study reported the incidence of females is increasing. Both authors theorize that the increase in the incidence can be related to an increase in sports activities."

No we cannot propose or support a single classification system. Although we agree this would be valuable, this goes beyond the scope and budget of the current effort. As you have suggested, we have added this as an area for future research initiatives in the guideline.

The work group identified several problems prohibiting the determination of the exact incidence of OCD including multiple classification systems; we did not identify any single problem as the most important factor. However, the work group did not construct a preliminary recommendation that compared the important criteria of any of the available classification systems and therefore, no evidence was searched for to support such a proposal. Some of the numerous classification systems used by the authors of the included studies in this systematic review were by the International Cartilage Repair Society (ICRS), Outerbridge, Cahill, Guhl, Ewing and Voto, and Hefti.

In Summary section- Page 2 – Burden of Disease section: This summary does not describe burden of disease; rather, it is a continuation of incidence. Can the study group give a review of the burden of disease, from both the immediate effects of OCD to a child, and to the chronic (i.e. increased risk of early onset OA)? If the data is not available, they should state that the burden of disease from JOCD is not known.

We agree and this section has been edited. It now reads as follows:

"The burden of disease from juvenile and adult Osteochondritis Dissecans is not known. Individuals affected by OCD limit activity and decrease sports participation to limit pain.<sup>14</sup>

• In Summary Section – Page 2. Potential benefits and harms: To be strict to EBM guidelines, my understanding from reading the report is that there is no level 1 or 2 evidence that an OCD leads to early onset OA. (This is correct.) In the light of the inclusion criteria for being considered in this analysis, the quoted paper cannot be included in this review; therefore, it is inappropriate to quote it in the summary statement. Instead, it can only be stated in the summary statement that the long term consequence of JOCD is unknown. Presenting the summary statement as to the potential benefits in an EBM review with a statement that is full of opinion or surgical bias is contrary to mission of this group. For example, a similar statement could be made with the same amount of data by physical therapists, AND, with as much data they could come to a consensus statement that JOCD should be treated with PT. It is important for the study group to make summary statements clear as to what was found from their hard work. They did not present any data that shows that operative vs. non operative treatment of JOCD changes the "integrity of the Joint" or the "development of OA".

We agree that the summary statement quoted from Schindler (2006), a historical review of OCD of the knee, may indicate undue bias and has therefore been replaced with information from Wall (2006) an included study in the systematic review.

Line 412

"Non-operative treatment may be associated with poor knee function, and early progression to osteoarthritis.<sup>13</sup> "If untreated (OCD), this may ultimately jeopardize the integrity of the joint and lead to the development of osteoarthritis."<sup>13</sup>

Replaced with information from Wall (2006) an included study for Rec 3:

Non operative treatment also presents with challenges because "it is difficult to predict which stable juvenile Osteochondritis Dissecans lesions will heal and the patient and family, at the advice of the treating physician, may wait to see if non-operative treatment allows the lesions to heal." {105}

It is permissible to include studies for reference only; this is generally done in the introduction section of the guideline where it is unlikely to find studies on epidemiological information, risk factors and burden of disease.

• Recommendation 7: It is difficult to define "salvageable unstable or displaced OCD lesions" with reliable data. The percentage of these lesions that move on to OA cannot be determined from the data available for this review. So, how can there be a recommendation anchor on both of these statements? A bit more clarity on how this recommendation is anchored on both of these statements would be helpful. This recommendation could potentially undermine the hard work the group has done. One might view this as the group being compelled to give a recommendation and this recommendation is laden with surgical bias.

We believe that you are referring to both Recommendation 7 and 11 in these comments. Both recommendations are opinion-based recommendations.

## **RECOMMENDATION 7**

In the absence of reliable evidence, it is the opinion of the work group that **symptomatic** skeletally immature patients with salvageable unstable or displaced OCD lesions be offered the option of surgery, which may include drilling and fixation, with or without bone grafting, to restore congruency.

## **RECOMMENDATION 11**

In the absence of reliable evidence, it is the opinion of the work group that **symptomatic** skeletally mature patients with salvageable unstable or displaced OCD lesions be offered the option of surgery, which may include drilling and fixation, with or without bone grafting to restore congruency.

You are correct. There is no study author who defined the terms "salvageable, unstable or displaced OCD". The authors present no evidence in any of the studies to define these terms. The work group defines these terms as follows:

"Salvageable OCD lesions (either unstable but in situ or displaced) are those that may be restored, using the patient's native tissue from the Osteochondritis region. Additional cartilage restoration techniques, such as tissue culture, matrix supplementation, autograft or allograft may or may not be necessary for these procedures."

The work group is allowed to make consensus based recommendations in the absence of evidence as indicated previously; please see the "Rules for Creating Opinion Based Recommendations.

Based on the reviewer comments, the rationales for Recommendations 7 and 11 were reconsidered. The rationales for Recommendations 7 and 11 were edited and now read as follows:

Children who are skeletally immature (i.e., those with open physes) who exhibit continued or progressing symptoms and signs of loosening (usually detected by MRI) are unlikely to heal without treatment. This is also true of skeletally mature patients with OCD lesions who have a history of not healing and/or there are already signs of loosening. Further, these skeletally immature and mature patients, because of loss of bone and cartilage, may be at higher risk of developing severe osteoarthritis (osteoarthrosis) at an early age. Although the exact degree of risk is not known, the work group deemed that it was imprudent to ignore it.

In issuing this consensus recommendation, the work group is issuing a recommendation consistent with current medical practice. However, the work group also acknowledges the paucity of evidence on the effectiveness of fixation of unstable OCD lesions, and that surgery entails risks. These risks include, but are not limited to, bleeding, infection, damage to nerves and blood vessels, venous thromboembolic events, anesthesia complications, and surgical failure. Again, however, not performing surgery also carries a risk, irreversible osteoarthritis/osteoarthrosis. This latter risk is of particular concern since effective treatments for young patients with severe osteoarthritis (osteoarthrosis) are limited. It is, therefore, the opinion of the work group that symptomatic patients with salvageable unstable or displaced OCD lesions (the work group defines "salvageable, unstable or displaced OCD lesions", either unstable but in situ or displaced, as those that may be restored, using the patient's native tissue from the osteochondritis region) be given the option of balancing the risks of performing or not performing surgery against the benefits of performing or not performing it. One potential benefit of surgery is the prevention or delay of severe osteoarthritis (osteoarthrosis). Another potential benefit is that these patients will be relieved of their existing symptoms.

The work group stresses that the choice to proceed with surgery is part of a shared decision making process between the patient, family, and physician. Offering patients the option of surgery is not a mandate that they have it. Patients can, and sometimes do, decline surgery.

Offering patients surgery requires informed consent. Failure to inform patients concerning the possible risks of surgical treatment is unethical and precludes them from surgery. Informed consent should provide patients with enough information about surgery to make a sound judgment about whether they wish to proceed to surgery given their individual situation.

The present recommendation does not apply to all patients with OCD. In many skeletal immature children (i.e., those with open physes), these lesions heal without treatment. This is particularly true in children who have incidentally discovered lesions and have minimal symptoms. Accordingly, the work group makes no recommendations about surgery or physical therapy for such patients.

• The group should consider drawing distinction drawn between medial and lateral lesions, younger vs. older age, or lesion size for treatment decision making.

Unfortunately, the work group was limited by the evidence. The authors of the included studies did not always specify or stratify their results by medial or lateral location, age or lesion size. The work group indicated patient population, skeletally mature versus immature patients, as the most important stratification; therefore, this is how the recommendations were defined. Other stratifications were noted based on the available evidence; see Line 759 and Line 821 (prognostic factors).

Dear Members of the POSNA EBM Committee,

We sincerely appreciate your comments and the time you took to review this guideline. Your comments help us to clarify the intent of the work group through edits in the document. We believe your comments also help strengthen the final document we ultimately present to the AAOS Board of Directors.

Thank you.

# ALL REVIEW COMMENTS, OUR RESPONSES AND REVIEWER COI WILL BE AVAILABLE FOR REVIEW ON OUR WEBSITE FOLLOWING BOD APPROVAL OF THIS DOCUMENT.

Review of any AAOS confidential draft allows us to improve the overall guideline but <u>does not imply endorsement</u> 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 be solicited until the AAOS Board of Directors officially approves the final guideline.

Please note that if you return a review:

- Your review will be published on the AAOS website with our explanation of why we did nor did not change the draft document in response to your comments
- Your conflicts of interest will be published on the AAOS website with your review

Reviewer Information:	
Name of ReviewerDr. Charles Reitman	-
Address_Baylor College of Medicine 1709 Dryden Road Suite 1200 Department of Orthop	aedics
City Houston State TX Zip Code 77030	
Phone 713-986-7410 E-mail creitman@bcm.tmc.edu	
Specialty Area/Discipline:	
Work setting:Credentials:MD	
May we list you as a Peer Reviewer in the final Guidelines (GL)? PLEASE READ: If you do not wish to be listed, your name will be removed for identi However, your review comments, our responses and your COI will still be available 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.

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.

☐ I have declared my conflicts of interest on page 2 of this form.
$oxed{\boxtimes}$ I have declared my conflicts of interest in the AAOS database; my customer # is
⊠ I understand that the AAOS will post my declared conflicts of interest with my comments concerning review of this guideline or technology overview 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 as required by the Accreditation Council for Continuing Medical Education (ACCME) guidelines.

#### Charles A Reitman, MD:

Submitted on: 05/31/2010 at 09:19 AM Last confirmed as accurate on: 09/09/2010 at 01:43 PM

- Item 1. Royalties from a company or supplier The following conflicts were disclosed
  - No Conflict Reported
- Item 2. Speakers bureau/paid presentations for a company or supplier The following conflicts were disclosed
  - No Conflict Reported
- Item 3A. Paid employee for a company or supplier The following conflicts were disclosed
  - No Conflict Reported
- Item 3B. Paid consultant for a company or supplier The following conflicts were disclosed
  - No Conflict Reported
- Item 3C. Unpaid consultant for a company or supplier The following conflicts were disclosed
  - No Conflict Reported
- Item 4.Stock or stock options in a company or supplierThe following conflicts were disclosed
  - No Conflict Reported
- Item 5. Research support from a company or supplier as a PI The following conflicts were disclosed
  - No Conflict Reported
- Item 6. Other financial or material support from a company or supplier The following conflicts were disclosed
  - No Conflict Reported
- Item 7.Royalties, financial or material support from publishersThe following conflicts were disclosed
  - No Conflict Reported
- Item 8.Medical/Orthopaedic publications editorial/governing boardThe following conflicts were disclosed

- No Conflict Reported
- Item 9. Board member/committee appointments for a society The following conflicts were disclosed
  - North American Spine Society

#### **Reviewer Instructions**

Please read and review this Draft Clinical Practice Guideline and its associated Technical Report with particular focus on your area of expertise. Your responses are confidential and will be used only 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 guideline and Technical Report. If you need more space than is provided, please attach additional pages.

Please complete and return this form electronically in WORD format to <u>wies@aaos.org</u>; please contact Jan Wies at (847) 823-9769 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 send the completed form and comments <u>in WORD format</u> by end of day <u>June 18, 2010</u>.

#### 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			Ō	
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 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 and Technical Report

## Dear Dr. Reitman,

We appreciate your thoughtful input. In order to address your concerns, please find below a point-by-point response that has been edited and approved by the AAOS Chair and Vice-Chair of the physician work group that developed this guideline.

Review of AAOS OCD Guideline

Line 96. To make it easier to understand, modify sentence. ... and/or MRI as *if they were* symptomatic ....

We edited Recommendation 10 to read as follows:

We are unable to recommend for or against treating asymptomatic skeletally mature patients with OCD progression (as identified by X-ray or MRI) like symptomatic patients.

Line 374. Consider adding; as well as the experience of the practitioner. For those questions lacking evidence, experience becomes particularly important until further research can provide better guidelines.

In response to your suggestion we edited this line to read:

"Treatments and procedures applicable to the individual patient rely on mutual communication between patient, physician and other healthcare practitioners."

It is not clear that we want to discuss experience. There is some literature showing that patients who see older physicians are at greater risk for receiving suboptimal treatment.

For recommendation 3 starting on line 784, one of stipulations of recommendation is for use of MRI to eval OCD and also look for other intraarticular problems, ligament tears, etc. In the text and tables there is not a single sentence discussing the latter part of the recommendation. It all centers around OCD. Either need to say something about it or leave it out of the recommendation.

## Recommendation 3 states the following:

"In a patient with a known OCD lesion on x-ray, an MRI of the knee is an option to characterize the OCD lesion or when concomitant knee pathology is suspected <u>such as meniscal pathology</u>, <u>ACL injury</u>, or <u>articular</u> <u>cartilage injury.</u>"

Lines 814 in the rationale, 839 in the "Supporting Evidence" section and 865 (Table 8) in the guideline address data from the studies that investigated MRI as a tool to distinguish OCD lesions from other knee pathologies. Kocher et al., 2001, obtained MRI on patients including "all suspected cruciate ligament injuries, meniscal injuries, discoid menisci, for further delineation of Osteochondritis Dissecans lesions, suspected osteochondral fractures, and uncertain clinical diagnoses but substantial pain, limited motion, limited function, or persistent effusion." Luhmann et. al., 2005, included patients with "suspected meniscal disorder, ligament disruption (anterior and posterior cruciate ligament), osteochondral fracture, or loose bodies."

For evaluation of OCD, the recommendation based on the evidence seems to be appropriate. In terms of the supporting text, specifically around lines 852 to 856, it mentions that value of MRI ranges to rule in or rule out OCD ranges from good to poor. I don't understand how they arrived at such a wide range of recommendations based on the tables, which show relatively few false negatives and positives. Please review to determine if this is accurate or just needs to be stated differently.

The value of the likelihood ratio for MRI as a diagnostic tool ranges from good to poor because of the associated large confidence intervals with the reported values. (See Tables 10 and 11 in the guideline.) We interpret likelihood ratios based on others reported methods (Jaeschke R, Guyatt G, Lijmer J. Diagnostic Tests. In: Guyatt G, Drummond R, editors. *Users' Guides to the Medical Literature: A Manual for Evidence-Based Clinical Practice*.Chicago: AMA; 2007. 121-140.) (See Table 3 in the guideline.)

Therefore, when the reported values are illustrated on a matrix corresponding to our *a priori* definitions of "good", "moderately good", "weak" and "poor" rule in or rule out tests, they overlap (see below). The associated ranges are wide. The text at lines 852 to 856 in the guideline is reflective of the fact that the reported values are less than precise when the large confidence intervals are taken into consideration. The reviewer is certainly welcome to assume his/her own definition of "good" to "poor" rule in tests, but we again, respectively chose to use those identified in the published literature.

	Limits of Confidence Interval				
Diagnostic Test		Good	Moderately Good	Weak	Poor
Evon v roug MPI	Rule In	••	•		
Exam, x-rays, MRI	Rule Out	••		•	
	Rule In	••	•		
MRI	Rule Out		•	•	•
Errore in norm	Rule In	••	•		
Exam, x-rays	Rule Out	•	•	•	
MRI for Instability,	Rule In	•	?		
immature	Rule Out	•			
	Rule In	•	?		
MRI for Instability, mature	Rule Out	••			
				:	

For recommendation 8, you have one good comparative study that shows significantly better clinical results for OAT than microfracture, yet recommendation is inconclusive. This study could provide a B recommendation (actually this would be a "weak" recommendation, see Table 1 in the guideline) but if the group was concerned about making this recommendation because there was only one study, that is understandable. However, if this is the case, just to make it clear that some good data exists, they should consider adding another sentence around Line 1099. Suggest something like, Although this study provided evidence to suggest that relative to MF, OAT

results in significantly better outcomes, in the absence of any other data, until further evidence is published there remains inconclusive evidence to make a recommendation.

The rationale and supporting evidence for this recommendation address one harm and the benefits reported in the study. These results indicate that there is no statistically significant difference for pain (a critical patientoriented outcome); this contributes to the "inconclusive" strength of recommendation. Further, this study did not evaluate some important outcomes. Accordingly, the rationale for this recommendation states:

## Rationale

The AAOS conducted a systematic review of the literature and found one quality study to address this recommendation. <u>Because there was only one Level II study and many applicable outcomes and techniques</u> were not addressed, the results of this single study were evaluated as inconclusive.

Therefore, based on the evidence, we respectfully decline to add "Although this study provided evidence to suggest that relative to MF, OAT results in significantly better outcomes, in the absence of any other data, until further evidence is published there remains inconclusive evidence to make a recommendation."

Line 1172. As stated for line 96, to make it easier to understand, modify sentence . . . and/or MRI as *if they were* symptomatic . . .

Recommendation 10 was edited as previously indicated. Thank you.

Dear Dr. Reitman,

We sincerely appreciate your comments and the time you took to review this guideline. Your comments help us to clarify the intent of the work group through edits in the document. We believe your comments also help strengthen the final document we ultimately present to the AAOS Board of Directors. Thank you.

#### **OVERALL ASSESSMENT**

#### Would you recommend these guidelines for use in practice? (check one)

- Strongly recommend
- Recommend (with provisions or alterations)
- U Would not recommend
- Unsure

# ALL REVIEW COMMENTS, OUR RESPONSES AND REVIEWER COI WILL BE AVAILABLE FOR REVIEW ON OUR WEBSITE FOLLOWING BOD APPROVAL OF THIS DOCUMENT.

Review of any AAOS confidential draft allows us to improve the overall guideline but <u>does not imply endorsement</u> 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 be solicited until the AAOS Board of Directors officially approves the final guideline.

Please note that if you return a review:

- Your review will be published on the AAOS website with our explanation of why we did nor did not change the draft document in response to your comments
- Your conflicts of interest will be published on the AAOS website with your review

Reviewer Information:	
Name of Reviewer:_Brian Rill, MD, Fred Nelson, MD	_
Address:6525 Second Ave	_
City: <u>Detroit</u> State: <u>MI</u> Zip Cod	de: <u>48202</u>
Phone: <u>1.313.972.4066</u> Fax : <u>1.313.972.4202</u>	E-mail: brill1@hfhs.org, fnelson1@hfhs.org
Specialty Area/Discipline: Sports Medicine	
Work setting: <u>Academic Institution</u> Credentials: <u>M</u>	<u>D</u>
May we list you as a Peer Reviewer in the final Guidelines (GL)? PLEASE READ: If you do not wish to be listed, your name will be However, your review comments, our responses and your COI w public review on our website with the posted Guideline if you co	e removed for identification purposes. /ill still be available for
Are you reviewing this guideline as a representative of a profess	sional society? 🗌 Yes x No
If yes, may we list your society as a reviewer of this guideline?	☐ Yes x No
Society Name:	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
× I understand that the AAOS will post my declared conflicts of interest with my comments concerning review of this guideline or technology overview 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 as required by the Accreditation Council for Continuing Medical Education (ACCME) guidelines.

Do you or a member of your immediate family receive royalties for any pharmaceutical, biomaterial or orthopaedic product or device?	🗌 Yes 🗴 No
If YES, please identify product or device:	
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?	☐ Yes x No
If YES, please identify company:	
Are you or a member of your immediate family a PAID EMPLOYEE for any pharmaceutical, biomaterial or orthopaedic device or equipment company, or supplier?	☐ Yes x No
If YES, please identify company or supplier:	
Are you or a member of your immediate family a PAID CONSULTANT for any pharmaceutical, biomaterial or orthopaedic device or equipment company, or supplier?	🗌 Yes 🗴 No
If YES, please identify company or supplier:	
Are you or a member of your immediate family an UNPAID CONSULTANT for any pharmaceutical, biomaterial or orthopaedic device or equipment company, or supplier?	🗌 Yes 🗴 No
If YES, please identify company or supplier:	
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)	☐ Yes x No
If YES, please identify company or supplier:	
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?	☐ Yes x No
If YES, please identify company or supplier:	
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?	☐ Yes x No
If YES, please identify company or supplier:	
Do you or a member of your immediate family receive any royalties, financial or material support from any medical and/or orthopaedic publishers?	☐ Yes x No
If YES, please identify publisher:	
Do you or a member of your immediate family serve on the editorial or governing board of any medical and/or orthopaedic publication?	🗌 Yes x No
If YES, please identify:	
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?	🗌 Yes 🛛 No

If YES, please identify:

#### **Reviewer Instructions**

Please read and review this Draft Clinical Practice Guideline and its associated Technical Report with particular focus on your area of expertise. Your responses are confidential and will be used only 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 guideline and Technical Report. If you need more space than is provided, please attach additional pages.

Please complete and return this form electronically in WORD format to <u>wies@aaos.org</u>; please contact Jan Wies at (847) 384-4311 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 send the completed form and comments **in WORD format** by end of day September **30**, **2010**.

#### 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		Ō		х
2. There is an explicit link between the recommendations and the supporting evidence				х
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			х	
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			х	
7. The reasons why some studies were excluded are clearly described				х
8. All important studies that met the article inclusion criteria are included				х
9. The validity of the studies is appropriately appraised				х
10. The methods are described in such a way as to be reproducible.				Х
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				х
13. Health benefits, side effects, and risks are adequately addressed				х
14. The writing style is appropriate for health care professionals.				х
15. The grades assigned to each recommendation are appropriate				х

#### COMMENTS

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 and Technical Report

#### **General Comments:**

1. The OCD guidelines represent a thorough effort for a poorly understood condition with significant gaps in treatment outcomes knowledge.

Thank you.

2. The guidelines do not help clinicians with difficult treatment dilemmas regarding which forms of non operative or operative treatment will lead to improved patient outcomes. Instead, the reader has a "list" which may or not be tried when another form of treatment has failed. The reader will then be forced to return to literature searches and read the same case series (for their own interpretation) that were not included here. It may be of benefit to direct the reader to an agreed upon reference(s) where the data is inconclusive.

The studies that we have excluded are either irrelevant to a recommendation or the quality of the study is so low that the results are not reliable enough to guide medical practice, hence we would not want to refer readers to this material.

The chair of this work group hopes that this guideline will spur future research and help investigators design the appropriate scientific studies to answer the questions that are still unresolved, particularly those graded as inconclusive.

#### Summary of Recommendations:

1. It is clearly stated that the summary is not meant for a stand alone reference. Including table 1 after the introduction or at the end of the recommendations would be helpful or as a last line in the introduction the reader to page 8 for explanation of level of recommendation.

Based on your comments we have added a statement directing the reader to table 1 following line 69 in the summary.

\*To see the description of the evidence linked to the strength of the recommendations, please refer to Table 1; "Strength of Recommendation descriptions" in the guideline.

#### Introduction:

1. Lines 357 and 358 state who is the target audience. Line 373 then goes on to mention many different providers. We would recommend a line between 373 and 374 Providers unfamiliar with the treatment of patient with OCD should be referred to qualified physicians and surgeons.

#### We agree and have added this statement at line 374.

#### Potential Benefits and Harms:

1. Line 415 states the aims of treatment include the prevention of DJD. We are aware of no intervention preventing DJD. The statement may be better reflective of current treatment by stating "potentially altering the degenerative joint process".

#### Based on your comment, we have edited this sentence to:

"The aim of treatment is pain relief, improved knee function, and potentially altering the degenerative joint process."

#### **Recommendations and Supporting Data:**

Again, as stated above in General Comments 2, where the evidence is inconclusive, the committee may consider adding "the reader is directed to historical texts, panel symposia, current best practices, etc" for additional reading

#### Please see our comments above.

In addition, the expert opinion of our work groups provides input as to the "current best practices". Retrospective case series studies do not constitute scientific evidence since they lack an *a priori* hypothesis and do not provide causally valid relationships. We are, therefore, not certain how retrospective studies are truly helpful to the practicing Orthopaedic surgeon.

Also, we are writing evidence- based guidelines. We try to limit bias and maintain transparency by our processes. Based on this goal, consensus opinion recommendations can only be made when there is no evidence identified by the systematic review and the results of not issuing a recommendation will be catastrophic. [Please see the "Rules for Making Opinion Based Recommendations" in Appendix VI of the guideline.] Therefore, when the work group has no evidence and the criteria for making a consensus statement cannot be met, the result is an inconclusive recommendation.

Thank you for allowing us the opportunity to review your work. The committee is to be commended for the work and effort directed toward the compilation and interpretation of the data.

Dear Drs. Nelson and Rill,

We sincerely appreciate the time you spent reviewing these materials. The input you provided helped strengthen the document we will present to the Board of Directors. Thank you.

#### **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.