

# Peer Review & Public Commentary Report

**Evidence-Based Clinical Practice Guideline on the Management of Anterior Cruciate Ligament Injuries** 

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## Management of Anterior Cruciate Ligament Injuries Evidence-Based Guideline

# Summary of Changes Made to Confidential Draft by the Work Group following consideration of peer review comments

## **Recommendation 2: ACL Radiographs (Revised Language)**

In the absence of reliable evidence, it is the opinion of the work group that in the initial evaluation of a person with a knee injury and associated symptoms [giving way, pain, locking, catching] and signs [effusion, inability to bear weight, bone tenderness, loss of motion, and/or pathological laxity] that the practitioner obtain AP and lateral knee x-rays to identify fractures or dislocations requiring emergent care.

## Recommendation 3: ACL Magnetic Resonance Imaging (Revised Language)

"MRI is a better tool for identifying concomitant injuries" was removed and "An MRI could be used in conjunction with the history and physical examination" was added.

## Recommendation 9a/9b: ACL Surgery Timing (Combined into 1 recommendation)

Workgroup approved to combine Recommendations 9a and 9b into one recommendation.

## New Recommendation 9:

When ACL reconstruction is indicated, moderate evidence supports reconstruction within five months of injury to protect the articular cartilage and menisci.

## **Recommendation 10: ACL Combined MCL (Revised Language)**

There is limited evidence in patients with acute ACL tear and MCL tear to support that the practitioner might perform reconstruction of the ACL and non-operative treatment of the MCL tear.

## <u>Recommendation 12: ACL Single or Double Bundle Reconstruction (Addition to Future Research Section)</u>

Future Research (Addition): "Double bundle surgery may include additional expense, and may increase the complexity of revision ACL surgery; future studies may analyze this surgical approach."

# <u>Recommendation 14: ACL Autograft vs Allograft (Revised Language, Additions to Rational and Future Research sections)</u>

Strong evidence supports that in patients undergoing ACL reconstructions, the practitioner should use either autograft or appropriately processed allograft tissue, because the measured outcomes are similar, although these results may not be generalizable to all allografts or all patients.

Rationale (Addition): "While outcomes following ACL reconstruction using autograft tissue and using non-irradiated allograft tissue are similar overall, these results may not be generalizable to specific subsets of patients with ACL rupture, such as athletes and young patients. In fact, a longitudinal cohort study indicated a higher failure rate of allograft tissue in younger patients (Figure 3, Kaeding -- Sports Health 2011). "

Future Research (Addition): "Further research is needed to assess the outcomes following ACL reconstruction using autograft tissue and using non-irradiated allograft tissue in patients with specific activity levels (including elite athletes), ages (including the young and very young), and associated injuries."

Correction of typo: "ACL Strength of Life" was revised to read, "ACL Quality of Life".

## **Recommendation 16 (Deleted)**

The workgroup voted to delete this recommendation because of a lack of relevant evidence, and it did not meet the standards for writing a consensus recommendation.

## Recommendation 18: ACL Neuromuscular Training Programs (Revised Language, Revised Rationale,)

Moderate strength evidence from pooled analyses with a small effect size (Number Needed to Treat=109) supports that neuromuscular training programs could reduce ACL injuries.

## Revised Rationale:

One moderate strength study of female adolescent handball players and two low strength studies of adult male and adolescent female soccer players demonstrated significant reduction in ACL injuries after neuromuscular training. Five moderate strength studies showed a non-significant reduction and one moderate strength study showed a non-significant increase in ACL injuries (note: we were unable to confirm statistically significant reductions in injury reported by some of the aforementioned studies when reanalyzing the raw data). No high strength double-blind randomized control trials implementing neuromuscular training interventions were identified, likely due to the difficulty in blinding of athletes and the need to cluster randomize athletes by team. A two-step process of pooled analyses was employed. The initial pooled analysis contained all best available quality studies meeting the a priori inclusion criteria for this recommendation, showed no quantitative heterogeneity (0%), and indicated a relative risk reduction of 53 (20 to 72%). However, content and delivery methods among programs in these studies demonstrated *qualitative* heterogeneity; therefore a subset of the most homogeneous programs was identified. Programs were considered homogeneous if they contained similar exercise modalities and training implementation strategies (e.g., plyometrics, strengthening, instructor feedback to athletes). The second pooled analysis of the homogeneous programs confirmed significant relative risk reduction of 62 (41 to 79%) favoring neuromuscular training programs for prevention of non-contact ACL injuries. The majority of the reported programs were coach-led and compliance was fair to poor, when reported. The current analyses indicate that the number needed to treat to prevent one ACL injury is approximately 109 athletes. An assessment of the studies included in this analysis demonstrated no publication bias (Figure 1D)

## Recommendation 19: ACL Post-Op Physical Therapy (Additions to Rationale and Future Research sections)

Rationale (Addition): "Early, accelerated protocols may include early weight bearing, range of motion, and strengthening including the addition of open kinetic chain exercises at six weeks."

Future Research (Addition): "Future Research should also address the influence of accelerated rehabilitation on graft integrity. This includes the use of imaging (MRI) to assess the effects of accelerated or delayed rehabilitation on graft healing and maturation."

Page 14, Line 816 "and" revised to read "an".

Page 18, Line 1010 Heading revised to read, "Intervention/Prevention".

- Page 23, Line 1161 Revised to read "5 domains" rather than "6".
- Page 24, Lines 1187 1188 Removed "not" in the description of "Analysis".
- Page 25, Line 1222 The text now references Table 8, rather than Table 7.
- Page 26, Line 1238 Table 10 has been revised to reflect the importance of decision aids in the event that the evidence supports no difference between two alternative interventions.
- Page 26, Line 1248 added subheadings to reflect diagnostic data analysis vs. intervention/prevention data analysis.

## Management of Anterior Cruciate Ligament Injuries Evidence-Based Guideline

# Summary of Changes Made to Confidential Draft following the Public Comment period

## Recommendation 14: ACL Autograft vs Allograft (Clarifying Language added)

Added the language, "such as young patients or highly active patients" to clarify the types of patients:

Strong evidence supports that in patients undergoing ACL reconstructions, the practitioner should use either autograft or appropriately processed allograft tissue, because the measured outcomes are similar, although these results may not be generalizable to all allografts or all patients, such as young patients or highly active patients.

## **Overview of Peer Review and Public Comment Submissions**

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. Names are removed from the forms of reviewers who requested that they remain anonymous; however their COI disclosures still accompany their response.

#### **Peer Review**

AAOS contacted 26 organizations with content expertise to review a draft of the clinical practice guideline during the peer review period in March 2014.

- Eleven societies participated in the review of the guideline and have given consent to be listed as a reviewer.
- Thirteen individuals provided comments via the electronic structured peer review form. Two reviewers asked to remain anonymous.
- If warranted and based on evidence, the guideline draft is modified by the work group members in response to the peer review comments.
- The workgroup considered all comments and made some modifications when they were consistent with the evidence.

## **Public Comment**

The new draft was then circulated for a 30-day public comment period starting on June 25<sup>th</sup>, 2014 and ending on July 25<sup>th</sup>, 2014.

- AAOS received 4 comments including one representing a specialty society, and three from individuals (one requested that they be listed as "anonymous").
- If warranted and based on evidence, the guideline draft is 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.

Reviewer	Reviewer #
AMSSM Review Committee	1
AOSSM Peer Review Committee	2
Anonymous	3
James J Irrgang, PT, PhD, ATC(APTA)	4
AAP Reviewer	5
Jay Smith, MD (AAPM&R)	6
William De Long, MD	7
Yvette Rooks, MD (AAFP)	8
Sean O'Leary, MB BChir, FRCS (Lon), FRCS (Tr & Orth) (BASK -British Association for Surgery of the Knee)	9
Patrick F Leary, DO FAOASM FACSM (AOASM President)	10
David J. Hoelting, MD (AAFP)	11
William J Doherty, MD (ABOS)	12
Amy Lynn McIntosh, MD	13

## **Peer Reviewers' Disclosure Information**

## Disclosure Information for Reviewers' without an AAOS Customer ID #

Reviewer #	1	3	4	5	6	8	9	10	11	13
Name of Reviewer	AMSSM Review Committee	Anonymous	James J Irrgang	AAP Reviewer	Jay Smith	Yvette Rooks	Sean O'Leary,	Patrick F Leary	David J. Hoelting	Amy Lynn McIntosh,
1a) Do you or a member of your immediate family receive royalties for any pharmaceutical, biomaterial or orthopaedic product or device?	NO	NO	NO	NO	Yes (Tenex Health - TX1 device)	NO	NO	NO	NO	NO
2a) 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	NO	NO	NO	NO	NO	NO	NO	NO	NO
3a) Are you or a member of your immediate family a PAID EMPLOYEE for any pharmaceutical, biomaterial or orthopaedic device or equipment company, or supplier?	NO	NO	NO	NO	Yes (Tenex Health - TX1 device)	NO	NO	NO	NO	NO
4a) 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	NO	NO	NO	Yes (Tenex Health - TX1 device)	NO	NO	NO	NO	Yes (Synthes)
5a) 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	NO	NO	NO	NO	NO	1	NO	NO	NO
6a) 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	NO	NO	NO	Yes (Tenex Health - TX1 device)	NO	NO	NO	NO	NO
7a) 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	NO	NO	NO	NO	NO	NO	NO	NO	NO
8a) 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?	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO
9a) Do you or a member of your immediate family receive any royalties, financial or material support from any medical and/or orthopaedic publishers?	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO
10b) You indicated that you or a member of your immediate family serve on the editorial or governing board of any medical and/or orthopaedic publication. Please identify the product or device:	Yes (Clinical Journal of Sport Medicine, Current Sports Medicine Reports)	NO	Yes (Member of the Editorial Board of Physical Therapy Journal)	NO	NO	NO	NO	NO	NO	NO

## Disclosure Information for Reviewers' with an AAOS Customer ID #

(AAOS disclosures can be viewed using this link: <a href="http://www7.aaos.org/education/disclosure/search.aspx">http://www7.aaos.org/education/disclosure/search.aspx</a>)

Name of Reviewer	Reviewer #	Link to AAOS Disclosure Form
Barton Mann, PhD	2	Click to View
William De Long, MD	7	Click to View
William J Doherty	12	Click to View

**Table 1. Overall Responses to Structured Peer Review Questions** 

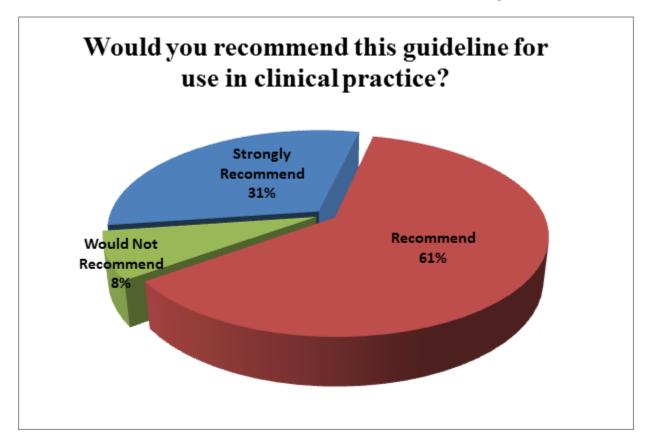
		Strongly Agree	Agree	Neutral	Disagree	Total
1. The overall objective(s) of the guideline is (are) specifically described.	Count	6	6	1	0	13
	%	46%	46%	8%	0%	1
2. The health question(s) covered by the guideline is (are) specifically described.	Count	5	7	1	0	13
	%	38%	54%	8%	0%	1
3. The guideline's target audience is clearly described.	Count	6	5	2	0	13
	%	46%	38%	15%	0%	1
4. The guideline development group includes individuals from all the relevant	Count	3	5	5	0	13
professional groups.	%	23%	38%	38%	0%	1
5. There is an explicit link between the recommendations and the supporting	Count	3	8	1	1	13
evidence.	%	23%	62%	8%	8%	1
6. Given the nature of the topic and the data, all clinically important outcomes are	Count	4	7	1	1	13
considered.	%	31%	54%	8%	8%	1
7. The patients to whom this guideline is meant to apply are specifically described.	Count	7	4	1	1	13
	%	54%	31%	8%	8%	1
8. The criteria used to select articles for inclusion are appropriate.	Count	5	5	2	1	13
	%	38%	38%	15%	8%	1
9. The reasons why some studies were excluded are clearly described.	Count	4	4	3	2	13
	%	31%	31%	23%	15%	1
10. All important studies that met the article inclusion criteria are included.	Count	4	6	1	2	13
	%	31%	46%	8%	15%	1
11. The validity of the studies is appropriately appraised.	Count	5	6	2	0	13
	%	38%	46%	15%	0%	1
12. The methods are described in such a way as to be reproducible.	Count	4	8	1	0	13
	%	31%	62%	8%	0%	1
13. The statistical methods are appropriate to the material and the objectives of this	Count	4	7	2	0	13
guideline.	%	31%	54%	15%	0%	1
14. Important parameters (e.g., setting, study population, study design) that could	Count	2	8	2	1	13
affect study results are systematically addressed.	%	15%	62%	15%	8%	1
15. Health benefits, side effects, and risks are adequately addressed.	Count	2	8	2	1	13
	%	15%	62%	15%	8%	1
16. The writing style is appropriate for health care professionals.	Count	4	8	0	1	13
	%	31%	62%	0%	8%	1
17. The grades assigned to each recommendation are appropriate.	Count	5	5	3	0	13
	%	38%	38%	23%	0%	1

**Table 2. Response Totals for Structured Peer Review Questions** 

Total Strongly Agree	Total Agree	Total Neutral	Total Disagree	Total Responses
73	107	30	11	221
33%	48%	14%	5%	100%

Figure 1. Overall Recommendation for Guideline Use in Clinical Practice

Note: The choice, "recommend with revisions" was not offered as an option.



**Table 3. Peer Reviewers' Responses to Structured Peer Review Questions** 

			1					Na	me of Re	viewer						
Structured Peer Rev	view Questio	ons	Anonymous	AMSSM Review Committee	Amy Lynn McIntosh	AOSSM Peer Review Committee	David J. Hoelting	James J Irrgang	Jay Smith	Patrick F Leary	Sean O'Leary,	AAP Representative	William De Long	William J Doherty	Yvette Rooks	Totals
	Strongly	Count	0	0	1	0	1	0	1	1	0	0	0	1	1	6
	Agree	Row Valid N %	0%	0%	17%	0%	17%	0%	17%	17%	0%	0%	0%	17%	17%	100%
1. The overall	Agree	Count	1	1	0	1	0	1	0	0	0	1	1	0	0	6
objective(s) of the guideline is (are) specifically described.		Row Valid N %	17%	17%	0%	17%	0%	17%	0%	0%	0%	17%	17%	0%	0%	100%
	Neutral	Count	0	0	0	0	0	0	0	0	1	0	0	0	0	1
		Row Valid N %	0%	0%	0%	0%	0%	0%	0%	0%	100%	0%	0%	0%	0%	100%
	Strongly	Count	0	1	1	0	1	0	1	0	0	0	0	0	1	5
	Agree	Row Valid N %	0%	20%	20%	0%	20%	0%	20%	0%	0%	0%	0%	0%	20%	100%
2. The health	Agree	Count	1	0	0	0	0	1	0	1	1	1	1	1	0	7
question(s) covered by the guideline is (are) specifically described.		Row Valid N %	14%	0%	0%	0%	0%	14%	0%	14%	14%	14%	14%	14%	0%	100%
-	Neutral	Count	0	0	0	1	0	0	0	0	0	0	0	0	0	1
		Row Valid N %	0%	0%	0%	100%	0%	0%	0%	0%	0%	0%	0%	0%	0%	100%
	Strongly	Count	0	0	1	0	0	0	1	0	1	1	1	0	1	6
	Agree	Row Valid N %	0%	0%	17%	0%	0%	0%	17%	0%	17%	17%	17%	0%	17%	100%
2 771 11 12	Agree	Count	0	1	0	0	1	1	0	1	0	0	0	1	0	5
3. The guideline's target audience is clearly described.		Row Valid N %	0%	20%	0%	0%	20%	20%	0%	20%	0%	0%	0%	20%	0%	100%
	Neutral	Count	1	0	0	1	0	0	0	0	0	0	0	0	0	2
N		Row Valid N %	50%	0%	0%	50%	0%	0%	0%	0%	0%	0%	0%	0%	0%	100%

								Na	me of Re	viewer						
Structure Peer Rev	iew Questio	ns	Anonymous	AMSSM Review Committee	Amy Lynn McIntosh	AOSSM Peer Review Committee	David J. Hoelting	James J Irrgang	Jay Smith	Patrick F Leary	Sean O'Leary,	AAP Representative	William De Long	William J Doherty	Yvette Rooks	Totals
	Strongly	Count	0	0	1	0	1	0	0	0	0	0	0	0	1	3
4 The soil letter	Agree	Row Valid N %	0%	0%	33%	0%	33%	0%	0%	0%	0%	0%	0%	0%	33%	100%
4. The guideline development group	Agree	Count	0	0	0	0	0	0	1	1	1	0	1	1	0	5
includes individuals from all the relevant professional groups.		Row Valid N %	0%	0%	0%	0%	0%	0%	20%	20%	20%	0%	20%	20%	0%	100%
professional groups.	Neutral	Count	1	1	0	1	0	1	0	0	0	1	0	0	0	5
		Row Valid N %	20%	20%	0%	20%	0%	20%	0%	0%	0%	20%	0%	0%	0%	100%
	Strongly	Count	0	0	1	0	0	0	0	0	0	0	0	1	1	3
	Agree	Row Valid N %	0%	0%	33%	0%	0%	0%	0%	0%	0%	0%	0%	33%	33%	100%
	Agree	Count	1	1	0	0	1	1	1	1	1	1	0	0	0	8
5. There is an explicit link between the recommendations and		Row Valid N %	13%	13%	0%	0%	13%	13%	13%	13%	13%	13%	0%	0%	0%	100%
the supporting	Neutral	Count	0	0	0	0	0	0	0	0	0	0	1	0	0	1
evidence.		Row Valid N %	0%	0%	0%	0%	0%	0%	0%	0%	0%	0%	100%	0%	0%	100%
	Disagree	Count	0	0	0	1	0	0	0	0	0	0	0	0	0	1
		Row Valid N %	0%	0%	0%	100%	0%	0%	0%	0%	0%	0%	0%	0%	0%	100%

								Na	me of Re	viewer						
Structure Peer Rev		ns	Anonymous	AMSSM Review Committee	Amy Lynn McIntosh	AOSSM Peer Review Committee	David J. Hoelting	James J Irrgang	Jay Smith	Patrick F Leary	Sean O'Leary,	AAP Representative	William De Long	William J Doherty	Yvette Rooks	Totals
	Strongly	Count	0	0	1	0	0	0	0	0	0	1	1	0	1	4
	Agree	Row Valid N %	0%	0%	25%	0%	0%	0%	0%	0%	0%	25%	25%	0%	25%	100%
	Agree	Count	1	0	0	0	1	1	1	1	1	0	0	1	0	7
6. Given the nature of the topic and the data, all clinically important		Row Valid N %	14%	0%	0%	0%	14%	14%	14%	14%	14%	0%	0%	14%	0%	100%
outcomes are	Neutral	Count	0	1	0	0	0	0	0	0	0	0	0	0	0	1
considered.		Row Valid N %	0%	100%	0%	0%	0%	0%	0%	0%	0%	0%	0%	0%	0%	100%
	Disagree	Count	0	0	0	1	0	0	0	0	0	0	0	0	0	1
		Row Valid N %	0%	0%	0%	100%	0%	0%	0%	0%	0%	0%	0%	0%	0%	100%
	Strongly	Count	0	0	1	0	1	1	0	0	1	1	0	1	1	7
	Agree	Row Valid N %	0%	0%	14%	0%	14%	14%	0%	0%	14%	14%	0%	14%	14%	100%
	Agree	Count	0	1	0	0	0	0	1	1	0	0	1	0	0	4
7. The patients to whom this guideline is		Row Valid N %	0%	25%	0%	0%	0%	0%	25%	25%	0%	0%	25%	0%	0%	100%
meant to apply are	Neutral	Count	1	0	0	0	0	0	0	0	0	0	0	0	0	1
specifically described.		Row Valid N %	100%	0%	0%	0%	0%	0%	0%	0%	0%	0%	0%	0%	0%	100%
	Disagree	Count	0	0	0	1	0	0	0	0	0	0	0	0	0	1
		Row Valid N %	0%	0%	0%	100%	0%	0%	0%	0%	0%	0%	0%	0%	0%	100%

								Na	ame of Ro	eviewer						
Structure Peer Rev	iew Questio	ns	Anonymous	AMSSM Review Committee	Amy Lynn McIntosh	AOSSM Peer Review Committee	David J. Hoelting	James J Irrgang	Jay Smith	Patrick F Leary	Sean O'Leary,	AAP Representative	William De Long	William J Doherty	Yvette Rooks	Totals
	Strongly	Count	0	0	1	0	1	0	1	0	0	0	0	1	1	5
	Agree	Row Valid N %	0%	0%	20%	0%	20%	0%	20%	0%	0%	0%	0%	20%	20%	100%
	Agree	Count	1	0	0	0	0	1	0	0	1	1	1	0	0	5
8. The criteria used to select articles for		Row Valid N %	20%	0%	0%	0%	0%	20%	0%	0%	20%	20%	20%	0%	0%	100%
inclusion are	Neutral	Count	0	1	0	0	0	0	0	1	0	0	0	0	0	2
appropriate.		Row Valid N %	0%	50%	0%	0%	0%	0%	0%	50%	0%	0%	0%	0%	0%	100%
	Disagree	Count	0	0	0	1	0	0	0	0	0	0	0	0	0	1
		Row Valid N %	0%	0%	0%	100%	0%	0%	0%	0%	0%	0%	0%	0%	0%	100%
	Strongly	Count	0	0	1	0	1	0	1	0	0	0	0	0	1	4
	Agree	Row Valid N %	0%	0%	25%	0%	25%	0%	25%	0%	0%	0%	0%	0%	25%	100%
	Agree	Count	1	0	0	0	0	0	0	0	0	1	1	1	0	4
9. The reasons why some studies were		Row Valid N %	25%	0%	0%	0%	0%	0%	0%	0%	0%	25%	25%	25%	0%	100%
excluded are clearly	Neutral	Count	0	1	0	0	0	0	0	1	1	0	0	0	0	3
described.		Row Valid N %	0%	33%	0%	0%	0%	0%	0%	33%	33%	0%	0%	0%	0%	100%
	Disagree	Count	0	0	0	1	0	1	0	0	0	0	0	0	0	2
		Row Valid N %	0%	0%	0%	50%	0%	50%	0%	0%	0%	0%	0%	0%	0%	100%

								Nai	me of Re	viewer						
Structure Peer Review Questions			Anonymous	AMSSM Review Committee	Amy Lynn McIntosh	AOSSM Peer Review Committee	David J. Hoelting	James J Irrgang	Jay Smith	Patrick F Leary	Sean O'Leary,	AAP Representative	William De Long	William J Doherty	Yvette Rooks	Totals
	Strongly	Count	0	0	1	0	1	0	1	0	0	0	0	0	1	4
	Agree	Row Valid N %	0%	0%	25%	0%	25%	0%	25%	0%	0%	0%	0%	0%	25%	100%
	Agree	Count	1	0	0	0	0	1	0	0	1	1	1	1	0	6
10. All important studies that met the		Row Valid N %	17%	0%	0%	0%	0%	17%	0%	0%	17%	17%	17%	17%	0%	100%
article inclusion	Neutral	Count	0	1	0	0	0	0	0	0	0	0	0	0	0	1
criteria are included.		Row Valid N %	0%	100%	0%	0%	0%	0%	0%	0%	0%	0%	0%	0%	0%	100%
	Disagree	Count	0	0	0	1	0	0	0	1	0	0	0	0	0	2
		Row Valid N %	0%	0%	0%	50%	0%	0%	0%	50%	0%	0%	0%	0%	0%	100%
	Strongly	Count	0	0	1	0	1	0	1	0	0	0	1	0	1	5
	Agree	Row Valid N %	0%	0%	20%	0%	20%	0%	20%	0%	0%	0%	20%	0%	20%	100%
11. The validity of	Agree	Count	1	0	0	0	0	1	0	1	1	1	0	1	0	6
the studies is appropriately appraised.	C	Row Valid N %	17%	0%	0%	0%	0%	17%	0%	17%	17%	17%	0%	17%	0%	100%
	Neutral	Count	0	1	0	1	0	0	0	0	0	0	0	0	0	2
		Row Valid N %	0%	50%	0%	50%	0%	0%	0%	0%	0%	0%	0%	0%	0%	100%
	Strongly	Count	0	0	1	0	1	0	1	0	0	0	0	0	1	4
	Agree	Row Valid N %	0%	0%	25%	0%	25%	0%	25%	0%	0%	0%	0%	0%	25%	100%
12. The methods are	Agree	Count	1	1	0	0	0	1	0	1	1	1	1	1	0	8
described in such a way as to be reproducible.		Row Valid N %	13%	13%	0%	0%	0%	13%	0%	13%	13%	13%	13%	13%	0%	100%
	Neutral	Count	0	0	0	1	0	0	0	0	0	0	0	0	0	1
		Row Valid N %	0%	0%	0%	100%	0%	0%	0%	0%	0%	0%	0%	0%	0%	100%

			Name of Reviewer													
Structure Peer Review Questions			Anonymous	AMSSM Review Committee	Amy Lynn McIntosh, MD	AOSSM Peer Review Committee	David J. HoeltingMD	James J Irrgang	Jay Smith	Patrick F Leary DO FAOASM FACSM	Sean O'Leary, MB BChir, FRCS (Lon), FRCS (Tr & Orth)	AAP Representative	William De Long, MD	William J Doherty	Yvette Rooks	Totals
	Strongly	Count	0	0	1	0	1	0	1	0	0	0	0	0	1	4
13. The statistical	Agree	Row Valid N %	0%	0%	25%	0%	25%	0%	25%	0%	0%	0%	0%	0%	25%	100%
methods are	Agree	Count	1	1	0	0	0	1	0	1	1	1	0	1	0	7
appropriate to the material and the objectives of this		Row Valid N %	14%	14%	0%	0%	0%	14%	0%	14%	14%	14%	0%	14%	0%	100%
guideline.	Neutral	Count	0	0	0	1	0	0	0	0	0	0	1	0	0	2
		Row Valid N %	0%	0%	0%	50%	0%	0%	0%	0%	0%	0%	50%	0%	0%	100%
	Strongly	Count	0	0	1	0	0	0	1	0	0	0	0	0	0	2
	Agree	Row Valid N %	0%	0%	50%	0%	0%	0%	50%	0%	0%	0%	0%	0%	0%	100%
14. Important	Agree	Count	1	0	0	0	1	0	0	1	1	1	1	1	1	8
parameters (e.g., setting, study population, study		Row Valid N %	13%	0%	0%	0%	13%	0%	0%	13%	13%	13%	13%	13%	13%	100%
design) that could	Neutral	Count	0	1	0	0	0	1	0	0	0	0	0	0	0	2
affect study results are systematically addressed.		Row Valid N %	0%	50%	0%	0%	0%	50%	0%	0%	0%	0%	0%	0%	0%	100%
	Disagree	Count	0	0	0	1	0	0	0	0	0	0	0	0	0	1
		Row Valid N %	0%	0%	0%	100%	0%	0%	0%	0%	0%	0%	0%	0%	0%	100%

			Name of Reviewer													
Structure Peer Review Questions			Anonymous	AMSSM Review Committee	Amy Lynn McIntosh	AOSSM Peer Review Committee	David J. Hoelting	James J Irrgang	Jay Smith	Patrick F Leary	Sean O'Leary,	AAP Representative	William De Long	William J Doherty	Yvette Rooks	Totals
	Strongly	Count	0	0	1	0	0	0	1	0	0	0	0	0	0	2
	Agree	Row Valid N %	0%	0%	50%	0%	0%	0%	50%	0%	0%	0%	0%	0%	0%	100%
	Agree	Count	1	0	0	0	1	1	0	1	1	1	1	0	1	8
15. Health benefits, side effects, and risks		Row Valid N %	13%	0%	0%	0%	13%	13%	0%	13%	13%	13%	13%	0%	13%	100%
are adequately addressed.	Neutral	Count	0	0	0	1	0	0	0	0	0	0	0	1	0	2
addressed.		Row Valid N %	0%	0%	0%	50%	0%	0%	0%	0%	0%	0%	0%	50%	0%	100%
	Disagree	Count	0	1	0	0	0	0	0	0	0	0	0	0	0	1
		Row Valid N %	0%	100%	0%	0%	0%	0%	0%	0%	0%	0%	0%	0%	0%	100%
	Strongly	Count	0	0	1	0	1	0	0	1	0	0	0	0	1	4
	Agree	Row Valid N %	0%	0%	25%	0%	25%	0%	0%	25%	0%	0%	0%	0%	25%	100%
16. The writing style	Agree	Count	1	1	0	1	0	1	1	0	0	1	1	1	0	8
is appropriate for health care professionals.		Row Valid N %	13%	13%	0%	13%	0%	13%	13%	0%	0%	13%	13%	13%	0%	100%
	Disagree	Count	0	0	0	0	0	0	0	0	1	0	0	0	0	1
		Row Valid N %	0%	0%	0%	0%	0%	0%	0%	0%	100%	0%	0%	0%	0%	100%
	Strongly	Count	0	0	1	0	1	0	1	0	0	0	1	0	1	5
17. The grades assigned to each recommendation are appropriate.	Agree	Row Valid N %	0%	0%	20%	0%	20%	0%	20%	0%	0%	0%	20%	0%	20%	100%
	Agree	Count	1	1	0	0	0	1	0	0	1	0	0	1	0	5
		Row Valid N %	20%	20%	0%	0%	0%	20%	0%	0%	20%	0%	0%	20%	0%	100%
	Neutral	Count	0	0	0	1	0	0	0	1	0	1	0	0	0	3
		Row Valid N %	0%	0%	0%	33%	0%	0%	0%	33%	0%	33%	0%	0%	0%	100%

Table 4. Peer Reviewers' Recommendation for Use of Guideline in Clinical Practice

	Would you recommend these guidelines for use in clinical practice?									
Name of Reviewer	Strongl	y Recommend	Rec	commend	Would Not Recommend					
	Count	Column %	Count	Column %	Count	Column %				
Anonymous	0	0%	1	13%	0	0%				
AMSSM Review Committee	0	0%	1	13%	0	0%				
Amy Lynn McIntosh, MD	1	25%	0	0%	0	0%				
AOSSM Peer Review Committee	0	0%	0	0%	1	100%				
David J. Hoelting	0	0%	1	13%	0	0%				
James J Irrgang	0	0%	1	13%	0	0%				
Jay Smith	0	0%	1	13%	0	0%				
Patrick F Leary	0	0%	1	13%	0	0%				
Sean O'Leary	0	0%	1	13%	0	0%				
AAP Representative	0	0%	1	13%	0	0%				
William De Long	1	25%	0	0%	0	0%				
William J Doherty	1	25%	0	0%	0	0%				
Yvette Rooks	1	25%	0	0%	0	0%				
Totals	4	100%	8	100%	1	100%				

## **Individual Peer Reviewer Comments**

The following comments were provided by the participating peer reviewers in response to various sections/recommendations contained within the guideline. Additionally, responses to the peer reviewers' comments are provided by the guideline workgroup. All responses are segregated by guideline section.

## Reviewer 1 - American Medical Society for Sports Medicine Review Committee

## **Peer Reviewer's Comments by Guideline Section General Comments**

The American Medical Society for Sports Medicine appreciates the opportunity to review the AAOS Management Of Anterior Cruciate Ligament Injuries Evidence-Based Clinical Practice Guideline. We want to suggest some changes to help ensure clear, concise recommendations for a successful guideline. We find that a few of the recommendations need further work to maximize clarity and conciseness. We would recommend rewording of some of these guidelines to increase their clarity with regard to a consistent expression of the level of evidence and an a priori statement dictating which levels of evidence were going to be acceptable: 17-18 & 20-21.

## **Recommendation 5**

We suggest "Moderate evidence does not support or refute surgical reconstruction in active young adult (18-35) patients with an ACL tear, except to establish a more stable knee examination"

- We disagree with your recommendation since the one high quality study (Frobell 2010) (with two other moderate quality studies making up the recommendation) came to the conclusion that "In young, active adults with acute ACL tears, a strategy of rehabilitation plus early ACL reconstruction was not superior to a strategy of rehabilitation plus optional delayed ACL reconstruction. The latter strategy substantially reduced the frequency of surgical reconstructions." Frobell 2013 states on 5-year follow up: "We found no evidence of one treatment" (rehabilitation, delayed reconstruction or early reconstruction (sic)) "being more harmful than the other over two or five years."
- The Marcacci 1995 study was randomized for graft type but not for early or late surgery.
  - The late and early reconstruction were presentation time to clinic, therefore it is uncertain the late reconstruction subjects level of activity and therapeutic treatment after injury were appropriate, which would affect outcome. The early recon group had 35% professional athletes and the late recon only 25% professional athletes so hard to state similar groups. Secondly, 39% of the subjects received a fascia lata graft augmented with a ligament augmentation device, a procedure currently not in common practice in the USA. There were significantly more problems from the fascia lata graft augmented with a ligament augmentation device especially in the late group, For instance, 2 of the people in the late group that had significant laxity from complications of the fascia lata graft augmented with a ligament augmentation device. This is a complication of the graft not entry point into the study. And it would skew the data in favor of early recon group.
- We are questioning the inclusion of the data presented in the Marcacci paper as having sufficient merit for inclusion in the review, specifically how were the reviewers able to determine that the findings were not secondary to poor graft choice of the fascia lata graft with ligament augmentation device.

As well, per the AAOS methodology this study does not meet the criteria listed page 16 line 927-931: Controlled trials in which patients were not stochastically assigned to groups (they are not randomized for early and late surgery but for graft choice) AND in which there was either a difference in patient characteristics or outcomes at baseline (number of professional athletes) AND where the authors did not statistically adjust for these differences when analyzing the results (they did not) are excluded.

• Raviraj 2010 states "Reconstruction of the anterior cruciate ligament gave a similar clinical and functional outcome whether performed early (< two weeks) or late at four to six weeks after injury." This study was placed in the active population group but "None was a competitive athlete at state or national level", with 50% or less

sports injuries as the cause of the ACL tears. We wonder if this study is best suited for a different recommendation, perhaps 9b.

o Almost all of the findings in Table 32-36 of the AAOS guideline were non-significant except the stability testing of pivot shift and Lachman test, which one would assume would be better after surgery. The guideline requires not statistical significant but minimally clinical important difference, referring to page 18 lines 978-991. The significant findings for KT in the studies do not meet this MCID standard as described by Myer (3). Secondly, the data that matters most to the patient like the KOOS, Lysholm, etc were not significant, especially in the one high quality study with extended follow up. So to state "Moderate evidence supports surgical reconstruction in active young adult (18-35) patients with an ACL tear", demonstrates a biased review of the literature and should be changed or removed. Furthermore, multiple reviews find that the current evidence in the medical literature would indicate that people following ACL rupture should receive non-operative rehabilitation interventions before surgical intervention is considered. We suggest from your data tables and your own requirements for MCID and further analysis that the recommendation be changed to: "Moderate evidence does not support or refute surgical reconstruction in active young adult (18-35) patients with an ACL tear, except to establish a more stable knee examination"

#### **Recommendation 16**

Recommendation #16 could be re-written, as "Moderate evidence demonstrates no efficacy in the routine use of functional knee bracing following isolated ACLR."

## **Recommendation 18**

Recommendation #17 re-wording would be "Limited evidence does not support practitioners prescribing prophylactic bracing to prevent ACL injury, because bracing appears to not reduce the risk of ACL injury."

## **Recommendation 18**

Recommendation #19 does not recognize any of the meta-analyses or compliance, duration, and athlete specific work done on ACL injury prevention programs because the guideline authors do not deem it proper to group athletes from different sports. While a scientifically valid viewpoint, this means that the guideline will not have sufficient evidence to draw a proper conclusion. Researching the effects of ACL injury prevention programs is a unique situation since cross-contamination between teams and pre-existing team structures do not allow implementation of randomization at the level of the individual. Additionally, compliance is much more difficult to quantify than in drug or other treatment trials. Given these constraints, we believe that different quality metrics should be utilized in evaluating these studies, rather than the standard criteria used in clinical RCTs that evaluate medications or surgical treatment. The AAOS system downgrades studies that are not double-blind and individually randomized because they do not ensure equal distribution of individual characteristics between groups. However, since these attributes are simply not feasible in team-based injury prevention studies, quality points should be awarded for studies which employ effective cluster-randomization, appropriate compliance measures, and utilize mixed-model analysis. In this way the most important and highest quality studies could be included AAOS review on ACL injury prevention programs.

Second, the guideline's suggestion of an RCT of 10K single sport athletes performing a standardized program with near-perfect compliance under professional supervision again demonstrates the guideline's sacrifice of practicality for scientific rigor. Even if this "perfect study" were done, it would still not help sports physicians because 90% of athletes at risk for ACL injury do not and will not ever have access to these "ideal" conditions. Therefore, from your review and taking suggestions of wording done in recommendation #17 and #18 we suggest the following re-wording. "Moderate strength evidence could not establish the efficacy of neuromuscular training programs in significantly reducing ACL injuries, because most studies were underpowered to detect significant reductions independently, were coach-led and had fair to poor compliance."

## **Recommendation 19**

commendation 20 and 21 could be re-written in similar manner to ensure a mor ommendation.	e concise and clear

## Workgroup Response to Reviewer 1

Dear American Medical Society for Sports Medicine Review Committee,

Thank you for your expert review of the Clinical Practice Guideline on the Management of Anterior Cruciate Ligament Injuries. We will address your comments by guideline section in the order that you listed them.

## **General Comments**

Regarding your comment on "dictating which levels of evidence were going to be acceptable", the acceptable levels of evidence are stated by article type (i.e. prognostic, treatment, diagnostic) on pages 18-24. For each recommendation, after assessing each study's quality and applicability (i.e. the strength of the evidence) we then use the best available evidence to provide the foundation for our recommendations (detailed on page 17 under "Best Evidence Synthesis").

## **Recommendation 5**

In formulating the CPG, our methodology requires use of the actual data. We do not simply consider the authors conclusions. The actual data is published with the CPG along with the rationale that supports the recommendation. We do not disagree that the written conclusion by Frobell et al, 2010 was that they found no differences between early reconstruction and rehabilitation with the option for delayed reconstruction. However, analyses of the actual data within the manuscript and appendices regarding laxity, instability, and especially the incidence of subsequent injuries to include meniscal tears support the conclusions stated in this guideline.

Additionally, there was no meta-analysis for Recommendation 5, nor did we include the Myer article reference in this comment. There was no MCID found or used for this recommendation.

## **Recommendation 16**

The workgroup voted to delete this recommendation because of a lack of relevant evidence, and it did not meet the standards for writing a consensus recommendation.

## **Recommendation 17**

The suggested rewording of the recommendation does not fit AAOS guideline language stems (see Table above).

## **Recommendation 18**

The guideline workgroup has voted to revise this recommendation based upon a pooled analysis to read, "Moderate strength evidence from pooled analyses with a small effect size (Number Needed to Treat=109) supports that neuromuscular training programs could reduce ACL injuries."

#### Recommendations 19 & 20

The guideline workgroup appreciated your suggested rewording; however, the original wording of each of these recommendations will remain unchanged.

Respectfully,

The 2014 AAOS ACL Guideline Workgroup

# Reviewer 2 - American Orthopaedic Society for Sports Medicine Peer Review Committee

## Peer Reviewer's Comments by Guideline Section

## **General Comments**

Our review committee commends the Academy for developing and utilizing a Clinical Practice Guideline process that is rigorous, transparent, and unbiased. We feel, however, that it is important that the Appropriate Use Criteria accompany the publication of the CPGs rather than having a long delay before the appearance of the AUC. Although we understand that the analyses used in the CPGs must be performed first to form the basis for topics considered by the AUC committees, the CPGs do not include clinician experiential knowledge which is critically important in the application of the guidelines to day-to-day clinical practice.

While the review is very well done, we feel the focus on level one studies leaves out many studies with very relevant clinical information that should be included.

Page 22 (lines 800-802): There is no reason to say the following: "Insurance payers, governmental bodies, and health-policy decision-makers may also find this guideline useful as an evolving standard of evidence regarding treatment of anterior cruciate ligament injuries." This sentence almost offers these bodies to use the guidelines to manage patient care. We recommend removing this sentence.

## **Recommendation 3**

There are plenty of data supporting the usefulness of MRI – however, in the clinical experience of our committee members, MRI must also be used in conjunction with clinical judgment (history, physical examination, etc.). The four star rating may lead surgeons to believe they should always order an MRI, resort to only reading an MRI report, and recommend an operation.

## Lines 1470-1473:

"A combination of history, clinical examination (Lachman test), and radiographs has similar diagnostic accuracy as MRI for identifying ACL tears. MRI is a better tool for identifying concomitant injuries." We disagree with these assertions. Of course, MRI is very helpful for diagnosing associated injuries and orthopaedic surgeons use it extensively. However, it is not "better" for identifying associated injuries because there is a high false positive rate for injuries that are not clinically relevant (such as for posterolateral corner injuries) and it should be used in conjunction with the history and physical examination, not "instead of," as the document implies by saying it is better. We recommend removing the two sentences noted above.

## **Recommendation 4**

Lines 1534-36: "Prospective studies on transphyseal versus all-epiphyseal reconstruction, intra-articular versus extra-articular techniques, and long-term outcomes of young patients following ACL reconstruction." Non-operative management, consisting of rehabilitation, bracing, and activity restriction, is often recommended in order to temporize for later conventional reconstruction near skeletal maturity. Nonoperative management of partial tears may be successful in certain patients (see Kocher MS, Micheli LJ, Zurakowski D, et al. Partial tears of the anterior cruciate ligament in children and adolescents. Am J Sports Med 2002;30(5):697-703). We suggest adding the following as an addition to future research: "Prospective comparative studies of non-operative treatment and ACL reconstruction in skeletally immature patients are necessary."

#### **Recommendation 5**

We questioned the apparent exclusion of adolescents (ages 13 to 17 years) in the review process. Many youth in this age group are skeletally mature but it is a very unique developmental period biologically and athletically

(when most of these injuries occur in this population). Therefore, we felt the meta-analysis was somewhat incomplete.

In addition, the meta-analysis did not separately examine outcomes by activity level (e.g., as assessed by the Marx Activity Scale or Tegner) following ACL reconstruction. It would be a great value to evaluate whether young athletes who return to highly ACL-dependent sports involving cutting and pivoting are likely to have worse or the same outcomes as those who do not.

## **Recommendation 6**

The recommendation concludes that there is limited evidence to support meniscus repair. We wish to bring to the attention of the CPG committee a very recent publication that addressed this issue in a large (n > 1300) cohort: Cox CL, Huston LJ, Dunn WR, Reinke EK, Nwosu SK, Parker RD, et al. Are Articular Cartilage Lesions and Meniscus Tears Predictive of IKDC, KOOS, and Marx Activity Level Outcomes After Anterior Cruciate Ligament Reconstruction?: A 6-Year Multicenter Cohort Study. Am J Sports Med. 2014 Mar 19. [Epub ahead of print]

## **Recommendation 7**

The only cited study was that by Daniel with ACLR which is over 25 years old. We believe this issue was addressed in the Frobell (2010, 2013) studies that found that mechanical stability was better in those assigned to early ACL reconstruction compared to those initially assigned to rehabilitation. We are confused as to why these results were not included in the analyses for this recommendation.

#### **Recommendation 9a**

We didn't dispute this recommendation but we were unclear why the recommendation specifies: "delayed for 12weeks." Much of the literature compares less than or greater than 6 weeks. Harrison T, Servant C. The optimal timing for anterior cruciate ligament reconstruction with respect to the risk of postoperative stiffness. Arthroscopy. 2013 Mar;29(3):556-65. Bottoni CR, Liddell TR, Trainor TJ, Freccero DM, Lindell KK. Postoperative range of motion following anterior cruciate ligament reconstruction using autograft hamstrings: a prospective, randomized clinical trial of early versus delayed reconstructions. Am J Sports Med. 2008 Apr;36(4):656-62.

## **Recommendation 9b**

When ACL reconstruction is indicated, moderate evidence supports early reconstruction within 5 months. Similarly, we were unclear why the recommendation specifies "5 months." We believe this is not representative of what has appeared in the literature which has not clearly delineated the timing of ACL reconstruction.

## **Recommendation 10**

We feel that the definition of a partial tear is nebulous and should be better specified. For example, would a grade 3 MCL tear associated with an ACL be considered a partial tear? We also believe that the recommendation should include a qualifier on the acuteness of the injury. In a delayed treatment scenario with chronic laxity, the optimal approach would be different from an acute injury. Hara K, Niga S, Ikeda H, Cho S, Muneta T. Isolated anterior cruciate ligament reconstruction in patients with chronic anterior cruciate ligament insufficiency combined with grade II valgus laxity. Am J Sports Med. 2008 Feb;36(2):333-9. Noyes FR1, Barber-Westin SD. The treatment of acute combined ruptures of the anterior cruciate and medial ligaments of the knee. Am J Sports Med. 1995 Jul-Aug;23(4):380-9.

## **Recommendation 11**

We suggest consideration of the following article: Gallacher PD, Gilbert RE, Kanes G, Roberts SN, Rees D. Outcome of meniscal repair prior compared with concurrent ACL reconstruction. Knee. 2012 Aug;19(4):461-3.

#### **Recommendation 12**

Although the outcomes are similar, the two surgeries are not comparable procedures. We believe it would be useful to clinicians to state that both procedures have empirical support for efficacy but that revision surgery following a double bundle procedure is more complicated. Also of note is that the double bundle procedure is more expensive.

We also would like to alert the CPG group to the recent article that is quite relevant to this recommendation: Ahldén M, Sernert N, Karlsson J, Kartus J. A prospective randomized study comparing double- and singlebundle techniques for anterior cruciate ligament reconstruction. Am J Sports Med. 2013 Nov;41(11):2484- 91.

## **Recommendation 13**

We did not have any objection to the recommendation but would like to make an observation. We noted that the vast majority of studies included in the analysis for this recommendation used patients from Australia and Europe, not the US. This perhaps reflects the deficiencies in the US literature but we questioned how applicable the findings are to the US population and to the sports commonly played in the US (e.g., American football). Also, two recent articles from large cohort studies indicated that hamstrings don't do as well as defined by graft failure (pathological laxity or revision surgery) as patellar tendon BTB: Rahr-Wagner L, Thillemann TM, Pedersen AB, Lind M. Comparison of hamstring tendon and patellar tendon grafts in anterior cruciate ligament reconstruction in a nationwide population-based cohort study: results from the danish registry of knee ligament reconstruction. Am J Sports Med. 2014 Feb;42(2):278-84. Persson A, Fjeldsgaard K, Gjertsen JE, Kjellsen AB, Engebretsen L, Hole RM, Fevang JM. Increased risk of revision with hamstring tendon grafts compared with patellar tendon grafts after anterior cruciate ligament reconstruction: a study of 12,643 patients from the Norwegian Cruciate Ligament Registry, 2004-2012. Am J Sports Med. 2014 Feb;42(2):285-91. We suggest that based on the recent literature that the recommendation include a qualified that stability is better with BTB but subjective outcomes appear to be better with hamstrings.

#### **Recommendation 14**

There are published reports of unacceptably high failure rates for ACL reconstruction with allograft tissue in teenagers and individuals with high activity levels after ACLR and we feel this should be included in the recommendation. Kaeding et al addressed this in a prospective longitudinal cohort which demonstrated a four times higher failure rate for allografts with the absolute failure rate increasing with younger age and higher activity (Kaeding et al. Allograft Versus Autograft Anterior Cruciate Ligament Reconstruction: Predictors of Failure From a MOON Prospective Longitudinal Cohort. Sports Health: A Multidisciplinary Approach. January 2011 3:73-81; see also Borcher, Pedroza, Kaeding. Activity level and graft type as risk factors for anterior cruciate ligament graft failure. American Journal of Sports Medicine. 2009: 37 2362-2367) Although the issue of the age and activity level of the graft recipient is noted in the Future Research section, we are concerned that surgeons may only read the recommendation. Therefore, we believe it is important to include a qualifier about age and activity level within the recommendation itself. We also felt it was important to include some information to describe the meaning of "appropriately processed."

## **Recommendation 15**

Our biggest objection to this recommendation is that it is based on analyses that grouped outside-in with medial portal. We believe that it is not appropriate to group these two together. We noted that there are only a few medial portal articles and 90% of tibial independent is two incision literature. In addition, most readers will not be familiar with the term "tibial independent."

## **Recommendation 16**

Our opinion was that the literature included in the analyses compared graft types and technique of insertion rather than fixation technique – they are not comparing fixation in this review. Accordingly, we would suggest that this recommendation not be included because it does not address the stated purpose.

## **Recommendation 18**

ACL injury prevention research will always require an enormous amount of subjects that is not feasible. A meta-analysis in JBJS showed a very clear effect of prevention. The guideline meta-analysis analyzed each study separately and thus missed the overall effect. Because so many patients are needed to find an effect, one study will never answer this question one way or the other. (The guideline stated that the study data was not suitable for pooling "due to heterogeneity of study populations and exercise programs). To conduct a study with 10,000 high risk patients as suggested is not feasible and possibly unethical. The JBJS meta-analysis pooled only ACL injury rate which dampens much of the heterogeneity. Our reading of the literature is that there is weak to moderate strength evidence to support neuromuscular training that prevents ACL injury but that we don't know the specifics of what is effective and consequently can't recommend a universal protocol. We suggest the modification of this guideline to reflect this as indicated below: "Moderate strength evidence exists that regular neuromuscular training can reduce ACL injuries. The specific program and frequency required to reduce injuries have not yet been determined."

#### **Recommendation 20**

We suggest the following modification to the wording of this recommendation: "For those undergoing post-operative rehabilitation after ACL reconstruction, moderate evidence supports early, accelerated, and non-accelerated protocols because they have similar outcomes. Early, accelerated protocols may include early weight bearing, range of motion, and strengthening including the addition of open kinetic chain exercises at six weeks."

## **Additional Comments**

Despite the fact that it is common practice for our members to refer anterior cruciate ligament (ACL) tears for ACL reconstructive (ACLR) therapy, we have found that there was not a recommendation in the guideline that specifically addressed ACL reconstructive surgery inability to reduce or mitigate adverse outcomes. We believe there is a deficit of literature specifically on longer-term outcomes of ACL injury.

## Workgroup Response to Reviewer 2

Dear American Orthopaedic Society for Sports Medicine Peer Review Committee,

Thank you for your expert review of the Clinical Practice Guideline on the Management of Anterior Cruciate Ligament Injuries. We will address your comments by guideline section in the order that you listed them.

## **General Comments**

We do use lower strength evidence when stronger evidence does not exist. However, when stronger evidence is available (i.e. studies with low risks of bias), it is important to detail those findings without the noise of additional data from poorly designed studies.

Regarding your suggestion to remove lines 800-802, the language of interest is standard between guidelines; however, revisions to this language will be suggested to the relevant AAOS committee.

## **Recommendation 3**

"MRI is a better tool for identifying concomitant injuries" was removed and replaced with "An MRI could be used in conjunction with the history and physical examination."

### **Recommendation 4**

We agree with the reviewer's recommendations, and will include this comment in our future research section.

#### **Recommendation 5**

We appreciate the reviewer's comments about the 13-17 year age groups. This age group is a mix of skeletally immature and mature, and separating them into separate groups is challenging due to variable rates of maturation. Future studies could focus upon clear distinction of those that are skeletally mature and immature, independent of age.

## **Recommendation 6**

AAOS guideline recommendations are based on research published in peer-reviewed publications. The suggested publication will be published after this guideline's final literature search date, thus it cannot be included for this recommendation. However, when this guideline literature is updated, this article may be useful for the next edition of the guideline and/or the AUC. We appreciate the suggestion.

## **Recommendation 7**

We agree with the reviewers' comments. Analyzing patients with recurrent instability after ACL injuries is difficult due to limited literature in this specific population. The Frobell 2010 study was focused on patients with ACL injury, not necessarily those with recurrent instability.

## Recommendation 9a & 9b

Regarding your suggested changing of Recommendation 9a from "delayed for 12 weeks" to "delayed for 6 weeks", the workgroup has approved the combining of Recommendations 9a and 9b based on the evidence, to read: "When ACL reconstruction is indicated, moderate evidence supports reconstruction within five months of injury to protect the articular cartilage and menisci."

## **Recommendation 10**

There is clearly some issue as to the definition of a "partial MCL tear", but it is not within the scope of this guideline to settle the vagaries of differing definitions. Both cited articles utilized relatively accepted definitions (little or no valgus laxity in full extension, with significant valgus laxity in 20°-30° of flexion). While treatment algorithms have evolved as to the timing of ACL reconstruction in acute complete ACL + partial MCL tears, the literature gives limited support to isolated reconstruction of the ACL in both acute and chronic cases. As noted in our Rationale, Potential Harms and Benefits, and Future Research Sections, the comparative values and risks of addressing the MCL non-operatively have not been adequately addressed in a high quality study.

#### **Recommendation 11**

Gallacher, et al. 2012 was excluded, because the finding had less than two year follow-up, thus it did not meet the *a priori* study inclusion criteria listed on pages 16-17.

## **Recommendation 12**

The following statement was added to the Future Research section, "Double bundle surgery may include additional expense, and may increase the complexity of revision ACL surgery; future studies may analyze this surgical approach."

## **Recommendation 13**

We appreciate the reviewer's recommendations; however, the suggested studies are outside of the dates of review for this guideline.

## **Recommendation 14**

Consistent with the evidence, Recommendation 14 has been amended to read, "Strong evidence supports that in patients undergoing ACL reconstructions, the practitioner should use either autograft or appropriately processed

allograft tissue, because the measured outcomes are similar, although these results may not be generalizable to all allografts or all patients."

## **Recommendation 15**

Although it may not be appropriate to group trans-tibial and tibial independent approaches together, the literature does not provide any evidence to support superiority of one technique compared to the other.

## **Recommendation 16**

The workgroup agreed with your comments and voted to delete this recommendation due to a lack of relevant evidence.

## **Recommendation 18**

The workgroup agreed with many of your comments and, based upon a pooled analysis, has revised the recommendation to read, "Moderate strength evidence from pooled analyses with a small effect size (Number Needed to Treat=109) supports that neuromuscular training programs could reduce ACL injuries." A new rationale was also written.

#### **Recommendation 20**

The following sentence was added to the rationale, "Early, accelerated protocols may include early weight bearing, range of motion, and strengthening including the addition of open kinetic chain exercises at six weeks."

## **Additional Comments**

The workgroup agrees that additional long term follow-up studies are necessary.

Respectfully,

The 2014 AAOS ACL Guideline Workgroup

## **Reviewer 3 - Anonymous**

## Peer Reviewer's Comments by Guideline Section

## **Recommendation 5**

The use of a hard cutoff at age 35 is questioned. What about healthy, active adults >35 years of age, many of whom may benefit from ACL reconstruction also?

#### **Recommendation 7**

For Recs 7, 9a, and 9b: should the role of undiagnosed posterolateral corner (PLC) injuries as a cause of instability be addressed? Similarly, should the PLC be addressed in considering the time frame for ACL reconstruction (i.e., staged repairs)?

## **Recommendation 9a**

Please clarify- the 12-week time frame is not clear- surgery "could" or "should" be delayed for 12 weeks?

## **Recommendation 10**

Should combined ACL and complete MCL injuries be addressed?

#### **Recommendation 12**

While success rates may be similar, should the increased technical demands of double bundle reconstruction be noted or factored into the recommendation?

## **Recommendation 14**

Though outcomes are similar for allograft and autograft, should failure rates for each be considered or discussed?

#### **Recommendation 16**

Recommend clarification regarding post-op functional bracing. Does this refer to post-op rehabilitative phase or bracing upon returning to athletics?

## **Recommendation 20**

We do not have any suggested changes to this recommendation but would like to note that there is currently no good evidence regarding the timing for when to return to sports. We believe that the literature is deficient in addressing this question but we believe that there be reasonable rehabilitation milestones that should be achieved before returning to sports. We also wanted to comment that the guideline defined accelerated rehabilitation as return to sports at 5 months but that clinicians (and athletes) often want to know the evidence about even earlier return to sports. These are perhaps issues for the Appropriate Use Criteria groups to consider.

## **Additional Comments**

This guideline addresses most, but not all, clinically relevant considerations for managing ACL injuries, and it is presented in a clear format. Thank you for the opportunity to review and comment on this document.

## Workgroup Response to Reviewer 3

Dear anonymous peer reviewer,

Thank you for your expert review of the Clinical Practice Guideline on the Management of Anterior Cruciate Ligament Injuries. We will address your comments below by guideline section.

## **Recommendation 5**

We appreciate the thoughtful response. Many practitioners treat patients at different stages of life, and we did break this down by age groups. This distinction may be somewhat arbitrary, as the reader points out, as activity levels may vary widely at different ages. The age categories may not reflect overall activity, and other recommendations address the issue of increased activity, and how this may impact knee function and the need for ACL reconstruction in more active patients, regardless of their age.

## **Recommendation 7**

We appreciate your comment on this important issue. For this CPG, we did not focus upon PLC injuries.

#### Recommendation 9a/9b

Regarding the "could" or "should" language in the recommendation, the language cannot be changed and is based on the available evidence, which is moderate. Therefore, the language has to be "could". For a strong recommendation, the language would use "should", instead of "could".

#### **Recommendation 10**

We appreciate your suggestion regarding addressing combined ACL and complete MCL injuries in this recommendation; however, the literature captured from our search only addresses ACL tears with partial MCL tears.

## **Recommendation 12**

The following statement was added to the Future Research section, "Double bundle surgery may include additional expense, and may increase the complexity of revision ACL surgery; future studies may analyze this surgical approach."

#### **Recommendation 14**

Recommendation 14 has been amended to read, "Strong evidence supports that in patients undergoing ACL reconstructions, the practitioner should use either autograft or appropriately processed allograft tissue, because the measured outcomes are similar, although these results may not be generalizable to all allografts or all patients."

## **Recommendation 16**

The workgroup voted to delete this recommendation because of a lack of relevant evidence, and it did not meet the standards for writing a consensus recommendation.

## **Recommendation 20**

The workgroup agrees that future research and AUC are appropriate for this.

Respectfully,

The 2014 AAOS ACL Guideline Workgroup

## Reviewer 4 - James J Irrgang, PT, PhD, ATC (APTA)

## Peer Reviewer's Comments by Guideline Section

## **Recommendation 2**

How is "significant" knee injury defined? Should the Pittsburgh and Ottawa knee rules be mentioned as decision tools for obtaining plain radiographs?

## **Recommendation 4**

Pg 60, Line 1523 - 1524 Given that the ACL does not heal, one would expect a difference in laxity between non-operative treatment and surgical reconstruction. Thus the relevance of the difference in laxity between non-operative and operative treatment is questionable. Did any of the studies evaluate the sense of instability or meniscus or cartilage injury between non-operative and operative treatment?

## **Recommendation 5**

Pg 69, Line 1546 The wording of the recommendation does not seem to be consistent with the guidelines for wording of recommendations based on the strength of the evidence as described in Table 9 on page 26.

## **Recommendation 7**

Pg 98, Lines 1630 – 1652 The level of detail provided in the Rational for this recommendation seems to be much more detailed compared to other recommendations. The reason for this should be provided.

#### **Recommendation 8**

Pg 115, Lines 1677 - 1679 Given the guidelines for wording recommendations in Table 9 on page 26, it is suggested that the wording of this recommendation be revised as follows: "There is limited evidence that non-surgical management might be considered for less active patients with less laxity."

## **Recommendation 12**

Pg 168, Lines 1862 - 1866 The wording of this recommendation is weak, as it seems obvious that ACL reconstruction should be either a single- or double-bundle reconstruction. I would suggest that the Work Group consider wording this recommendation as "There is strong evidence that there are no differences between single- and double-bundle ACL reconstruction."

Pg 168, Lines 1868 - 1873 Why did the Rationale exclude a statement on differences in laxity between single-and double-bundle ACL reconstruction? Many other recommendations referenced differences or lack of differences in laxity as the basis for the recommendation. Why was that not done for this recommendation?

## **Recommendation 14**

Pg 314, Lines 1978 - 1986 The Potential Harms of Implementation should address the increased risk for failure of allograft when used for ACL reconstruction of young active athletes.

## **Recommendation 16**

Pg 461, Lines 2108 - 2110 The wording of this recommendation does not seem to be consistent with the guidelines for wording or recommendations in Table 9 on page 26. Based on the guidelines for wording, this guideline could be revised as follows: "Moderate evidence indicates that functional knee bracing could or could not be used after isolated ACL reconstruction, because there is no demonstrated efficacy." Wording of the recommendation by stating the evidence "does not support the routine use" of a functional knee brace seems to be too strong based on the level of evidence.

Page 461, Line 2117 Clarify the phrase "ACL Strength of Life" – do the authors mean "ACL Quality of Life"?

Pg 461, 2126 Given only a moderate level of existing evidence, why wouldn't further high-level research investigating the benefits of functional knee braces be recommended?

## **Recommendation 18**

Pg 493, Lines 2189 - 2192 It is unfortunate that the heterogeneity among study populations and exercise programs precluded performing a meta-analysis.

## **Recommendation 19**

Pg 508, Lines 2255 – 2262 The Potential Harms of Implementation should include the risk of graft failure with accelerated rehabilitation after ACL reconstruction.

Pg 508, Lines 2263 – 2267 Future Research should address the influence of accelerated rehabilitation on graft integrity. This include the use of imaging (MRI) to assess the effects of accelerated or delayed rehabilitation on graft healing and maturation.

## **Recommendation 20**

Pg 531, Lines 2297 – 2306 The Work Group is congratulated for including a statement regarding the risk for graft failure and injury to the contra-lateral knee with early return to sports.

Pg 531, Lines 2307 – 2312 The recommendations for Future Research should include investigation of the use of imaging (MRI) to assess graft maturation and healing to determine readiness for return to sports while minimizing the risk of graft re-rupture.

# Workgroup Response to Reviewer 4

Dear Dr. James J Irrgang,

Thank you for your expert review of the Clinical Practice Guideline on the Management of Anterior Cruciate Ligament Injuries on behalf of the American Physical Therapy Association. We will address your comments by guideline section in the order that you listed them.

#### **Recommendation 2**

The workgroup has amended the recommendation language to read, "In the absence of reliable evidence, it is the opinion of the work group that in the initial evaluation of a person with a knee injury and associated symptoms [giving way, pain, locking, catching] and signs [effusion, inability to bear weight, bone tenderness, loss of motion, and/or pathological laxity] that the practitioner obtain AP and lateral knee x-rays to identify fractures or dislocations requiring emergent care.

#### **Recommendation 4**

We appreciate the insightful comments, and thoughtful question. Future research directed towards answering this question would be beneficial.

#### **Recommendation 5**

Thank you for your suggestion. The workgroup believes the language is consistent with AAOS standards and did not approve revisions to this recommendation's language.

#### **Recommendation 7**

The length of each rationale is determined by the amount of content deemed necessary by the workgroup to support the recommendation.

#### **Recommendation 8**

Thank you for your suggestion. The workgroup believes the language is consistent with AAOS standards and did not approve revisions to this recommendation's language.

#### **Recommendation 12**

Respectfully, the sample sizes listed in the guideline are correct. The Hussein, et al 2012 study originally started with a total N of 101 participants, 32 patients in the single-bundle group (ASB) and 69 patients in the double-bundle group (ADB). However, a total of 94 patients met the inclusion criteria of the study and the final group numbers were 30 patients in the ASB group and 64 patients in the ADB).

We neglected to add differences in laxity as a rationale for this recommendation. After sentence three "the majority of the studies demonstrate no statistically significant difference in any outcome parameters." Specifically, there was no significant difference in the KT-1000, Lachman, and pivot shift tests or the IKDC Objective Knee Form scores.

#### **Recommendation 14**

Recommendation 14 has been amended to read, "Strong evidence supports that in patients undergoing ACL reconstructions, the practitioner should use either autograft or appropriately processed allograft tissue, because

the measured outcomes are similar, although these results may not be generalizable to all allografts or all patients."

#### **Recommendation 16**

The workgroup voted to delete this recommendation because of a lack of relevant evidence, and it did not meet the standards for writing a consensus recommendation.

#### **Recommendation 19**

The following statement was added to the Future Research section, "Future Research should also address the influence of accelerated rehabilitation on graft integrity. This includes the use of imaging (MRI) to assess the effects of accelerated or delayed rehabilitation on graft healing and maturation."

#### **Recommendation 20**

The workgroup appreciates and agrees with these points. The future research section recommends studies on graft healing times.

Respectfully,

# **Reviewer 5 - AAP Representative (AAP)**

### Peer Reviewer's Comments by Guideline Section

#### **General comments**

It is highly encouraged throughout the guidelines that references to the IKDC be clarified. Not doing so leads to confusion because it is not clear if the reference is to the IKDC Subjective Knee Form (SKF), the overall IKDC Knee Ligament Rating System ( with ratings of normal, nearly normal, abnormal or severely abnormal) or the symptom and activity ratings within the original IKDC Knee Ligament Rating System.

#### **Methods**

Page & Line Number Comment

- a. Pg 14, Line 816 "and" should be "an"
- b. Pg 14, Lines 842 848 Here the guideline peripherally addresses shared decision making. Recommend that this be strengthened to emphasize the importance of shared decision making, where the clinician presents all treatment options, including the benefits and risks of each and there is a discussion of the patient's expectations before the patient decides on treatment.
- c. Pg 17, Lines 959 960 The guidelines should define the range of surrogate outcomes that were considered. Further review of the guidelines reveals that multiple surrogate outcomes (laxity, radiographic/symptomatic OA etc.) were considered. These surrogate outcomes should be stated in this section.
- d. Pg 18, Line 1010 In this heading, it should be made clear that this section is related to Intervention/Prevention.
- e. Pg 19, Line 1024 This line states that studies with low power were given an increase in the rating of quality, which does not seem logical.
- f. Pg 20, Line 1082 Additional information should be provided to define/explain the criteria for applicability listed in Table 2. For example, what does the "Full Range of Expt'l Practitioners" mean?
- g. Pg 23, Line 1161 It is stated that 6 domains were used to judge quality of prognostic studies, however only 5 domains are listed in the text.
- h. Pg 24, Lines 1187 1188 The wording of the explanation for "Analysis" is confusing and should be clarified.
- i. Pg 25, Line 1222 The text references Table 7, but it should reference Table 8.
- j. Pg 26, Line 1238 Table 10 indicates that Decision Aids are least important for a Strong Recommendation; however that is not correct in all cases. If there is strong evidence that supports no difference between 2 alternative interventions, than greater participation by the clinician with the patient in shared decision making is more critical so that the patient can determine what is best for them. In this case, a decision aide to facilitate the discussion is more critical. The Table should be revised to reflect this.
- k. Pg 26, Line 1248 Subheadings should be used in the section on "Statistical Analysis" to indicate the analyses that were used for diagnosis and for intervention/prevention.
- Pg 27, 1270 It is stated that when measures of dispersion, other than a standard deviation were provided, the value was estimated to facilitate calculation of the treatment effect. An explanation of how this was done should be provided.

#### **Recommendation 18**

The second and more major concern of this study was the recommendation on lines 219-223 that moderate strength evidence could not determine the efficacy of neuromuscular training for a significant reduction in ACL tear. I am concerned that the stringent grading system utilized by AAOS limited the studies included in the analysis and resulted in the determination of an insignificant benefit from neuromuscular training programs.

Due to the nature of neuromuscular training as an intervention, it is nearly impossible to do a RCT that would meet the AAOS criteria for a strong quality study, since it would require the following criteria:

- 1. Double blinded
- 2. Randomized on the individual level (vs. cluster-randomized)
- 3. Large enough sample size (sufficient power would require close to 10,000-12,000 athletes)

In addition, several large studies showed a statistically significant change in ACL injury rate in their studies, but were found to be insignificant by this working group after re-analysis of the data. Many studies were not utilized in the meta-analysis because the group felt that the heterogeneity of the groups (athlete types, intervention, etc) did not allow for the data to be pooled. However, a meta-analysis using all groups with the single outcome measure of ACL tear would further enhance the idea that neuromuscular training of any kind could reduce injury risk in many athletic groups. Finally, it is known that neuromuscular training programs not only assist to reduce the risk of ACL, but also have been shown to reduce patellofemoral pain syndrome, improve child health, provide key components of an essential warm-up program and improve muscle recruitment. These benefits come with little or no risk to the patient. I am concerned that this clinical practice guideline's outright recommendation that ACL prevention programs are ineffective will result in their discontinued use and increased rate of non-contact ACL injuries. I hope the committee will strongly consider a re-evaluation of this recommendation.

#### **Additional Comments**

I would highly suggest review of Recommendation regarding ACL Prevention programs.

## Workgroup Response to Reviewer 5

Dear Dr. AAP Representative,

Thank you for your expert review of the Clinical Practice Guideline on the Management of Anterior Cruciate Ligament Injuries on behalf of the American Academy of Pediatrics. We will address your comments by guideline section in the order that you listed them.

#### **General Comments**

The workgroup appreciates your request for clarification of the IKDC variants; however, IKDC variants are detailed in the summary of findings tables for each recommendation.

#### **Summary of Recommendations**

#### Introduction

#### Methods

- a. Revised
- b. Thank you for your comment.
- c. Surrogate outcomes are detailed and addressed separately within their relevant recommendations.
- d. This is a good suggestion and the workgroup has approved your suggested revision.
- e. The introductory sentence for this section was changed to "We incorporate a coding scheme adaptable to all research designs that involves incremental increases or decreases based on the following criteria:"
- f. For additional information regarding the PRECIS instrument used to assess applicability, the indicated reference should be consulted.
- g. The workgroup has approved your suggested revision.
- h. Removed "not" in the description of "Analysis".
- i. The workgroup has approved your suggested revision.
- j. This is a very good point. Table 10 has been revised to reflect the importance of decision aids in the event that the evidence supports no difference between two alternative interventions.
- k. This is a good suggestion. The workgroup has approved adding subheadings to reflect diagnostic data analysis vs. intervention/prevention data analysis.
- 1. Thank you for your comment.

#### **Recommendation 19**

The workgroup agreed with many of your comments and, based upon a pooled analysis, has revised the recommendation to read, "Moderate strength evidence from pooled analyses with a small effect size (Number Needed to Treat=109) supports that neuromuscular training programs could reduce ACL injuries."

Respectfully,

The 2014 AAOS ACL Guideline Workgroup

# Reviewer 6 - Jay Smith, MD (AAPM&R)

# Peer Reviewer's Comments by Guideline Section

#### **General Comments**

Thank you for the opportunity to review this document. The guideline development group has done an excellent job on a monumental task addressing a clinically relevant problem.

It is noted that the literature search and analysis pertained to articles published through mid-2013. I am not aware of AAOS policies/procedures pertaining to guidelines such as this but would recommend:

- a. Having one or more individuals on the guideline development group perform extend the literature search from mid-2013 to current to determine if there are relevant articles that have been published in the interim, or
- b. Specifically and clearly state in the guidelines, as well as the published summative statements in JBJS, that the guidelines are based on published literature prior to July 2013, and include a disclaimer that additional relevant literature may have been published since that time.

#### **Methods**

- a. Lines 797-806 On line 797, there is a reference to orthopaedic surgeon and physicians, yet some physician groups are lumped in the non-physician groups later in this paragraph. I would recommend rewriting to include orthopadic surgeons and physicians (and list the specific physician types in parentheses)
- b. Lines 838, 843, 846-8 editorial errors. Just pointing out but did not point out all of them because the instructions were for non-editorial comments. I assume that the document will be edited for errors, etc.
- c. Lines 1010-1044 I read this section multiple times yet cannot understand it completely. It might be just me but consider rewording.

#### **Recommendation 4**

Lines 101 and 109-110 - The recommendation for ACL Pediatric includes some detail regarding why the practitioner "might" perform surgery, in terms of reducing activity related disability and recurrent instability, etc. However, the correlative ACL Young Active Adult recommendation does not include any specific detail. I would recommend adding some detail on the Adult side to explain the "why" of the recommendation, particularly since the evidence for the Adult Recommendation is stronger than the evidence for the Pediatric Recommendation.

#### **Recommendation 7**

Lines 122-6 - I am not sure why this recommendation requires inclusion as this is more of a symptom and is essentially included in the Age Group related recommendations. This recommendation seems to not fall into line with the prior age-orientated recommendations included in the document. Is there an age dependent factor in the instability that is discussed here? If not, then perhaps the guidelines should suggest that regardless of age, surgery might be considered to reduce laxity, which may improve instability.

#### **Recommendation 8**

Lines 131-133 - I would encourage the group to place some parameters on the "less active" or "less laxity" criteria, or directly refer the reader to the relevant Executive Summary explaining the guideline in the larger document. Although I agree with the recommendation, as written, the lack of detail renders it not very user friendly.

Lines 122-133 - Despite the fact that both Recommendations 7 and 8 have similar, limited evidence, the ways they are written convey different messages to the casual reader. It would be easy for the casual reader to conclude that there is limited evidence for non-operative management in any ACL problem, regardless of age/laxity. I recognize the limited but evolving evidence on non-operative management but I feel that the language of these recommendations should represent the data fairly. For example, Recommendation 7 can simply be written as "Limited evidence supports that the practitioner might perform ACL reconstruction in patients with recurrent instability because....." The first part of the recommendation suggests that surgery is better than rehabilitation. The "limited" available evidence simply is not enough to support this contention. Of

course, as previously stated, I think the issue can be solved by simply removing Recommendation 7 because I fail to see its purpose.

Lines 1703-1706 - We are aware of recent literature trying to identify copers vs non copers for ACL, including younger populations. Given the paucity of literature on non-op management, I would recommend considering mentioning that this is an area of active research and perhaps providing a reference or two (e.g. L. Snyder-Mackler's research).

#### **Recommendation 9**

Line 141 - Recommend changing to "up to 12 weeks"

Lines 1731-1733 - This information is lost in the final recommendation as it suggests that surgery done "too early" may have an increased complication rate. The final Recommendation as written only says that surgery could be delayed for up to 12 weeks. It does not suggest any detriment to very early surgery. I point this out in case our surgical colleagues feel that this should be modified somehow. Can the Recommendation include something about limited evidence and/or consensus suggesting that early surgery may increase the risks of x, y and z?

#### **Recommendation 10**

Line 1810 - I appreciate this clinically relevant qualification of a "partial MCL tear" in the context of the recommendation. I would recommend including (no or minimal laxity when tested in full extension) in the final Recommendation.

#### **Recommendation 13**

Lines 176-179 - It is noted that this recommendation does not include any statements pertaining to other autograft types and ipsilateral vs contralateral grafts. I am wondering if there should be some recognition of this in the Recommendation itself, in the Preface paragraph I referred to above, or in the Executive Summary for this Recommendation. I suspect that the reason for not including any recommendations is the shear lack of guiding evidence.

#### **Recommendation 18**

As suggested by my comments with respect to the ACL Prevention Program recommendations below, as a non-operative sports medicine physician, I am concerned that the document mis-represents the potential role of rehabilitation. Admittedly, there is a paucity of guiding evidence FOR or AGAINST rehabilitation in non-Operative (more so) and post-operative (less so) ACL cases. I think some of the recommendations as currently written are written in a more NEGATIVE manner, as opposed to simply stating that there is insufficient evidence. This is most evident in the ACL Prevention Program Recommendation, which I discussed in great detail below. However, it is also evident in the Return to Activity/Play Recommendation and in the Instability Recommendation. I think a lot of this potential for misinterpretation and mis-representation can be managed by:

- a. Including the Executive Summaries with any publication of the Recommendations, so the casual reader can place the recommendations into context.
- b. Considering rewording of recommendations as suggested below for several of them.
- c. Including a Preface or similar paragraph or two, as indicated elsewhere in my comments. In this section,

The Guidelines group can clearly state that further research in non-operative management is ongoing, etc.

Lines 219-21 - I recommend rewording this recommendation for clarity. I also do not entirely agree with the recommendation as written, particularly when the Executive Summary accurately identifies that the majority of studies were insufficiently powered to detect an effect. See my additional comments on this later in this review.

#### **Recommendation 19**

Lines 2175-78 - As previously stated, I disagree with the way in this recommendation is presented. The Recommendation is worded such that is suggests that "moderate" evidence "failed" to document the efficacy. This is worded much differently than many of the other recommendations and presents this in a negative light. There have been two recent meta-analysis (Myer et al AJSM 2013 and Gagnier et al AJSM 2013) indicating the the literature suggests that these training programs reduce ACL injuries in specific groups. The AAOS Guideline recommendation appears contradictory. Obviously, some of this contradiction can be explained by methodology, but nonetheless the fact that two recent analyses in a reputable journal should indicate that the Recommendation should be worded with great care. We do not want to misrepresent the data and have practitioners, patients and coaches concluding that these prevention programs are a "waste of time and money". This particular recommendation is very contentious as written and I believe warrants careful consideration in revising. Some other considerations:

- a. Need to reconcile this recommendation with the two recent meta-analyses published in a high powered journal
- b. I recognize that some studies specifically demonstrate ACL injury reduction, whereas others demonstrate total knee injury reduction. Depending on what the group wants to do, they could indicate that there may be some evidence that the programs may reduce total knee injury risk.
- c. Need to reconcile that this AAOS recommendation is based on underpowered studies, as recognized in the Executive Summary (Lines 2190-93). The facts that the majority of studies were underpowered...and the AAOS recommended larger studies of > 10000 athletes (Line 2202)...and that the two previously mentioned meta-analyses arrived at different conclusions, seem contradictory with the ability of the literature to support the Recommendation with "Moderate" strength evidence.
- d. In the context of "c", some of the larger studies were the ones that did demonstrate injury reduction.
- e. Despite the apparent lack of statistical significance for some studies, many of them demonstrated a marked reduction in relative risk of injury. In the context of the discussion within the Guidelines pertaining to "Minimally Clinically Important Differences", I'm not convinced that these quantitative injury reductions can be overlooked. For example, on Table 120, page 503, Olsen et al demonstrated a reduction from 10/879 to 3/958 a three fold reduction. Peterson demonstrated a reduction from 5/142 to 1/134, a 5 fold reduction. Gilchrist et al demonstrated a reduction from 18/852 to 7/583, Caraffa 70/300 to 10/300, and Mandelbaum 32/1905 to 2/1041. For the casual reader of the guidelines, these data may be lost and may be clinically significant.

My point is that this Recommendation as currently written is not entirely accurate, mis-represents the data depending on who's reading it and what their threshold for "signficance" is, and will be very contentious in the public and professional sector if published in its current form.

#### **Additional Comments**

I actually found the Executive Summaries of each Recommendation to be extremely useful (these are the one page summaries that are included in the larger document). I would strongly recommend publication of these one page summaries with any publication of the document. This would significantly enhance the usability of the document, as well as educate the professional and public community. At the very least, any publication of the guidelines should explicitly state that interested readers are encouraged to view the one page Executive Summaries of each Recommendation at website XXX. At that location, the summaries are easily viewed in order and the reader doesn't have to scroll through the 500+ page document to find them.

For example, virtually anyone I spoke with regarding Recommendation 13 said "sure, the BTB and HS are similar but BTB has more kneeling pain.". This is a clinically significant issue for some and is not evident in the actual recommendation. However, it is clearly stated in the Executive Summary for Recommendation #13, as supported by two high strength studies and one moderate strength study.

# Workgroup Response to Reviewer 6

Dear Dr. Jay Smith,

Thank you for your expert review of the Clinical Practice Guideline on the Management of Anterior Cruciate Ligament Injuries on behalf of the American Academy of Physical Medicine and Rehabilitation. We will address your comments by guideline section in the order that you listed them.

#### **General Comments**

Regarding comment "a." we do updated searches as close to the final guideline workgroup meeting as possible to ensure that our workgroup members have the most current evidence available at their meeting. We perform updated searches every five years after publication of each of our guidelines to assess guideline revision plans. Additionally, for derivative products, such as appropriate use criteria (AUC) we perform updated literature searches to supplement the guideline search.

#### **Methods**

Regarding comment "a.": We will take this into consideration.

Regarding comment "b.": Thank you, we will edit for editorial errors.

Regarding comment "c.": We will take this into consideration.

#### **Recommendation 4**

We appreciate the insightful comments. The levels of evidence are different in these different groups, and therefore, the language used to support the recommendations is different.

#### **Recommendation 7**

We agree with the reviewers comments. Regardless of age, this recommendation provides limited support for reconstruction in patients with clinically significant laxity.

#### **Recommendation 8**

We appreciate the thoughtful responses. "Less active" is defined in the rationale.

#### **Recommendation 9**

The workgroup agreed with your suggestions and has combined Recommendation 9a and 9b into one recommendation to read, "When ACL reconstruction is indicated, moderate evidence supports reconstruction within 5 months of injury to protect the articular cartilage and menisci."

#### **Recommendation 10**

There is clearly some issue as to the definition of a "partial MCL tear", but it is not within the scope of this guideline to settle the vagaries of differing definitions. Both cited articles utilized relatively accepted definitions (little or no valgus laxity in full extension, with significant valgus laxity in 20°-30° of flexion). While treatment algorithms have evolved as to the timing of ACL reconstruction in acute complete ACL + partial MCL tears, the literature gives limited support to isolated reconstruction of the ACL in both acute and chronic cases. As noted in our Rationale, Potential Harms and Benefits, and Future Research Sections, the comparative values and risks of addressing the MCL non-operatively have not been adequately addressed in a high quality study

#### **Recommendation 13**

There is insufficient evidence comparing ipsilateral to contra-lateral grafts. The following sentence was added to the future research section, "Additional research comparing ipsilateral grafts to contralateral grafts is also needed."

## **Recommendation 18**

The workgroup agreed with many of your comments and, based upon a pooled analysis, has revised the recommendation to read, "Moderate strength evidence from pooled analyses with a small effect size (Number Needed to Treat=109) supports that neuromuscular training programs could reduce ACL injuries."

#### **Recommendation 21**

We appreciate the comments. The evidence in this field is limited but of great significance to patients and clinicians. This is an important area of future clinical research.

Respectfully,

# Reviewer 7 - William De Long, MD (ACS)

### Peer Reviewer's Comments by Guideline Section

#### **General Comments**

The clinical practice guideline was put together with much thought and scientific scrutiny. The levels of evidence are appropriate and match recommendations with an even hand. The majority of ideas presented are already being followed by many practitioners in the community. This document will give practitioners a sound reference for making practice decisions on individual patients.

#### **Summary of Recommendations**

Regarding the Summary of Recommendations (pages ii-viii), in my experience, these are what are ultimately published in JBJS and in the "lay press", with very few individuals going to the original document to read the relevant background. This can lead to misinterpretation and incomplete understanding of the published statements. My recommendations:

- a. The "Strength of Recommendation" should be easily available as a separate document on the AAOS website for those who are interested.
- b. Ensure that the text descriptions of the strength of recommendations that appear under each Recommendation are published with any publication of the recommendations themselves. This allows the reader to better understand the evidence behind the recommendation without having to refer to other sources.
- c. Publish lines 1211-1239, including Tables 9 and 10, with any publication of the Recommendations. This is crucial to the clinical interpretation of the strength of the recommendations. It is similar to "statistical significance" vs. "clinical significance". Similarly, the recommendation for "limited" strength means x, y and z in terms of supportive studies within the Guidelines methodology, but what it really means "clinically" is that there is a good probability that the recommendation will be significantly modified or overturned by future evidence. This latter recognition is key to appropriately framing the recommendations. Similarly, Figure on lines 1382-1386 should be published with any Recommendations synopsis or be readily available without having to search. It is very useful as a "big picture" detailing the quality of studies that went into each recommendation. I can't overemphasize how useful this would be to practitioners.

#### Introduction

There are specific recommendations pertaining to Pediatrics and the Young Active Adult, but none addressing the older individual. Of course, we recognize that age isn't everything and activity and laxity are probably most important, and we also recognize that Recommendation 8 probably covers the "older less active" individual. However, I wonder if the document might be enhanced by explaining this somewhere in a preface or something similar. Such a paragraph would certainly improve the acceptance of the document by explaining what is covered, what is not covered, the time frame of the articles reviewed as part of the study, etc.

#### **Additional Comments**

This provides sound direction for clinical decision making. It is clear and concise and will be easy to use. The challenge always is to provide guide lines that can be tailored into clinical needs of individual patients. I feel that this document is in position to function that way without much modification.

# **Workgroup Response to Reviewer 7**

Dear Dr. William De Long,

Thank you for your expert review of the Clinical Practice Guideline on the Management of Anterior Cruciate Ligament Injuries. We will address your comments by guideline section in the order that you listed them.

#### **Summary of Recommendations**

In 2013 the AAOS investigated the web usage statistics of those who access/download the summary of recommendations only versus those who access/download the full guideline and found that more people were accessing/downloading the full guideline than the summary of recommendations for all of the published guidelines.

Regarding comment "a.", this is a good suggestion. We will post this on our website.

Regarding comment "b.", assuming you are suggesting including the "Rationale" section along with the summary of recommendations, we will take this into consideration.

Regarding comment "c.", this will be added to our summary of recommendations document.

#### Introduction

We appreciate the thoughtful response. Many practitioners treat patients at different stages of life, and we did break this down by age groups. This distinction may be somewhat arbitrary, as the reader points out, as activity levels may vary widely at different ages. The age categories may not reflect overall activity, and other recommendations address the issue of increased activity, and how this may impact knee function and the need for ACL reconstruction in more active patients, regardless of their age.

Respectfully,

# Reviewer 8 - Yvette Rooks, MD (AAFP)

# Peer Reviewer's Comments by Guideline Section

#### **General Comments**

I have reviewed this clinical practice guide from a primary care physician viewpoint. The document has tremendous research back round to support each topic area which is very relevant for evidence based medicine.

# **Workgroup Response to Reviewer 8**

Dear Dr. Yvette Rooks, MD (AAFP),

Thank you for your expert review of the Clinical Practice Guideline on the Management of Anterior Cruciate Ligament Injuries on behalf of the American Academy of Family Physicians.

Respectfully,

# Reviewer 9 - Sean O'Leary, MB BChir, FRCS (Lon), FRCS (Tr & Orth) (BASK)

# Peer Reviewer's Comments by Guideline Section

#### **General Comments**

Congratulations of the thoroughness of this review. When composing such an 'evidence based' article it is often revealing how much or little of our practice we have evidence for. This is stated to be one of the underlying reasons for this paper and it is a success in this regard.

#### **Recommendation 5**

I have a slight concern about the 'general' recommendation for reconstruction in the skeletally immature patients. Whilst I agree with the reported evidence base I don't feel enough is made of potential adverse effects in this group of patients and the high reported rates of re rupture. This is specialized surgery and should be recommended with appropriate caution.

#### **Additional Comments**

This is an excellent and thorough document but (as is the stated intention) should form the starting point for further clinical research to 'fill in the gaps'.

We can only report on the success or otherwise of our interventions if we have information about the various outcome(s) of these interventions. I feel that these guidelines do miss an opportunity to encourage data collection on ACL surgery as part of our routine practice. I accept that there is no (US) National ACL Registry and no such measures could be mandated but 'best practice' guidance could be suggested. This could initially be in the form of suggested outcome scores which could be compared to existing Registry information from Norway, Denmark, Sweden and the UK.

# Workgroup Response to Reviewer 9

Dear Sean O'Leary, MB BChir, FRCS (Lon), FRCS (Tr & Orth),

Thank you for your expert review of the Clinical Practice Guideline on the Management of Anterior Cruciate Ligament Injuries on behalf of the British Association for Surgery of the Knee. We will address your comments by guideline section in the order that you listed them.

#### **General Comments**

Thank you, we will take your suggested addition into consideration.

#### **Additional Comments**

The guideline workgroup agrees with the importance of better, longer term, follow-up research.

Respectfully,

# **Reviewer 10 - Patrick F. Leary (AOASM)**

### Peer Reviewer's Comments by Guideline Section

#### **General Comments**

It is always difficult to grade the validity of any supportive study. Noyes studied 42 ACL Prevention Programs but found only 2 that had a positive influence on injury reduction and athletic performance tests. Sports Health Jan 2012. These two, Sportsmetrics and PEP bear mentioning. Return to Play Criterion is nebulous but the FMS and Biodex Sway data bears mentioning. Qualifications of Surgeons/ Institutions and frequency of procedures has been implicated in outcomes. This bears mentioning.

#### Introduction

I would question the incidence of the 'problem' and it seems that a 'lower end' incidence has been used to calculate the figure of 125,000. The most recent Swedish ACL Registry report (2012) has suggested (from population figures) an incidence of approximately 80/100,000. This would suggest approximately 252,000 cases per annum in the United States.

#### **Additional Comments**

Data could be included which reflects the incidence of subsequent TKR after previous ACL repair. Data could be included which details the RTP at maximum capacity/competition vs. merely return to sport or return to practice. Data could be added which details hamstring strength before and after hamstring graft harvesting as it relates to further neuromuscular imbalances and subsequent re rupture of ACL. (Females) Contralateral or Ipsilateral. Data could be included regarding incidence and risk of post op re rupture of ACL, both contralateral and Ipsilateral

## Workgroup Response to Reviewer 10

Dear Dr. Patrick F Leary,

Thank you for your expert review of the Clinical Practice Guideline on the Management of Anterior Cruciate Ligament Injuries on behalf of the American Osteopathic Academy of Sports Medicine. We will address your comments by guideline section in the order that you listed them.

#### **General Comments**

The authors agree with the reviewer and have included the data from these programs Hewett 1999 (Sportsmetrics) and Gilchrest 2008 (PEP). Sportsmetrics and PEP programs are commercially trademarked names for the protocols that are marketed based off of these data (Hewett 1999-Sportsmetrics; and Gilchrest 2008-PEP). The authors disagree that there is evidence indicating the validity of isolated FMS or Biodex Sway data for RTP criteria and there review does not meet the criteria for this recommendation.

#### Introduction

We will modify the incidence/prevalence rates to reflect those published in this registry report.

Respectfully,

# Reviewer 11 - David J. Hoelting, MD (AAFP)

### Peer Reviewer's Comments by Guideline Section

#### **General Comments**

Overall impression of recommendations was positive. Strength of recommendations, especially when to intervene, appropriate waiting time before surgery, and types of intervention were well documented and unambigious. Strength of recommendation with immature individuals was less conclusive. Overall, straightforward and easily understood. As a Family Practitioner, some of this was beyond our area of expertise, but most was very appropriate for pre-and post-op management and decision-making concerning these injuries. I believe this is valuable from a Family Practice standpoint.

#### **Additional Comments**

Probably more appropriate for orthopedic practices, but certainly helpful in decision-making concerning patients with these injuries in our practices. Especially with decisions about when to recommend surgery versus conservative management, when to wait, when to push for surgical intervention.

### Workgroup Response to Reviewer 11

Dear Dr. David J. Hoelting,

Thank you for your expert review of the Clinical Practice Guideline on the Management of Anterior Cruciate Ligament Injuries on behalf of the American Academy of Family Physicians.

Respectfully,

# Reviewer 12 - William J Doherty, MD

# Peer Reviewer's Comments by Guideline Section

#### **General Comments**

The applicable issues of ACL injury management are addressed and will be useful for many clinicians.

# **Workgroup Response to Reviewer 12**

Dear Dr. William J Doherty,

Thank you for your expert review of the Clinical Practice Guideline on the Management of Anterior Cruciate Ligament Injuries.

Respectfully,

# Reviewer 13 - Amy Lynn McIntosh, MD (POSNA)

# Peer Reviewer's Comments by Guideline Section

#### **General Comments**

As a representative of the Pediatric Society of North America (POSNA) I feel that the questions raised were appropriate. The specific question on ACL reconstruction in the skeletally immature patient was well worded. Unfortunately the paucity of high level literature on the topic makes the recommendation level low. I agree that prospective, multi-center, outcomes focused research in this age group is necessary to ensure that high quality and safe procedures are being performed by members of our society. This CPG highlights the lack of research on the specific topic of open growth plate, ACL deficient athletes. I also thought the wording and recommendations regarding allograft vs. autograft ACL reconstruction were accurate. I have no revisions for those sections. The functional bracing and prophylactic bracing sections were also well written with accurate recommendations. I have no revisions.

### **Workgroup Response to Reviewer 13**

Dear Dr. Amy Lynn McIntosh, MD,

Thank you for your expert review of the Clinical Practice Guideline on the Management of Anterior Cruciate Ligament Injuries on behalf of the Pediatric Orthopaedic Society of North America.

Respectfully,

# PUBLIC COMMENT RESPONSES

# **Public Comment Participant Key**

Participant #	Name of Participant	Primary Specialty	Work Setting	What is the name of the society that you are representing?	
1	Omer Ilah, MD	Sports Medicine	Private Group or Practice	None Listed	
2	Richard Hawkins, MD	Shoulder and Elbow	Academic Practice	None Listed	
3	Anonymous	Adult Spine	Academic Practice	None Listed	
4	MARLENE DEMAIO, MD	Sports Medicine	Military	RUTH JACKSON ORTHOPAEDIC SOCIETY	

# **Public Comment Participant's Disclosure Information**

All public comment participants 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 public comment participant was asked to provide details on their possible conflict.

# **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?
E	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?

# **Disclosure Information for Public Comment Participants**

Participant Number	Name of Participant (Required)	A	В	С	D	E	F	G	Н	I	J
1	Omer Ilah, MD	None	None	None	None	None	None	None	None	None	Western Orthopaedics Association Texas Orthopaedic Association
2	Richard Hawkins, MD	Ossur	None	None	DJ Orthopaedics	None	None	None	Wolters Kluwer Health - Lippincott Williams & Wilkins		American Shoulder and Elbow Surgeons
3	Anonymous	None	None	None	None	None	None	None	None	Journal of Bone and Joint Surgery - American Surgery - American Journal of the American Academy of Orthopaedic Surgeons Spine	Lumbar Spine Research Society Medicare Coverage and Advisory Commission
4	MARLENE DEMAIO, MD	None	None	None	None	None	None	None	None	American Journal of Sports Medicine Clinical Orthopaedics and Related Research	American Orthopaedic Society for Sports Medicine Association of Bone and Joint Surgeons Ruth Jackson Orthopaedic Society

# **Public Comment Participants' Responses to Structured Public Comment Questions**

# **Questions 1-4**

Reviewer #	Name of Reviewer (Required)	of the society that	1. The overall objective(s) of the guideline is (are) specifically	question(s) covered by the guideline is (are) specifically	guideline's target audience is clearly	4. There is an explicit link between the recommendations and the supporting evidence.
1	Omer Ilah, MD	None Listed	Agree	Agree	Agree	Neutral
2	Richard Hawkins, MD	None Listed	Agree	Neutral	Agree	Agree
3	Anonymous	None Listed	Agree	Strongly Agree	Agree	Neutral
4	MARLENE DEMAIO MD	RUTH JACKSON ORTHOPAEDIC SOCIETY	Strongly Agree	Strongly Agree	Strongly Agree	Strongly Agree

# **Questions 5-8**

Reviewer #	Name of Reviewer (Required)	What is the name of the society that you are representing?	5. Given the nature of the topic and the data, all clinically important outcomes are considered.	6. The patients to whom this guideline is meant to apply are specifically described.	7. The criteria used to select articles for inclusion are appropriate.	8. The reasons why some studies were excluded are clearly described.
1	Omer Ilah, MD	None Listed	Neutral	Disagree	Disagree	Strongly Disagree
2	Richard Hawkins, MD	None Listed	Disagree	Agree	Agree	Agree
3	Anonymous	None Listed	Agree	Agree	Neutral	Agree
4	MARLENE DEMAIO, MD	RUTH JACKSON ORTHOPAEDIC SOCIETY	Neutral	Disagree	Strongly Agree	Strongly Agree

# **Questions 9-12**

Reviewer	Name of Reviewer	What is the name of the society that you are representing?	the article inclusion	appropriately	are described in such a way as to be reproducible.	12. The statistical methods are appropriate to the material and the objectives of this guideline.
1	Omer Ilah, MD	None Listed	Strongly Disagree	Disagree	Neutral	Neutral
2	Richard Hawkins, MD	None Listed	Agree	Agree	Agree	Agree
3	Anonymous	None Listed	Agree	Agree	Agree	Agree
4	MARLENE	RUTH JACKSON ORTHOPAEDIC SOCIETY	Strongly Agree	Strongly Agree	Strongly Agree	Strongly Agree

# **Questions 13-16**

Reviewer #	Name of Reviewer (Required)	What is the name of the society that you are representing?	13. Important parameters (e.g., setting, study population, study design) that could affect study results are systematically addressed.	14. Health benefits, side effects, and risks are adequately addressed.	15. The writing style is appropriate for health care professionals.	assigned to each
1	Omer Ilah, MD	None Listed	Neutral	Strongly Agree	Agree	Disagree
2	Richard Hawkins, MD	None Listed	Agree	Neutral	Neutral	Neutral
3	Anonymous	None Listed	Agree	Agree	Disagree	Neutral
4	MARLENE DEMAIO, MD	RUTH JACKSON ORTHOPAEDIC SOCIETY	Agree	Agree	Strongly Agree	Strongly Agree

# Would you recommend these guidelines for use in clinical practice?

Participant Number	Name of Participant (Required)		Would you recommend these guidelines for use in clinical practice?	
1	Omer Ilah, MD	None Listed	Would Not Recommend	
2	Richard Hawkins, MD	None Listed	Recommend With Revisions	
3	Anonymous	None Listed	Would Not Recommend	
4	MARLENE DEMAIO, MD	RUTH JACKSON ORTHOPAEDIC SOCIETY	Strongly Recommend	

# Public Comment Participants' Responses

#### Public Comment Participant #1, Omer Ilah, MD

Under the "ACL Radiographs" recommendation: Getting patellar views of both knees should be included as a suggestion so as to help exclude patellar instability. Under the "ACL Pediatric" recommendation: "Skeletally mature" for the purpose at hand should be defined as the closure of the distal femoral and proximal tibial physes, as one can be skeletally immature elsewhere even when the growth plates about the knee are fused. Just using the term "skeletally mature" without further defining it for the purposes of ACL surgery could lead to confusion. Under the "ACL Young Adult" recommendation: The word "active" should be added to the title. Also, this group of patients really begins with the closing of physes about the knee (see "skeletally mature" discussion above). Finally, to end this group of patients at age 35 comes across as arbitrary. I suggest the round number of 40 instead. Indeed, 40 is often used in various fields of medicine as the age at which evaluation and treatment often alters, such as the need for routine pre-op EKG, screening mammography, etc. Forty would be both easier to remember and more consistent with other age cut offs used in medicine. Under the "ACL Combined MCL" rationale section: I both question and disagree about complete MCL injury being defined as valgus laxity at full extension, as that usually implies additional posterior injury or incompetence. Indeed, I have seen complete MCL disruption seen on MRI - with the MCL actually folded back upon itself - without increased valgus laxity at full extension, but with grade 3 valgus laxity at 30 degrees of flexion. The caveat of this recommendation not applying to complete MCL injury in misleading and should be eliminated. Because the strength of each recommendation is explicitly sated below it in the "Strength of Evidence" section, it need not be stated in the recommendation itself. This should be throughout the guidelines. The "ACL Autograft vs. Allograft" analysis should have included the study by Barrett et al, Arthroscopy, 2010; 26:1593-1601. I really don't understand why it was excluded for deemed being "not best available evidence". Furthermore, the guidelines should indicate their focus is on primary ACL surgery, as the studies used are focused on that, and not on revision surgery. From my review of available literature (including the MOON data) it would be more truthful to state. "Results of autograft reconstruction appear to be superior to those of allograft reconstruction for primary ACL surgery in general; though some appropriately processed allografts may be a reasonable option, especially in select patients." The "ACL Post-Op Physical Therapy" title should be changed to "ACL Post-Op Rehabilitation Protocols". I feel strongly about this as most of my patients do not get formal PT following ACL surgery, but rather either do a home program that I give them, or work with a school athletic trainer who follows my protocol. Also, in the "Potential Harms of Implementation" section, it would appear that the word "elevated" is missing from the last line of the paragraph.

I noticed in the "ACL CPG Peer Review Report" that the AOSSM also would not recommend these guidelines for use in clinical practice. However, I did not see a review from the Arthroscopy Association of North America. Was AANA not invited to participate in the peer review process? Or, did they decline? Clearly, the members of that organization are major stake holders in guidelines about ACL surgery, and should have been encourage to participate. Although many members of AANA, like myself, are also members of AOSSM, these two organizations can have different takes on important clinical issues.

#### Public Comment Participant #2, Richard Hawkins, MD

1. EBM is the best we have available and is seldom level 1 or 2 studies. We need consider other levels and concensus. 2. No comment on allograft in younger patients. The Moon study gp published 20% failure. So allograph should not be used in younger patients. Evidence level 4 but it is the best we have. This area requires addressing. 3. Return to sports was poorly described. We have and need timelines. Even minimum time might apply. 4 these guidelines are better than some previous guidelines eg rotator cuff. There remains inherent weaknesses still in how we look at evidence and make recommendations. We are getting better.

#### **Public Comment Participant #3, Anonymous**

I commend the authors of the guidelines for the work they have done. The recommendations are generally appropriate. I recognize that standard "guidelines" methodology has been followed. The statements are likely all accurate in terms of "guidelines language" but developing a moderate recommendation on the basis of two published papers is of questionable benefit. Specific comments on the summary section: Clunky writing: ACL PEDIATRIC There is limited evidence in skeletally immature patients with torn ACLs, but it supports that the practitioner might perform surgical reconstruction because it reduces activity related disability and recurrent instability which may lead to additional injury Clunky writing: ACL MENISCAL REPAIR There is limited evidence in patients with combined ACL tears and reparable meniscus tears, but it supports that the practitioner might repair these meniscus tears when combined with ACL reconstruction because it improves patient outcomes. Unclear what the "reliable evidence" refers to? ACL LOCKED KNEE In the absence of reliable evidence, it is the opinion of the work group that patients with an ACL tear and a locked knee secondary to a displaced meniscal tear have prompt treatment to unlock the knee in order to avoid a fixed flexion contracture.

#### Public Comment Participant #4, Marlene DeMaio, MD (Ruth Jackson Orthopaedic Society

The AAOS and the Guideline authors are to be complimented on creating a very well organized and thorough document. It is clearly written with recommendations that reflect evidenced based medicine and SORT criteria. The Tables are especially helpful. The future directions section will help direct researchers and demonstrates areas of research gaps. I have read the Guideline and the Reviewers Comments document. My evaluation is based on the target audience, practicing orthopaedic surgeons. That is, my comments are less detailed that the Reviewers Comments because those specific areas that I had identified were either corrected on the Guideline I received for review or were addressed in the AAOS response to the specific reviewer's comments. (The majority of my questions were covered in the American Medical Society for Sports Medicine and the American Orthopaedic Society for Sports Medicine sections.) There are some remaining typographical errors: p21. III. Methods--there is no space between the roman numeral and Methods. p189. A number of references are missing. In their place is an error notation. In the meniscal repair section beginning on p92, there is no discussion on meniscal repair not coincident with the ACL reconstruction. There are some conditions in which the surgeon would consider repairing the meniscus first and then reconstructing the ACL at a later date. If it is too late to add literature discussing this, the authors may wish to make a statement regarding this or specifically stating that the review addressed meniscus repair done at the same time as the ACL reconstruction. Starting on page 76, ACL adult reconstruction is addressed. However, specific criteria for non-operative treatment or situations in which a non-operative approach should be considered is not included. Again, if it is too late in the process to include a literature review on this, the authors might consider making a statement on athletes in season, pregnant females, patients whose medical or surgical conditions are not optimized, and other situations in which non-operative management should be considered. Similarly, there are patients with ACL tears with no giving way or 3 or less episodes of giving way per year who meet criteria (balance, strength, agility) who may delay or elect not to have an ACL reconstruction. Graft selection recommendations begin on p198. The authors should state that the hamstring graft recommendations pertain to a quadrupled hamstring. The headings of some of the Tables specify quadrupled hamstrings and others don't. For the Tables that include hamstring grafts that are less than a quadrupled graft, this should be noted for clarity. The size of the hamstring quadrupled graft is not address. If it is too late to include literature on this, the authors may wish to make a statement or discuss size in the future directions section. Grafts 7mm or less have been noted to have a higher failure rate. Allografts are discussed on p313. There is a statement: "appropriately processed allograft." However, the authors do not specify what constitutes an appropriately processed graft. Consideration should be given to deleting "appropriately" and replacing it with "non-irradiated or low level irradiated graft." There is no discussion on the heterogeneity of allografts regarding the anatomic source. The most popular types of commercially available grafts include: BTB, hamstring, tibialis anterior, tibialis posterior, peroneal, and fascia lata. Quadriceps tendon allografts are not as easily obtained. Each of these grafts have different biomechanical properties (which, of course, are affected by processing and the age of the donor). It would be helpful to surgeons to point out that these grafts are not the same. There is no recommendation or statement on the use of allografts in the older patient (older that 35 or older than 45). A statement should be included for this patient group. Younger patients and the pediatric population are addressed. The location of the femoral tunnel for the ACL graft is evaluated beginning on p358. There is no

statement regarding the position of the anatomic (single bundle graft). Addition of this information would be helpful to surgeons. Neuromuscular ACL injury prevention programs are reviewed starting on p441. While poor compliance is referred to, additional comments would be helpful. For example: "It is unclear regarding the effect of compliance on outcome." "Most studies did not specifically record compliance." Also, it is unclear how the training programs affect the neuromuscular system after the program is stopped. The intervention (ACL prevention program) may not be permanent and probably has to be repeated for each season. Return to play and athletic activities are reviewed starting on p484. The use of functional movements screens is not included. This topic might be considered. In summary, this is an extremely thorough guideline. It will, no doubt, be extensively referred to by orthopaedic surgeons.

# Appendix A – Structured Peer Review/Public Comment Form

Peer reviewers are asked to read and review the draft of the clinical practice guideline with a particular focus on their area of expertise. Their responses to the answers below are used to assess the validity, clarity, and accuracy of the interpretation of the evidence. To view a live example of the structured peer review form, please select the following link: <a href="Structured Peer Review Form">Structured Peer Review Form</a>.

	Strongly Disagree	Disagree	Neutral	Agree	Strongly Agree
1. The overall objective(s) of the guideline is (are) specifically described.	0	0	0	0	0
<ol><li>The health question(s) covered by the guideline is (are) specifically described.</li></ol>	©	0	©	0	0
3. The guideline's target audience is clearly described.	0	0	0	0	0
<ol> <li>The guideline development group includes individuals from all the relevant professional groups.</li> </ol>	0	0	0	0	0
5. There is an explicit link between the recommendations and the supporting evidence.	0	0	0	0	0
<ol><li>Given the nature of the topic and the data, all clinically important outcomes are considered.</li></ol>	0	0	©	0	0
<ol><li>The patients to whom this guideline is meant to apply are specifically described.</li></ol>	0	0	0	0	0
<ol><li>The criteria used to select articles for inclusion are appropriate.</li></ol>	0	0	©	0	0
<ol><li>The reasons why some studies were excluded are clearly described.</li></ol>	0	0	0	0	0
<ol> <li>All important studies that met the article inclusion criteria are included.</li> </ol>	0	0	0	0	0
11. The validity of the studies is appropriately appraised.	0	0	0	0	0
12. The methods are described in such a way as to be reproducible.	0	0	©	0	0
<ol> <li>The statistical methods are appropriate to the material and the objectives of this guideline.</li> </ol>	0	0	0	0	0
<ol> <li>Important parameters (e.g., setting, study population, study design) that could affect study results are systematically addressed.</li> </ol>	0	0	0	0	0
15. Health benefits, side effects, and risks are adequately addressed.	0	0	0	0	0
<ol> <li>The writing style is appropriate for health care professionals.</li> </ol>	0	0	©	0	0
17. The grades assigned to each recommendation are appropriate.	0	0	0	0	0

Please provide a brief explanation of both your positive and negative answer If applicable, please specify the draft page and line numbers in your comme comment on the overall structure and content of the Guideline.	
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Would you recommend these guidelines for use in clinical practice?★	
<ul> <li>Strongly Recommend</li> <li>Recommend</li> <li>Would Not Recommend</li> <li>Unsure</li> </ul>	
Additional Comments:	
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