

Peer Review and Public Commentary Report

Evidence-Based Clinical Practice Guideline on the Management of Rotator Cuff Injuries

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Management of Rotator Cuff Injuries Clinical Practice Guideline

Overview of Peer Review and Public Commentary

The reviews and comments related to this clinical practice guideline are reprinted in this document and posted on the AAOS website. All peer reviewers and public commenters are required to disclose their conflict of interests.

Peer Review

AAOS contacted 13 organizations with content expertise to review a draft of the clinical practice guideline during the two-week peer review period in January 2019.

- Four individuals provided comments via the electronic structured peer review form. No reviewers asked to remain anonymous.
- All four reviews were on behalf of a society.
- The work group considered all comments and made some modifications when they were consistent with the evidence.

Public Comment

The new draft was then circulated for a two-week public comment period ending in February 2019.

- AAOS received 4 comments including 1 representing specialty societies, 3 from individuals, and 0 from industry.
- If warranted and based on evidence, the guideline draft s modified by the work group members in response to the public comments.

Peer Reviewer Key

Each peer reviewer was assigned a number (see below). All responses in this document are listed by the assigned peer reviewer's number.

Table 1. Peer Reviewer Key

Reviewer Number	Name of Reviewer (Required)	What is the name of the society that you are representing?
1	Charles Thigpen, PhD, PT, ATC	American Society of Shoulder and Elbow Therapists (ASSET)
2	Lynn Fisher, MD, FAAFP	American Academy of Family Physicians (AAFP)
3	William Kibler, MD	American College of Sports Medicine (ACSM)
	American Physical Therapy	Individual Reviewers: Paula Marie Ludewig, PT, PhD, FAPTA Brian G. Leggin, PT, DPT, OCS
4	Association	

Peer Reviewer Demographics

Reviewer #	Name of Reviewer (Required)	Primary Specialty	Work Setting	What is the name of the society that you are representing?
	Charles Thigpen, PhD, PT,			American Society of Shoulder and
1	ATC	Shoulder and Elbow	Academic Practice	Elbow Therapists (ASSET)
				American Academy of Family
2	Lynn Fisher, MD, FAAFP	Family Medicine	Private Group or Practice	Physicians (AAFP)
				American College of Sports Medicine
3	William Kibler, MD	Shoulder and Elbow	Private Group or Practice	(ACSM)
				Individual Reviewers:
4	American Physical Therapy	Discoursed Theorem		Paula Marie Ludewig, PT, PhD, FAPTA Brian G. Leggin, PT, DPT, OCS
4	Association	Physical Therapy		

Peer Reviewers' Disclosure Information

All peer reviewers are required to disclose any possible conflicts that would bias their review via a series of 10 questions (see Table 2). For any positive responses to the questions (i.e. "Yes"), the reviewer was asked to provide details on their possible conflict.

Table 2. Disclosure Question Key

Disclosure Question	Disclosure Question Details
A	A) Do you or a member of your immediate family receive royalties for any pharmaceutical, biomaterial or orthopaedic product or device?
В	B) 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?
С	C) Are you or a member of your immediate family a PAID EMPLOYEE for any pharmaceutical, biomaterial or orthopaedic device or equipment company, or supplier?
D	D) Are you or a member of your immediate family a PAID CONSULTANT for any pharmaceutical, biomaterial or orthopaedic device or equipment company, or supplier?
Е	E) Are you or a member of your immediate family an UNPAID CONSULTANT for any pharmaceutical, biomaterial or orthopaedic device or equipment company, or supplier?
F	F) 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)
G	G) 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?
Н	H) 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?
I	I) Do you or a member of your immediate family receive any royalties, financial or material support from any medical and/or orthopaedic publishers?
J	J) Do you or a member of your immediate family serve on the editorial or governing board of any medical and/or orthopaedic publication?

Table 3. Peer Reviewer's Disclosure Information

Reviewer #	Name of Reviewer (Required)	Disclosure Available via AAOS Disclosure System	A	В	С	D	E	F	G	Н	I	J
	Charles Thigpen, PhD, PT,											
1	ATC	Yes										
2	Lynn Fisher, MD, FAAFP	No	No	No	No	No	No	No	No	No	No	No
3	William Kibler, MD	Yes										
	American Physical Therapy											
4	Association	Yes										

Peer Reviewer Responses to Structured Peer Review Form Questions

All peer reviewers are asked 16 structured peer review questions which have been adapted from the Appraisal of Guidelines for Research and Evaluation (AGREE) II Criteria*. Their responses to these questions are listed on the next few pages.

Table 5. Peer Reviewer Responses to Structured Peer Review Questions 1-4

Reviewer #	Name of Reviewer (Required)	What is the name of the society that you are representing?	1. The overall objective(s) of the guideline is (are) specifically described.	2. The health question(s) covered by the guideline is (are) specifically described.	3. The guideline's target audience is clearly described.	4. The guideline development group includes individuals from all the relevant professional groups.
1	Charles Thigpen, PhD, PT, ATC	American Society of Shoulder and Elbow Therapists (ASSET)	Strongly Agree	Strongly Agree	Strongly Agree	Strongly Agree
2	Lynn Fisher, MD, FAAFP	American Academy of Family Physicians (AAFP)	Strongly Agree	Strongly Agree	Strongly Agree	
3	William Kibler, MD	American College of Sports Medicine (ACSM)	Agree	Agree	Agree	Strongly Agree
4	American Physical Therapy Association	Individual Reviewers: Paula Marie Ludewig, PT, PhD, FAPTA Brian G. Leggin, PT, DPT, OCS	Strongly Agree	Strongly Agree	Strongly Agree	Strongly Agree

Table 6. Peer Reviewer Responses to Structured Peer Review Questions 5-8

Reviewer #	Name of Reviewer (Required)	What is the name of the society that you are representing?	5. There is an explicit link between the recommendations and the supporting evidence.	6. Given the nature of the topic and the data, all clinically important outcomes are considered.	7. The patients to whom this guideline is meant to apply are specifically described.	8. The criteria used to select articles for inclusion are appropriate.
1	Charles Thigpen, PhD, PT, ATC	American Society of Shoulder and Elbow Therapists (ASSET)	Strongly Agree	Strongly Agree	Strongly Agree	Strongly Agree
2	Lynn Fisher, MD, FAAFP	American Academy of Family Physicians (AAFP)	Strongly Agree	Strongly Agree	Agree	Strongly Agree
3	William Kibler,	American College of Sports Medicine (ACSM)	Strongly Agree	Agree	Agree	Agree
4	American Physical Therapy Association	Individual Reviewers: Paula Marie Ludewig, PT, PhD, FAPTA Brian G. Leggin, PT, DPT, OCS	Strongly Agree	Strongly Agree	Strongly Agree	Strongly Agree

Table 7. Peer Reviewer Responses to Structured Peer Review Questions 9-12

Reviewer #	Name of Reviewer (Required)	What is the name of the society that you are representing?	9. The reasons why some studies were excluded are clearly described.	10. All important studies that met the article inclusion criteria are included.	11. The validity of the studies is appropriately appraised.	12. The methods are described in such a way as to be reproducible.
1	Charles Thigpen, PhD, PT, ATC	American Society of Shoulder and Elbow Therapists (ASSET)	Strongly Agree	Strongly Agree	Strongly Agree	Strongly Agree
2	Lynn Fisher, MD, FAAFP	American Academy of Family Physicians (AAFP)	Agree	Agree	Strongly Agree	Strongly Agree
3	William Kibler, MD	American College of Sports Medicine (ACSM)	Agree	Agree	Agree	Agree
4	American Physical Therapy Association	Individual Reviewers: Paula Marie Ludewig, PT, PhD, FAPTA Brian G. Leggin, PT, DPT, OCS	Strongly Agree	Strongly Agree	Strongly Agree	Strongly Agree

Table 8. Peer Reviewer Responses to Structured Peer Review Questions 13-16

Reviewer #	Name of Reviewer (Required)	What is the name of the society that you are representing?	13. The statistical methods are appropriate to the material and the objectives of this guideline.	14. Important parameters (e.g., setting, study population, study design) that could affect study results are systematically addressed.	15. Health benefits, side effects, and risks are adequately addressed.	16. The writing style is appropriate for health care professionals.	Additional comments regarding this CPG?
1	Charles Thigpen, PhD, PT, ATC	American Society of Shoulder and Elbow Therapists (ASSET)	Strongly Agree	Strongly Agree	Strongly Agree	Strongly Agree	
2	Lynn Fisher, MD, FAAFP	American Academy of Family Physicians (AAFP)	Agree	Agree	Strongly Agree	Strongly Agree	I find that this could be helpful as I talk to a patient about what the next options would be for various types of rotator cuff tears
3	William Kibler, MD	American College of Sports Medicine (ACSM)	Agree	Strongly Agree	Strongly Agree	Agree	
4	American Physical Therapy Association	Individual Reviewers: Paula Marie Ludewig, PT, PhD, FAPTA Brian G. Leggin, PT, DPT, OCS	Strongly Agree	Strongly Agree	Strongly Agree	Strongly Agree	

Peer Reviewers' Recommendation for Use of this Guideline in Clinical Practice Would you recommend these guidelines for use in clinical practice?

Reviewer #	Name of Reviewer (Required)		Would you recommend these guidelines for use in clinical practice? (Required)
1	Charles Thigpen, PhD, PT, ATC	American Society of Shoulder and Elbow Therapists (ASSET)	Strongly Recommend
2		American Academy of Family Physicians (AAFP)	Strongly Recommend
3	William Kibler, MD	American College of Sports Medicine (ACSM)	Strongly Recommend
		Individual Reviewers: Paula Marie Ludewig, PT, PhD, FAPTA Brian G. Leggin, PT, DPT, OCS	

Peer Reviewer Detailed Responses

Reviewer #1, Charles Thigpen, PhD, PT, ATC

Reviewer #	Name of Reviewer (Required)	What is the name of the society that you are representing?	Please provide a brief explanation of both your positive and negative answers in the preceding section. If applicable, please specify the draft page and line numbers in your comments. Please feel free to also comment on the overall structure and content of the Guideline:
1	Charles Thigpen, PhD, PT, ATC	American Society of Shoulder and Elbow Therapists (ASSET)	A. The structure and clinical take aways from the guideline are appropriate and reflect the best, current evidence. While the timing of post-operative mobilization is addressed (line 872), and supervised exercise (1427))the appropriateness and timing of post-operative rehabilitation is not addressed. All level 1/2 evidence evaluating outcomes following rotator cuff repair include a standardized, supervised therapy program. While not comparative the overwhelming evidence consistently includes supervised post-operative therapy. In my opinion, this evidence should be summarized and reported as a statement.

Dear Charles Thigpen, PhD, PT, ACT,

Thank you for your expert review of the Clinical Practice Guideline on the Postoperative Management of Surgical Site Infection. We will address your comments by guideline section in the order that you listed them.

A. The papers in which the study design does not directly compare treatments (e.g. timing of post-operative rehabilitation vs comparator) and report each treatment group's outcomes would not meet inclusion criteria to be used as evidence in the data summary.

Reviewer #2, Lynn Fisher, MD, FAAFP

Reviewer #	Name of Reviewer (Required)	What is the name of the society that you are representing?	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:
2	(Required) Lynn Fisher, MD, FAAFP	representing? American Academy of Family Physicians (AAFP)	 A. Page 8 Corticosteroid for RTC Tears Would clarify single dose injection of steroids for people with pain from RTC tear (on line 161) as other interventions are all for RTC tear). Same information applies to page 38, line 927. B. Page 13 line 176 ?VAS (had to look this up to see what this might be) C. Appreciate under each section the information about the trials, the potential harm, need for future research in areas. D. P 29, line 636 has included this repeated multiple times; confused as the position statement says evidence support distal clavicle resection but the comments state the studies showed no difference E. Starting on P 30 Positive and Negative LR: would consider adding a 0 in front of the decimal place of less than 1. Just makes it easier to see where the decimal place is located. F. P 38, line 946: They were instead of There; line 949 remove the word of; I think it is important to know that giving a corticosteroid injection for a RTC could cause more damage for surgery. The way the recommendation stands currently makes it sound like there is no risk and that pain and function may will improve short term. As a primary care provider, if I know that giving the injection to a possible surgical candidate may worsen their surgical chances, I would be more hesitant to give one. G. P 49, line 1142: Should the guideline have at the end of it "for small to medium tears" added? There are several discussion points in the text that follows that states
			1

	H. P 58, lines 1444 and 1445: thickness, improve (spelling errors. You likely have someone read for these, but they just caught my attention)

Dear Lynn Fisher, MD, FAAFP,

Thank you for your expert review of the Clinical Practice Guideline on the Postoperative Management of Surgical Site Infection. We will address your comments by guideline section in the order that you listed them.

- A. The studies used in support showed improvements in pain and function in patient populations not limited to rotator cuff tears.
- B. Visual analog scale (VAS) has been defined in line 176.
- C. Thank you.
- D. Thank you for catching this, the multiple words in like 636 have been deleted.
- E. One high quality and two moderate quality randomized controlled studies addressing distal clavicle resection were included. A moderate recommendation requires consistent findings from two or more moderate quality studies or evidence from at least one high quality study. Although there were no differences within the moderate quality studies, distal clavicle resection combined with rotator cuff repair showed better functional outcomes and no reoperation rate at 2 years within the one high quality study.
- F. Decimals less than one have been a rewritten with a 0 preceding them, as well as a 0 hundredth place as appropriate, for clarity.
- G. Thank you. The typographical errors have been corrected in lines 946 and 949.
- H. Single injections have been shown to improve function, but with some potential for unestablished risk. This risk is defined in detail in the 'Risks and Harms of Implementing this Recommendation' statement "Corticosteroid injections in the setting of rotator cuff tears may be detrimental to the healing potential following cuff repair. Considering that rotator cuff diagnoses are clinical, a single corticosteroid injection may be given to confirm the presence of a symptomatic rotator cuff tear, but may adversely affect surgical outcomes."
- I. The recommendation language is based on 9 high quality studies supporting no difference between single row and double row and only two studies in support of double row. The rationale provides additional information regarding the supporting studies.
- J. Thank you. The spelling errors have been corrected in lines 1444 and 1445.

Reviewer #3, William Kibler, MD

Reviewer	Name of	What is the name of	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	
Keviewer #	Reviewer	the society that you are	in your comments. Please feel free to also comment on the overall structure and	
,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,	(Required)	representing?	content of the Guideline:	
3	William Kibler, MD	American College of Sports Medicine (ACSM)	 A. Line 640: There is a potential harm to the patients from the increased risk of AC joint instability following an over extensive DCE. This complication is frequently difficult to treat because of the loss of bone length and loss of ligament attachments B. Line 923: Other factors may include the range of motion through which the shoulder/arm is moved, the method of movement (active, passive, active assisted), and the length of the lever arm (long vs short). In addition to these factors that may affect tensile loading of the repair, the effect of compression loading (scapular dyskinesis with acromial downward tilt) has been shown to affect repair integrity 	
			and should be evaluated. C. Line 1469: There are multiple papers reporting the use of PT, partial repairs, tendon transfers, and superior capsular reconstruction in this group of patients. Was the rationale for the consensus recommendation due to the poor quality of the papers?	

Dear William Kibler, MD,

Thank you for your expert review of the Clinical Practice Guideline on the Postoperative Management of Surgical Site Infection. We will address your comments by guideline section in the order that you listed them.

- A. The risk for symptomatic instability is minimal, and is noted within the rationale for this recommendation.
- B. While we agree with the underlying logic of these comments, there is no high-level evidence available to answer these questions.
- C. The included studies addressing unrepairable tears without arthropathy were comprised of multiple low-level observational articles. Additional studies under consideration were excluded for very low quality. Due to the lack of reliable evidence, the recommendation was molded into a consensus statement.

Reviewer #4, American Physical Therapy Association

Reviewer #	Name of Reviewer (Required)	What is the name of the society that you are representing?	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:	
4	American Physical Therapy Association (APTA)	Individual Reviewers: Paula Marie Ludewig,	This is a very comprehensive and well written clinical practice guideline. We agree that the recommendations are based on a thorough review of the current evidence. Below are some specific items that were identified by the review from APTA.	
		PT, PhD, FAPTA Brian G. Leggin, PT, DPT, OCS	 A. Consider restating comment on Page 19, Line 351-352 a. "Rotator cuff pathology is the leading cause of shoulder-related disability seen by orthopaedic surgeons, and surgical volume is on the rise (Narvy 2016)." b. To c. "Rotator cuff pathology is the leading diagnosis applied (or condition identified) for shoulder-related disability seen by orthopaedic surgeons," d. There is increasing evidence that rotator cuff pathology is highly present on MR imaging regardless of patient symptom status or disability level. The frequency results in a presumption of causation, but in fact the condition of the rotator cuff is poorly associated with patient self-reported functional status or disability, outside of massive cuff tears. 	
			 B. Consider restating comment on Page 19, Line 363-365: a. "Degenerative tears are more common and are the result of a wearing down of the tendon that occurs slowly over time." b. To. c. "Degenerative tears are more common and are presumed the result of a wearing down of the tendon that occurs slowly over time. This degeneration is presumed to naturally occur as we age." d. The etiology knowledge also seems overstated. These statements are presumptions but overall the mechanisms of rotator cuff degeneration and non-acute failure, particularly in younger individuals, are not as yet well elucidated 	

			Please provide a brief explanation of both your positive and negative answers in the	
Reviewer	Name of	What is the name of	preceding section. If applicable, please specify the draft page and line numbers in	
#	Reviewer	the society that you	your comments. Please feel free to also comment on the overall structure and	
	(Required)	are representing?	content of the Guideline:	
			 C. Consider restating comment on Page 19, Lines 376-384 and 382-384 a. "Because most rotator cuff tears are largely caused by the normal wear and tear that goes along with aging, people over 40 are at greater risk." b. "Although overuse tears caused by sports activity or overhead work also occur in younger people, most tears in young adults are caused by a traumatic injury, like a fall or shoulder dislocation (OrthoInfo, 2007)". c. As started above, the same concern with overstatement applies to the risk factor section. With limited data presented or references, it would be beneficial to see data and data-based references, or restatement of these sections. In particular, further explanation or support of epidemiologic data regarding the statement. 	
			D. Consider additional details on Page 27, lines 570-72 a. The summary of the Lambers Heerspink should include the fact that only 5 of the 19 surgical repair patients resulted in intact repairs. Superior results were seen for patients with intact repairs versus physical therapy and retears. However, only 26% of the surgical repair patients resulted in an intact repair.	
			E. Page 38, line 926: "improvement" is misspelled	
			F. Consider modifying recommendations to clarify the role of the physical therapist in the collaborative care of patients with rotator cuff injury by replacing "physical therapy" with "physical therapist management". Locations are as follows: a. Page 7 Line 2 b. Page 7 Line 10	
			c. Page 7 Line 18	
			d. Page 14 Line 192 "supervised physical therapy" to "physical therapist	
			management"	
			e. Page 14 Line 208	

Reviewer #	Name of Reviewer (Required)	What is the name of the society that you are representing?	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:	
	. •		 f. Page 14 Line 214 g. Page 25 Line 501 h. Page 26 Line 530 i. Page 27 Line 563 j. Page 58 Line 1429 "supervised physical therapy" to "physical therapist management" k. Page 58 Line 1445 l. Page 59 Line 1467 	

Dear American Physical Therapy Association,

Thank you for your expert review of the Clinical Practice Guideline on the Postoperative Management of Surgical Site Infection. We will address your comments by guideline section in the order that you listed them.

- A. The scope of the introduction is establishing incidence. Narvi et al. base the incidence of rotator cuff tear on surgical findings, not imaging. The discussion of false positive MRI's and asymptomatic rotator cuff tears, which places it outside the scope of the introduction.
- B. We drew this language directly from the AAOS OrthoInfo website and has been previously vetted and approved by AAOS. For consistency across AAOS publications, we will not be modifying this language in the guideline.
- C. This language was also drawn directly from the AAOS OrthoInfo website and will not be modified in the guideline.
- D. This recommendation addresses comparing patient-reported and functional outcomes in the patient population, which was demonstrated by the Lambers Heerspink, et. al, study. The study reported improvements in function as measured by a patient-reported outcome tool (the Constant-Murley score) and the rationale notes the improved Constant-Murley scores Although re-tears are not the focus of the recommendation, this rationale does report the re-tear rate cited in this article.
- E. We'd like to thank the reviewer for his/her suggestion to substitute "physical therapist management" for "physical therapy" throughout the document. We have reviewed the articles which serve as justification for this CPG and can find only one previous use of the term "physical therapist management". Since the terms "rehabilitation" and "physical therapy" are used interchangeably at times within these articles, after active deliberation, we are recommending the original term "physical therapy".

Public Commenter Demographics

T ubite commenter				1
Name of Reviewer (Required)	Robert L. Waltrip, MD	David Ring, MD Chair, AAOS Patient Safety Committee	Edward McDevitt, MD	Alan Reznik, MD, MBA, FAAOS
Please list your primary specialty (Required):	Shoulder and Elbow, Sports Medicine	Hand	Sports Medicine, Shoulder and Elbow	Sports Medicine
Please list your work setting (Required):	Private Group or Practice	Academic Practice	Private Group or Practice	Private Group or Practice
Are you reviewing this guideline as a representative of a professional society?	No	Yes	No	No
May we list your society as a reviewer of this guideline?		Yes		
If reviewing on behalf of a professional society, please list the name of the society that you are representing		American Academy of Orthopaedic Surgeons		
Have you declared your conflicts of interest in the AAOS Disclosure database?	No	Yes	Yes	Yes
A) Do you or a member of your immediate family receive royalties for any pharmaceutical, biomaterial or orthopaedic product or device?	No			
B) 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?	No			
C) Are you or a member of your immediate family a PAID EMPLOYEE for any pharmaceutical, biomaterial or orthopaedic device or	No			

Name of Reviewer (Required)	Robert L. Waltrip, MD	David Ring, MD Chair, AAOS Patient Safety Committee	Edward McDevitt, MD	Alan Reznik, MD, MBA, FAAOS
equipment company, or supplier?				
D) Are you or a member of your immediate family a PAID CONSULTANT for any pharmaceutical, biomaterial or orthopaedic device or equipment company, or supplier?	No			
E) Are you or a member of your immediate family an UNPAID CONSULTANT for any pharmaceutical, biomaterial or orthopaedic device or equipment company, or supplier?	No			
F) 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)	No			
G) 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?	No			
H) Do you or a member of your immediate family receive any other financial or material support from any pharmaceutical, biomaterial or orthopaedic device and	No			

Name of Reviewer (Required)	Robert L. Waltrip, MD	David Ring, MD Chair, AAOS Patient Safety Committee	Edward McDevitt, MD	Alan Reznik, MD, MBA, FAAOS
equipment company or supplier?				
I) Do you or a member of your immediate family receive any royalties, financial or material support from any medical and/or orthopaedic publishers?	No			
J) Do you or a member of your immediate family serve on the editorial or governing board of any medical and/or orthopaedic publication?	No			
What CPG topic are you reviewing?	Management of Rotator Cuff "Injuries"	AAOS Clinical Practice Guideline on Rotator Cuff Injuries		RTC Tears

Public Comment Responses to Structured Public Comment Form Questions

Name of Reviewer (Required)	Robert L. Waltrip, MD	David Ring, MD	Edward McDevitt, MD	Alan Reznik, MD, MBA, FAAOS
1. The overall objective(s) of the guideline is (are) specifically described.	Agree	Strongly Agree	Strongly Agree	Agree
2. The health question(s) covered by the guideline is (are) specifically described.	Agree	Strongly Agree	Strongly Agree	Strongly Agree
3. The guideline's target audience is clearly described.	Agree	Strongly Agree	Strongly Agree	Agree
4. There is an explicit link between the recommendations and the supporting evidence.	Agree	Disagree	Strongly Agree	Agree
5. Given the nature of the topic and the data, all clinically important outcomes are considered.	Agree	Disagree	Strongly Agree	Agree
6. The patients to whom this guideline is meant to apply are specifically described.	Agree	Disagree	Strongly Agree	Agree
7. The criteria used to select articles for inclusion are appropriate.	Neutral	Disagree	Strongly Agree	Agree
8. The reasons why some studies were excluded are clearly described.	Neutral	Neutral	Strongly Agree	Agree
9. All important studies that met the article inclusion criteria are included.	Neutral	Disagree	Strongly Agree	Agree
10. The validity of the studies is appropriately appraised.	Agree	Disagree	Strongly Agree	Agree
11. The methods are described in such a way as to be reproducible.	Agree	Agree	Strongly Agree	Agree
12. The statistical methods are appropriate to the material and the objectives of this guideline.	Agree	Agree	Strongly Agree	Agree
13. Important parameters (e.g., setting, study population, study design) that could affect study results are systematically addressed.	Agree	Disagree	Strongly Agree	Agree
14. Health benefits, side effects, and risks are adequately addressed.	Agree	Strongly Disagree	Strongly Agree	Agree
15. The writing style is appropriate for health care professionals.	Agree	Neutral	Strongly Agree	Agree
16. The grades assigned to each recommendation are appropriate.	Agree	Strongly Disagree	Strongly Agree	Agree
Would you recommend these guidelines for use in clinical practice?	Strongly Recommend	Would Not Recommend	Recommend	Recommend

Public Comment Open Responses

Name of	Robert L. Waltrip, MD	David Ring, MD
Reviewer (Required)	• /	G.
Public Comment Open Responses	I had difficulty understanding how quality was determined for the evidence. Strength of evidence was clearly based on assessed quality of the studies reviewed, but the method for	I have some important misgivings about this CPG. I would be happy to discuss them in greater detail.
	determining quality was not defined. Perhaps a	Title:
	more clear description of quality assessment by the CQV Dept/methodologists should be included.	"Injuries" is not the correct word. Most rotator cuff tendinopathy and defects are age-appropriate and not related to acute or chronic damage. These changes are more
	Also, I listed above the CPG topic title with the word "Injuries" in quotation marks because the title implies that rotator cuff pathology is solely	akin to the changes in the hair on a man's head: greying and thinning, often with a defect (bald spot). The title should be
	due to injury. This is false and misleading. We all should recognize that most rotator cuff	"Rotator Cuff Tendinopathy".
	pathology is not caused by an injury but rather occurs on an attritional basis. This CPG draft	Management of Small to Medium "Tears" The word "tear" should be replaced with
	on page 19 line 362 in reference to the etiology of rotator cuff tears correctly states, "Degenerative tears are more common and are	defect throughout for the same reasons. The word tear is inaccurate, misleading, and counterproductive. I understand that the
	the result of a wearing down of the tendon that	AAOS might feel uncomfortable avoid a
	occurs slowly over time." I believe a better title	word that is in common usage. But this is a
	for the CPG would be, "Management of Rotator Cuff Pathology."	singularly important opportunity to undo what might be considered an important misstep by our forebears. There is no
	Guideline page 8, line 30 only addresses	downside to switching to a term such as
	support for DCR in patients with symptomatic	defect. Then you could separate out the
	AC joints. There is no guideline regarding treatment (or the absence of treatment) for	uncommon defect due to acute traumatic rupture. This is such an important concept
	asymptomatic arthritic AC joints. I believe that	that it should not go unaddressed. The entire
	we all recognize that AC arthritis is highly	report is infused with a misinterpretation of
	prevalent in asymptomatic patients.	rotator cuff tendinopathy as injuries or
	Perhaps an additional consensus statement would be appropriate to address this. My	tears—that is not consistent with best evidence.
	suggestion, assuming the work group is in	evidence.
	agreement, would be, "In the absence of	Long-term Nonoperative Management
	reliable evidence, the work group does not	The way this question is posed ignores the
	recommend the routine use of distal clavicle	natural history of rotator cuff tendinopathy
	resection for asymptomatic patients with	and the fact that symptoms are often relieved
	radiological evidence of AC arthritis."	by nonspecific effects (placebo, Hawthorne, regression to the mean, self-limiting course,
	Guideline page 15, line 218 only addresses the	etc.). The only way this evidence can be
	consensus recommendation regarding reverse	strong is if it is compared to simulated
	arthroplasty for massive, unrepairable rotator	treatments. I feel strongly that cohort studies
	cuff with pseudoparalysis. Pseudoparalysis is	cannot be said to strongly support efficacy or
	not further defined. Notably, Tokish, et al in J	effectiveness of treatment. Another

Shoulder Elbow Surg 2017 indicated that pseudoparalysis of the shoulder has a variable definition in the literature. Burks and Tashijan in Arthroscopy 2017 suggested a new definition of pseudoparalysis with several criteria. including limited elevation of up to 45 degrees rather than the traditional description allowing elevation of up to 90 degrees. Would the guideline be more effective if pseudoparalysis is clarified? Also, what about patients without true pseudoparalysis that have pain limiting their function despite conservative treatment. This subset of patients does not always have secondary arthropathy. Should we also address those concerns through a consensus recommendation? Certainly, many shoulder surgeons are now expanding their use of reverse arthroplasty in these patients.

Guideline page 15, line 225: It's hard to believe we have no reliable evidence support for this consensus recommendation. I briefly searched and did not find good literature support even though this seems to be standard of care for appropriate age patients with rotator cuff arthropathy. I agree with the consensus but I would suggest a thorough literature review to assure that the strength of the recommendation cannot be increased.

Recommendations page 25, line 518: This implies that there is no harm in suggesting that PT and surgical repair are equivalent in PROs following RCR of small to medium full thickness tears. While this may be true in the short term (the studies reference data for 2-5 year follow-up), I strongly believe that the long-term data will show otherwise. We know that many of these tears will ultimately progress and develop atrophy; this is when clinical results will deteriorate. In fact, on the next page of the CPG - page 26, line 536 states "...the rotator cuff tears continue to enlarge with time." Then on the same page, line 550 states, "Patients who select physical therapy should be informed that over a 9 year period their tear size may progress and this could lead to a substantial decline in their perceived and measurable outcome." If one were to read page 25 without continuing on to the next page, one might erroneously conclude that physical therapy is the same in the long term as surgical repair. I realize that the CPG also notes on page 25 line 518 that "There were no reported

important issue: Physical therapy is a profession, not a treatment. The treatment is an exercise program. The exercises can be done independently or under the direction of a physical therapist.

Operative Management

The data on this are not as strong as you suggest. The degree to which surgery to close a rotator cuff defect alters the natural history of rotator cuff tendinopathy is unknown. The correlation of symptom relief and decrease limitations is associated with post-operative defect size is limited and inconsistent (see your conclusions on single vs. double row for more evidence). The ability of simulated rotator cuff defect closure to relieve symptoms as well as actual defect closure is unstudied. Subacromial decompression was recently shown to be no more effective than simulate subacromial decompression. We need a similar studies of various sizes of rotator cuff defect. The differences in Constant scores between surgery and exercises is very small and likely due to the placebo effect. Only one trial. Weak evidence.

Distal Clavicle Resection. Similar concerns here. Without simulate distal clavicle resection, you don't really have any valid evidence.

Diagnosing (imaging)

A misleading question was asked here. Orthopedic surgeons do not use or benefit from MRI to diagnosis rotator cuff tendinopathy or large defects. MRI is a surgery planning tool. The way this question was phrased risks reinforcing misuse of MRI by primary care doctors for their patients with shoulder pain.

Corticosteroid injections
Other recent reviews of the evidence have reached different conclusions.

Hyaluronic acid

Why was this question asked? What is the rationale for using HA for rotator cuff? This seems like a mistake akin to the one our group made when we asked a question about Vitamin C after distal radius fractures. It's not an interesting or clinically relevant

statistical differences between primary or secondary repair, when physical therapy fails." However, there is a continuum of structural deterioration as tears enlarge with time and the muscle atrophies in the presence of a full thickness tear; long term secondary results will not be equivalent. We just don't know the transition point when it becomes clinically significant.

Page 27, line 590 on a similar note states, "The long-term consequences of a persistent rotator cuff tear or a re-tear is currently not known." I disagree with this statement. We know that tears, especially larger tears, progress. We know that patients with tears develop progressive muscular atrophy. We know that larger tears often lead to superior subluxation with altered glenohumeral kinematics and secondary degenerative changes. We may not know specifically which tears will progress and the time period to develop rotator cuff arthropathy, but a blanket statement that we don't know long-term potential consequences is ill-stated.

Page 28, lines 592-595: Should the guideline add "...for patients with small to medium sized full-thickness rotator cuff tears and a Type 2 acromion"? At least one of the studies (Gartsman, et al.) specifies that the inclusion criteria include patients with a Type 2 configuration. The later quoted study by MacDonald, et al. indicated a higher reoperation rate for the patient group without acromioplasty and specified that 3/4 patients with reoperations had a Type 3 configuration.

Page 49, lines 1188-1189: This statement is broad and does not specify that it is implied for small to medium size tears. Also, I am not sure it is applicable to most single vs double row comparison studies or clinical practice. I think that many of the single row repair constructs used in both research studies and clinical practice utilize simple suture repair constructs rather than vertical mattress repair constructs. It may be better to specify as follows, "Strong evidence does not support double row repair constructs on improving patient-reported outcomes for repair of small to medium size rotator cuff tears compared to single row repair constructs."

question. Without excellent simulate HA injection and blinding, the evidence must be considered weak. And the question and line of research is distracting and misleading.

PRP

Same comments as for other injections.

High-grade "partial thickness" defects. This should be referred to as "thinning" or something more accurate than "tear". Without simulate surgery trials we cannot claim that operative treatment is helpful.

Prognostic factors

Please avoid the word "failure". I think you mean "recurrence of defect". Isn't this related more to size and age of defect (fat atrophy of the rotator cuff muscles) than it is to age. Is the question posed correctly?

Worker Compensation

Another misleading question. I bet people with large acute defects do equally well when injured on the job or off the job. The problems arise when age-appropriate changes are treated as an

injury. See: https://www.ncbi.nlm.nih.gov/pubmed/28600690

Page 50, lines 1225-1226: I am wondering if there is a typographical error - Shouldn't it read, "...however, when evaluating the data for only full thickness retears, limited evidence SUPPORTS lower re-tear rates after double row primary repair." The subsequent rationale specifies on lines 1241-1242 "...which indicates limited evidence to support lower risk of re-tear (Full thickness) after double row compared to single row repairs." Unless I am reading this incorrectly, the statements are inconsistent as written. It seems like the evidence is strong for evaluating partial and full thickness retears and only limited for evaluating full thickness retears exclusively.

Page 19, lines 361-362: I don"t think that a traumatic rotator cuff tear should be associated with "a broken collarbone" as this association is exceedingly uncommon. It is appropriate to associate rotator cuff tears with dislocations, but not with fractured clavicles. It would be better to just say "...with other shoulder injuries, such as a dislocated shoulder." Line 362 would be better clarified by stating, "Degenerative tears in the absence of trauma are more common than tears associated with an injury and are the result of wearing down of the tendon slowly over time."

Page 19, line 367: "age" is incorrectly written twice

Page 19, line 370: Correct to state, "Tempelhof et al. reveal that 13% of ASYMPTOMATIC individuals ..."

Page 19, lines 377-380: These statements describe increased risk for specific sports and occupations, but are limited in scope and imply relationships for workers than may not be justified. Rather than specifying tennis and baseball, it would be better to simply state, "...as observed in overhead sports." Rather than specifying painters and carpenters, it would be better to note that occupations with forceful overhead work MAY have a greater risk of tears. Listing specific occupations has implications for worker's compensation patients in those fields; it is important to recognize that most rotator cuff tears are caused by normal wear and tear from aging as stated in line 375 of page 19.

	Page 19, lines 381-383: It would be better to state, "most FULL THICKNESS tears in young adults are caused by a traumatic injury, like a fall or a shoulder dislocation." Page 20, line 387: It would be better to replace "increased structural damage" with "progression of rotator cuff pathology and potential secondary arthropathy" Thank you for considering my changes/opinions.	
Additional Comments regarding this clinical practice guideline?	As I mentioned earlier, the current title of this CPG "Management of Rotator Cuff Injuries" implies that rotator cuff pathology is solely due to injury. This is false and misleading. We all should recognize that most rotator cuff pathology is not caused by an injury but rather occurs on an attritional basis. This CPG draft on page 19 line 362 in reference to the etiology of rotator cuff tears correctly states, "Degenerative tears are more common and are the result of a wearing down of the tendon that occurs slowly over time." I believe a better title for the CPG would be, "Management of Rotator Cuff Pathology."	Needs a complete rewrite and the reasons the questions were asked as they were needs to be justified.

Name of	Edward McDevitt, MD	Alan Reznik, MD, MBA, FAAOS
Reviewer (Required)		
Public Comment Open Responses	Well done, well researched, easy to read.	I Understand that this is the review document - for the CPG - in general i am concerned with some of the recommendations that conflict prior thoughts- like use of PRP and PRP injection on RTC tears- its great there is wiggle room since the answer is not there yet we cause more problems when we give that room to the powers that control payments also for acromioplasty there is no indications on when they should be used - if the ac joint has large spurs - and it is on both sides of the ac joint - acromioplasty to remove the kissing spur seems needed along with the mumford procedure for the ac joint pain. also Does type of acromion (al la near) still matter? the CPG does not seem to address these issues. thanks
Additional	Minor issues: would it help Surgeons, et al to	AMR See the issues discussed above.
Comments regarding this	see the age of older patients with poorer results? over 60, 65,70, 75 80? line 88	See the issues discussed above.
clinical practice guideline?	Would it help to have the BMI that is associated with poorer results? over 35, 40, 45, 50!?	
	Thanks for all that worked on such a large project	