AAOS
American Academy of Orthopaedic Surgeons

Treatment of Pediatric Supracondylar Humerus Fractures Evidence-Based Clinical Practice Guideline

Peer Review and Public Comments with AAOS Responses

Changes Made to the Confidential Draft of the Guideline on the Treatment of Pediatric Supracondylar Humerus Fractures

Peer Review

November 15, 2010 – January 5, 2011

Public Comment

April 15, 2011 – May 15, 2011

Line 5 Title

Added "Evidence-Based" to the title.

Line 59-61 Summary of Recommendations

We edited these lines to include reference to the patient's guardian.

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

Line 490 Intended User Section

Removed: Insurance payers, governmental bodies, and health-policy decision-makers may also find this guideline useful. Physical therapists, occupational therapists trained in upper extremity rehabilitation, nurse practitioners, athletic trainers, primary care physicians, physician assistants and other healthcare professionals who routinely see this type of patient in various practice settings may also benefit from this guideline.

New section:

This guideline is intended to be used by orthopaedic surgeons and all physicians managing children with supracondylar fractures of the humerus. Typically, orthopaedic surgeons will have completed medical training, a qualified residency in orthopaedic surgery, and some may have completed additional sub-specialty training.

The guideline is intended to both guide clinical practice and to serve as an information resource for medical practitioners. An extensive literature base was considered during the development of this guideline. In general, practicing clinicians do not have the resources necessary for such a large project. The AAOS hopes that this guideline will assist practitioners not only in making clinical decisions about their patients, but also in describing, to patients and others, why the chosen treatment represents the best available course of action.

This guideline is not intended for use as a benefits determination document. Making these determinations involves many factors not considered in the present document, including available resources, business and ethical considerations, and need.

Users of this guideline may also want to consider any appropriate use criteria (AUC) that the AAOS has developed on the topic of this guideline. The focus of AAOS guidelines is on the question "Does it work?" When an AAOS guideline or an AAOS-endorsed guideline shows effectiveness, the AAOS may undertake development of AUC that ask the question "In whom does it work?" This dichotomy is necessary because the medical literature (both orthopaedic and otherwise) typically does not adequately address the latter question.

That having been said, evidence for the effectiveness of medical services is not always present. This is true throughout all areas of medicine. Accordingly, all users of this clinical practice guideline are cautioned that an absence of evidence is not evidence of ineffectiveness. An absence means just that; there are no data. It is the AAOS position that rigorously developed clinical practice guidelines should not seek to guide clinical practice when data are absent unless the disease, disorder, or condition in question can result in loss of life or limb. The AAOS incorporates expert opinion into a guideline under these circumstances, and only under these circumstances. Accordingly, when the AAOS states that it cannot recommend for or against a given intervention or service, it is stating that currently available data do not provide clear guidance on which course of action is best, and that it is therefore reluctant to make a recommendation that has potentially national ramifications. Although true in all circumstances, the AAOS believes that when evidence is absent, it is particularly important for the treatment for pediatric supracondylar fractures of the humerus in children to be based on the assumption that decisions are predicated on guardian and physician mutual communication with discussion of available treatments and procedures applicable to the individual patient. Once the patient's guardian has been informed of available therapies and has discussed these options with his/her child's physician, an informed decision can be made. Clinician input based on experience with conservative management and the clinician's surgical experience and skills increases the probability of identifying patients who will benefit from specific treatment options.

Line 510 Patient Population

Clarification has been added directing the reader to the study selection criteria for specific age criteria of included studies.

"This document addresses the treatment of isolated supracondylar fractures of the humerus in children who have not yet reached skeletal maturity (see Study Selection Criteria for specific age criteria of included studies)."

Line 567 Methods Section

The dates for this section were corrected. The Introductory Meeting for this guideline took place in October 2009 and the final meeting took place in October 2010.

Line 645 Outcomes Considered

We added the number of unique outcomes in the guideline.

Line 696 Methods for Evaluating the Quality of the Evidence

Additional text was added discussing the definition of "acute" and the classifications systems used for pediatric supracondylar fractures of the humerus. This text was also referenced in the rationale for Recommendation 2.

Classification of the Fracture

Timing

Based on the evidence, acute fracture we defined patients with "acute" fractures as those patients who presented for treatment within fourteen days of injury. Please see the supporting evidence for Recommendation 1 for additional information.

Systems of Classification

There are numerous fracture classification systems employed by surgeons to help evaluate, plan and standardize treatment. Classification systems communicate the displacement, comminution and rotation of the fracture being treated but no single classification system has perfect inter and intra observer reliability. Further, no classification system can precisely classify all fractures without consideration of additional clinical factors including the mechanism of injury, time and duration since injury, soft tissue damage and swelling and/or presence of neurovascular compromise. Hence, within the guideline we reference the Gartland classification system as a point of reference and not a standard for fracture classification.

The Gartland classification system also applies only to extension and not flexion fractures. However, within our guideline all recommendations that address a displaced fracture refer to both extension and flexion fractures. The ultimate goal of treatment is to achieve optimal outcomes for the patient. As stated throughout the guideline, treatments and procedures applicable to the individual patient rely on mutual communication between the patient's guardian and physician, weighing the potential risks and benefits for that patient based on their individual circumstances, injury and presentation.

Line 984 Recommendation 1

"e.g. Gartland Type I" was added for clarification.

Line 995 Recommendation 2

The parenthetical was changed to include e.g. and delineate that the Gartland Classification system is one of many.

Line 1149 Recommendation 3

The recommendation was edited from:
The practitioner might use two or three laterally introduced pins to stabilize the reduction of displaced pediatric supracondylar fractures of the humerus.

To:

The practitioner might use two or three laterally introduced pins to stabilize the reduction of displaced pediatric supracondylar fractures of the humerus. Considerations of potential harm indicate that the physician might avoid the use of a medial pin.

Line 1166 Recommendation 3

The word “significant” was edited to remove the “l” at the end; a typographical error.

Line 1247 Recommendation 3

The following sentence was added to the rationale: “*The risk of potential harm from a medial pin must be weighed against the potential advantages*.”

Line 1283 Recommendation 3

The following sentence was added for clarification:

“The risk of potential harm from a medial pin must be weighed against the potential advantages.”

Line 1345 Recommendation 4

The recommendation was edited from:

We cannot recommend for or against using an open incision to introduce a medial pin to stabilize the reduction of displaced pediatric supracondylar fractures of the humerus.

To:

We cannot recommend for or against using an open incision as a means of increasing the safety of introduction of a medial pin.

Line 1470 Recommendation 6

The recommendation was edited for clarification from:

> *The practitioner might perform open reduction for displaced pediatric supracondylar fractures of the humerus with varus or other malposition after closed reduction.*

To:

> *The practitioner might perform open reduction for displaced pediatric supracondylar fractures of the humerus following closed reduction if varus or other malposition of the bone occurs.*

Line 1724 Recommendation 8

Changed from:

In the absence of reliable evidence, the opinion of the work group is that open exploration of the antecubital fossa be performed in patients with absent wrist pulses and decreased perfusion, if the hand remains underperfused after reduction and pinning of displaced pediatric supracondylar humerus fractures.

To:

In the absence of reliable evidence, the opinion of the work group is that open exploration of the antecubital fossa be performed in patients who have absent wrist pulses and underperfusion after reduction and pinning of displaced pediatric supracondylar humerus fractures.

Line 1699 Recommendation 11

The word “blind” was corrected to “blinded”.

Line 1702 Recommendation 11

We removed the word “*slightly*” from the following sentence:

Patients in the physical therapy group had [*slightly*] better range of motion at both 12-13 weeks and 18-19 weeks.

Line 1759 Recommendation 12

We added the following text to identify the critical outcomes that were searched:

“Two critical outcomes were searched to answer this recommendation, incidence of refracture and timing of refracture.”

The reference for the Gartland Classification system was added to the excluded study list:

Gartland JJ. *Management of Supracondylar Fractures of the humerus in children*. Surgery, Gynecology and Obstetrics, 1959 (PMID: 13675986)

American Academy of Orthopaedic Surgeons
[The Treatment of Pediatric Supracondylar Fractures]
Guidelines Peer Review Form

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

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

Please note that if you return a review:

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

Reviewer Information:

Name of Reviewer Anonymous
Address_ _____

City _____ State____MD_____ Zip Code_____

Phone _____Fax __
E-mail_ _____

Specialty Area/Discipline: ___Pediatrics, Urgent Care Medicine_____

Work setting: ___ _____Credentials: ___ _____

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

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

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

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

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

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

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

☒ **I have declared my conflicts of interest on page 2 of this form.**

☐ **I have declared my conflicts of interest in the AAOS database; my customer # is _____**

☒ **I understand that the AAOS will post my declared conflicts of interest with my comments concerning review of this guideline on the AAOS website.**

American Academy of Orthopaedic Surgeons
[The Treatment of Pediatric Supracondylar Fractures]
Guidelines Peer Review Form

REVIEWER CONFLICT OF INTEREST - The Orthopaedic Disclosure Program

Each item below requires an answer. Please report information for the last 12-months as required by the Accreditation Council for Continuing Medical Education (ACCME) guidelines.

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

American Academy of Orthopaedic Surgeons
[The Treatment of Pediatric Supracondylar Fractures]
Guidelines Peer Review Form

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

Please complete and return this form electronically in **WORD format** to wies@aaos.org; please contact Jan Wies at (847) 384-4311 if you have any questions. Thank you in advance for your time in completing this form and giving us your feedback. We value your input and greatly appreciate your efforts. Please return the completed form **in WORD format** by end of day **January 5, 2011**.

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

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

COMMENTS

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

Dear Dr. Anonymous,
We appreciate your thoughtful input. We sincerely appreciate the time and expertise you have contributed to the review of this document. Your input has helped us strengthen the final document we will present to the AAOS Board of Directors for approval.

Thank you.

OVERALL ASSESSMENT

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

☒ Strongly recommend

☐ Recommend (with provisions or alterations)

☐ Would not recommend

☐ Unsure

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

American Academy of Orthopaedic Surgeons
[The Treatment of Pediatric Supracondylar Fractures]
Guidelines Peer Review Form

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

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

Please note that if you return a review:

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

Reviewer Information:

Name of Reviewer___David Ring, MD PhD; Chair of the ASSH Evidence Based Practice Committee_____

Address_Massachusetts General Hospital; Yawkey 2100; 55 Fruit St_____

City___Boston_____ State_____MA_____ Zip Code___02114_____

Phone __617-643-7527_____Fax ___617-724-8532_____E-mail__dring@partners.org_____

Specialty Area/Discipline: _____Orthopaedic Surgery; Hand Surgery_____

Work setting: ___Academic Medical Center_____Credentials: ____MD PhD_____

May we list you as a Peer Reviewer in the final Guidelines (GL)? ☒ Yes ☐ No
PLEASE READ: If you do not wish to be listed, your name will be removed for identification purposes. However, your review comments, our responses and your COI will still be available for public review on our website with the posted Guideline if you complete this review.

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

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

Society Name: ___American Society for Surgery of the Hand_____
(Listing the specialty society as a reviewing society does not imply or otherwise indicate endorsement of this guideline.)

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

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

☒ **I have declared my conflicts of interest on page 2 of this form.**

☒ **I have declared my conflicts of interest in the AAOS database; my customer # is _136145_____**

☒ **I understand that the AAOS will post my declared conflicts of interest with my comments concerning review of this guideline on the AAOS website.**

American Academy of Orthopaedic Surgeons
[The Treatment of Pediatric Supracondylar Fractures]
Guidelines Peer Review Form

REVIEWER CONFLICT OF INTEREST - The Orthopaedic Disclosure Program

Each item below requires an answer. Please report information for the last 12-months as required by the Accreditation Council for Continuing Medical Education (ACCME) guidelines.

Do you or a member of your immediate family receive royalties for any pharmaceutical, biomaterial or orthopaedic product or device? If YES, please identify product or device: Wright Medical Evolve Elbow Plates; Contract with Biomet and Skeletal Dynamics but nothing yet received.	☒ Yes ☐ No
Within the past twelve months, have you or a member of your immediate family served on the speakers bureau or have you been paid an honorarium to present by any pharmaceutical, biomaterial or orthopaedic product or device company? If YES, please identify company: Acumed	☒ Yes ☐ No
Are you or a member of your immediate family a PAID EMPLOYEE for any pharmaceutical, biomaterial or orthopaedic device or equipment company, or supplier? If YES, please identify company or supplier:	☐ Yes ☒ No
Are you or a member of your immediate family a PAID CONSULTANT for any pharmaceutical, biomaterial or orthopaedic device or equipment company, or supplier? If YES, please identify company or supplier: Acumed, Tornier, Wright, Biomet, Skeletal Dynamics	☒ Yes ☐ No
Are you or a member of your immediate family an UNPAID CONSULTANT for any pharmaceutical, biomaterial or orthopaedic device or equipment company, or supplier? If YES, please identify company or supplier:	☐ Yes ☒ No
Do you or a member of your immediate family own stock or stock options in any pharmaceutical, biomaterial or orthopaedic device or equipment company, or supplier (excluding mutual funds) If YES, please identify company or supplier: Illuminoss, Mimedex.	☒ Yes ☐ No
Do you or a member of your immediate family receive research or institutional support as a principal investigator from any pharmaceutical, biomaterial or orthopaedic device or equipment company, or supplier? If YES, please identify company or supplier: Stryker, Joint Active Systems, Biomet	☒ Yes ☐ No
Do you or a member of your immediate family receive any other financial or material support from any pharmaceutical, biomaterial or orthopaedic device and equipment company or supplier? If YES, please identify company or supplier:	☐ Yes ☒ No
Do you or a member of your immediate family receive any royalties, financial or material support from any medical and/or orthopaedic publishers? If YES, please identify publisher: Quarterly stipend as Deputy Editor for The Journal of Hand Surgery	☒ Yes ☐ No
Do you or a member of your immediate family serve on the editorial or governing board of any medical and/or orthopaedic publication? If YES, please identify: Several including deputy or associate editor for JHS, JOT, and JSES	☒ Yes ☐ No
Do you or a member of your immediate family serve on the Board of Directors or a committee of any medical and/or orthopaedic professional society? If YES, please identify:	☐ Yes ☒ No

American Academy of Orthopaedic Surgeons
[The Treatment of Pediatric Supracondylar Fractures]
Guidelines Peer Review Form

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

Please complete and return this form electronically in **WORD format** to wies@aaos.org; please contact Jan Wies at (847) 384-4311 if you have any questions. Thank you in advance for your time in completing this form and giving us your feedback. We value your input and greatly appreciate your efforts. Please return the completed form **in WORD format** by end of day **January 5, 2011**.

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

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

COMMENTS

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

Dear Dr. Ring and the ASSH EBP Committee,

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

1. **It should be more clearly emphasized that these are Evidence based guidelines rather than consensus based guidelines. Given the limited amount of evidence for orthopaedic conditions, that means that the guideline is more of a roadmap for the evidence that we need to generate, or a report card on how we are doing than it is a guide for surgeons and patients.**

   Based on your comments, we have added "Evidence-Based" to the title of the guideline at line 5. Also, the AAOS is now transitioning away from topics that are of interest to only one or two Orthopaedic specialty societies and turning to broader topic areas.

2. **The existence of consensus statements such as items 7 and 8 are a product of the guideline process. I think this type of question is asked not because it is a debatable aspect of management for which we look to scientific evidence for clarification or resolution. Rather, the work group feels the need to be comprehensive and address each aspect of management. It's reminiscent of the distal radius fracture guideline where the group foolishly asked a question about complex regional pain syndrome and had to life with the consequence of doing to. I think we are still getting familiar with this process and it would help advance growth, improvement, and acceptance of evidence-based guidelines if you are very open about these shortcomings.**

   We will consider any additional suggestions you have concerning improving the process.

   During the "Introductory Meeting" for each guideline, we ask that the work group construct preliminary recommendations based on the treatment pathway for patients. This helps organize, clarify and, as you suggest, comprehensively cover the guideline topic. We also try to give direction when consulted as to the consequences of some recommendations and we have been fortunate in that some members who have participated on past work groups are now repeating their participation. Work group members with previous experience add additional input that is always helpful. They often highlight the problems that result from "fishing expeditions". If you have additional input as to how we can improve the process, we welcome your suggestions.

3. **Consider that only 4 of 14 statements have weak or moderate support. This document is an indictment of orthopaedic science. It should be framed as such. Framing it as an algorithm or recipe for how to manage patients leads readers to misinterpret or overinterpret what they read.**

   This guideline conforms to the general template used for all AAOS guidelines. AAOS Guidelines are meant to have the same "look" and "feel" for our members. It is however, incumbent on any reader of these documents to fully read and understand the evidence for all recommendations.

   Further, work group members who have participated on other guidelines, have already initiated several studies to answer critical questions and we are heartened that they are making progress to improving the evidence-base in Orthopaedics.

OVERALL ASSESSMENT

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

☐ Strongly recommend

☒ Recommend (with provisions or alterations)

☐ Would not recommend

☐ Unsure

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

Dear Dr. Ring and the ASSH EBP Committee,
We sincerely appreciate the time and expertise you have contributed to the review of this document. Your input has contributed to strengthening the final document we will present to the AAOS Board of Directors for approval.
Thank you.

American Academy of Orthopaedic Surgeons
[The Treatment of Pediatric Supracondylar Fractures]
Guidelines Peer Review Form

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

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

Please note that if you return a review:

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

Reviewer Information:

Name of Reviewer___Joshua M. Abzug, MD _____

Address__109 Voyager Dr._____

City__Deptford_____ State__NJ_____ Zip Code_08096_____

Phone _717-495-3761_____Fax _____E-mail_jabzug1@yahoo.com_____

Specialty Area/Discipline: __Pediatric Upper Extremity_____

Work setting: _Shriner's Hospital – Philadelphia/ St. Christopher's Hospital for Children_Credentials: _____

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

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

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

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

Society Name: __American Association for Hand Surgery_____
(Listing the specialty society as a reviewing society does not imply or otherwise indicate endorsement of this guideline.)

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

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

X **I have declared my conflicts of interest on page 2 of this form.**

☐ **I have declared my conflicts of interest in the AAOS database; my customer # is _____**

☐ **I understand that the AAOS will post my declared conflicts of interest with my comments concerning review of this guideline on the AAOS website.**

American Academy of Orthopaedic Surgeons
[The Treatment of Pediatric Supracondylar Fractures]
Guidelines Peer Review Form

REVIEWER CONFLICT OF INTEREST - The Orthopaedic Disclosure Program

Each item below requires an answer. Please report information for the last 12-months as required by the Accreditation Council for Continuing Medical Education (ACCME) guidelines.

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

American Academy of Orthopaedic Surgeons
[The Treatment of Pediatric Supracondylar Fractures]
Guidelines Peer Review Form

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

Please complete and return this form electronically in **WORD format** to wies@aaos.org; please contact Jan Wies at (847) 384-4311 if you have any questions. Thank you in advance for your time in completing this form and giving us your feedback. We value your input and greatly appreciate your efforts. Please return the completed form **in WORD format** by end of day **January 5, 2011**.

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

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

COMMENTS

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

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

As we are dealing with pediatric patients, page iii, line 59, should include a statement regarding the decision maker for the child: ie. …communication between patient and their parent or representative, physician…. (akin to page 2 line 501)

We agree and have edited line 59-61 to read as follows:

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

Consideration should be made to include discussion/recommendations regarding utilization of semi-sterile technique when treating these fractures in the operating room with closed reduction and percutaneous pinning as opposed to formal sterile technique.

(J Pediatr Orthop. 2007 Jan-Feb;27(1):17-22. **Percutaneous pinning of pediatric supracondylar humerus fractures with the semisterile technique: the Miami experience.** Iobst CA, Spurdle C, King WF, Lopez M.)

The workgroup cannot introduce new recommendations into the guideline at this time. We must adhere to the AAOS production schedule for guidelines. New recommendations would require both additional literature searches and additional peer review.

Consideration should be made to discuss/recommend the need for post-operative observation compared to the safety of same day surgery.

The workgroup cannot introduce new recommendations into the guideline at this time. We must adhere to the AAOS production schedule for guidelines. New recommendations would require both additional literature searches and additional peer review.

Consideration should be made to discuss/recommend the need for pre-operative and/or post-operative antibiotics when performing closed reduction and pinning of pediatric supracondylar fractures.

The workgroup cannot introduce new recommendations into the guideline at this time. We must adhere to the AAOS production schedule for guidelines. New recommendations would require both additional literature searches and additional peer review.

Page 4, lines 567-570, chronological order does not make sense….Introductory meeting on Oct. 4, 2010 but then finalized recommendations on Oct 2-3, 2010.

We agree and this error has been corrected:

"To develop this guideline, the work group held an introductory meeting on October 4, 2009 to establish the scope of the guideline and the systematic reviews. Upon completing the systematic reviews, the work group participated in a two-day recommendation meeting on October 2 and 3, 2010 at which the final recommendations and rationales were edited, written and voted on. An initial draft was completed and submitted for peer review November 15, 2010.

OVERALL ASSESSMENT

American Academy of Orthopaedic Surgeons
[The Treatment of Pediatric Supracondylar Fractures]
Guidelines Peer Review Form

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

☐ Strongly recommend

X☐ Recommend (with provisions or alterations)

☐ Would not recommend

☐ Unsure

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

Dear Dr. Abzug,

We sincerely appreciate the time and expertise you have contributed to the review of this document. Your input has contributed to strengthening the final document we will present to the AAOS Board of Directors for approval. Thank you.

American Academy of Orthopaedic Surgeons
[The Treatment of Pediatric Supracondylar Fractures]
Guidelines Peer Review Form

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

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

Please note that if you return a review:

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

Reviewer Information:

Name of Reviewer___Donald S. Bae_____

Address____300 Longwood Avenue, Hunnewell 2_____

City__Boston_____ State___MA_____ Zip Code_____02115_____

Phone ___617-355-6808_____Fax _617-730-0459___E-mail___donald.bae@childrens.harvard.edu_____

Specialty Area/Discipline: ____Pediatric Orthopaedic and Hand Surgery_____

Work setting: ____Childre's Hospital Boston_____Credentials: _____

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

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

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

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

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

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

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

X **I have declared my conflicts of interest on page 2 of this form.** X I **have declared my conflicts of interest in the AAOS database; my customer # is _209983_____**
X **I understand that the AAOS will post my declared conflicts of interest with my comments concerning review of this guideline on the AAOS website.**

American Academy of Orthopaedic Surgeons
[The Treatment of Pediatric Supracondylar Fractures]
Guidelines Peer Review Form

REVIEWER CONFLICT OF INTEREST - The Orthopaedic Disclosure Program

Each item below requires an answer. Please report information for the last 12-months as required by the Accreditation Council for Continuing Medical Education (ACCME) guidelines.

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

American Academy of Orthopaedic Surgeons
[The Treatment of Pediatric Supracondylar Fractures]
Guidelines Peer Review Form

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

Please complete and return this form electronically in **WORD format** to wies@aaos.org; please contact Jan Wies at (847) 384-4311 if you have any questions. Thank you in advance for your time in completing this form and giving us your feedback. We value your input and greatly appreciate your efforts. Please return the completed form **in WORD format** by end of day **January 5, 2011**.

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

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

COMMENTS

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

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

Page 2, line 510: Not all supracondylar humerus fractures in "skeletally immature patients" are the same. The current guidelines are most applicable to the supracondylar humerus fracture in the child between 2 and 12 years of age. While this is in part addressed with recommendation #14, I question whether for clarity's sake, the phrase "skeletally immature patients" be replaced with something more specific or descriptive.

We understand that the term "skeletally immature patients" is vague. The work group made it deliberately vague so as not to be overly restrictive in how physicians practice.

The patient population for the included studies is defined in the inclusion criteria at line 607 as follows:

- *≥80% of the enrolled study population must be < 12 years of age at the time of fracture (for all Recommendations except 14) For Recommendation 14, ≥80% of the enrolled study population must be >12 and <18.*

Based on your comments, we have added clarification to page 2, line 510:
"This document addresses the treatment of isolated supracondylar fractures of the humerus in children who have not yet reached skeletal maturity (see Study Selection Criteria for specific age criteria)."

Page 15, line 923: There is no reference to the sensitivity and specificity of the "posterior fat pad sign" in diagnosing the radiographically occult supracondylar humerus fracture in the younger child. Prior published information (Skaggs, JBJS, 1999) suggests this is associated with fractures 76% of the time in the setting of recent trauma and pain/tenderness.

Recommendation 1 addresses treatment. This recommendation does not question the diagnostic precision of the posterior fat pad sign; rather the work group considered this common practice. The study authored by Skaggs DL, 1999 was therefore not relevant.

Skaggs DL, Mirzayan R. The posterior fat pad sign in association with occult fracture of the elbow in children. J Bone Joint Surg Am 1999; 81(10):1429-1433.

Page 53, line 1149: is the term "might" appropriate here?

Recommendation 3:
The practitioner might use two or three laterally introduced pins to stabilize the reduction of displaced pediatric supracondylar fractures of the humerus.

Yes, the word "might" is appropriate in this recommendation. Please see Table 6, AAOS Guideline Language, line 801 in the document. We write each recommendation so that the language of the recommendation accounts for the final strength of the evidence. The overall strength of the evidence for Recommendation 3 is "weak". The supporting evidence is from "low" strength studies and correspondingly indicates our degree of confidence in this evidence. Future high quality studies could potentially overturn the conclusions of this evidence. As

indicated in Table 6, the corresponding guideline language used for this strength of recommendation is "The Practitioner Might".

Table 1 AAOS guideline language

Guideline Language	Strength of Recommendation
We ***recommend***	Strong
We ***suggest***	Moderate
The Practitioner ***might***	Weak
We are ***unable to recommend for or against***	Inconclusive
In the absence of reliable evidence, the ***opinion*** of this work group is*	Consensus*

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

Page 91, line 1346-7: There seems to be a leap between recommendations #3 and #4. No comment or recommendation is made regarding the use of a medial-entry pin.

Recommendation 3 is based on weak evidence, includes consideration of harms and benefits associated with lateral and medial introduction of pins, and is based on 65 outcomes from 15 low or moderate quality studies. The work group wrote the recommendation indicating a mild preference for laterally introduced pins based on the entire body of evidence weighing the harms and benefits. Both Recommendation 3 and 4 have been edited for clarification in response to peer review comments. Recommendation 3 now reads:

The practitioner might use two or three laterally introduced pins to stabilize the reduction of displaced pediatric supracondylar fractures of the humerus. In the absence of strong evidence, considerations of potential harm indicate that the physician might avoid the use of a medial pin.

Recommendation 4 now reads:

We cannot recommend for or against using an open incision as a means of increasing the safety of introduction of a medial pin.

OVERALL ASSESSMENT

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

Strongly recommend

X Recommend (with provisions or alterations)

☐ Would not recommend

☐ Unsure

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

Dear Dr. Bae,

American Academy of Orthopaedic Surgeons
[The Treatment of Pediatric Supracondylar Fractures]
Guidelines Peer Review Form

We sincerely appreciate the time and expertise you have contributed to the review of this document. Your input has contributed to strengthening the final document we will present to the AAOS Board of Directors for approval. Thank you.

American Academy of Orthopaedic Surgeons
[The Treatment of Pediatric Supracondylar Fractures]
Guidelines Peer Review Form

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

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

Please note that if you return a review:

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

Reviewer Information:

Name of Reviewer__Randall S. Burd, MD, PhD_____

Address__Children's National Medical Center, 111 Michigan Ave NW

City__Washington_____ State_____DC_____ Zip Code____20010__

Phone ___202-476-2151_____Fax _202-476-4174__E-mail_____rburd@cnmc.org____

Specialty Area/Discipline: _____Pediatric trauma/pediatric surgery

Work setting: __Academic/hospital-based Credentials: __Board certified in surgery and pediatric surgery

---

May we list you as a Peer Reviewer in the final Guidelines (GL)? xYes ☐ No
PLEASE READ: If you do not wish to be listed, your name will be removed for identification purposes. However, your review comments, our responses and your COI will still be available for public review on our website with the posted Guideline if you complete this review.

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

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

Society Name: ___American Pediatric Surgery Association__
(Listing the specialty society as a reviewing society does not imply or otherwise indicate endorsement of this guideline.)

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

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

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

American Academy of Orthopaedic Surgeons
[The Treatment of Pediatric Supracondylar Fractures]
Guidelines Peer Review Form

REVIEWER CONFLICT OF INTEREST - The Orthopaedic Disclosure Program

Each item below requires an answer. Please report information for the last 12-months as required by the Accreditation Council for Continuing Medical Education (ACCME) guidelines.

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

American Academy of Orthopaedic Surgeons
[The Treatment of Pediatric Supracondylar Fractures]
Guidelines Peer Review Form

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

Please complete and return this form electronically in **WORD format** to wies@aaos.org; please contact Jan Wies at (847) 384-4311 if you have any questions. Thank you in advance for your time in completing this form and giving us your feedback. We value your input and greatly appreciate your efforts. Please return the completed form **in WORD format** by end of day **January 5, 2011**.

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

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

COMMENTS

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

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

My evaluation and overall assessment is focused mainly on the recommendations that I have the expertise to comment on, namely the management of vascular injury associated with supracondylar fractures (recommendations 8 and 9). I believe that the review and associated recommendations for this issue are appropriate and have no additional comments.

Thank you for your input Dr. Burd.

OVERALL ASSESSMENT

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

x Strongly recommend

☐ Recommend (with provisions or alterations)

☐ Would not recommend

☐ Unsure

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

American Academy of Orthopaedic Surgeons
[The Treatment of Pediatric Supracondylar Fractures]
Guidelines Peer Review Form

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

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

Please note that if you return a review:

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

Reviewer Information:

Name of Reviewer_Steven L Frick___

Address_____5939 Cabell View Ct_____

City__Charlotte_____ State____NC_____ Zip Code__28277_____

Phone ___7045409888_____Fax _E-mail_steven.frick@carolinashealthcare.org_____

Specialty Area/Discipline: _____orthopedics / pediatric_____

Work setting: ____academic_____Credentials: __MD, peds ortho fellowship_____

May we list you as a Peer Reviewer in the final Guidelines (GL)? xYes ☐ No
PLEASE READ: If you do not wish to be listed, your name will be removed for identification purposes. However, your review comments, our responses and your COI will still be available for public review on our website with the posted Guideline if you complete this review.

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

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

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

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

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

☐ **I have declared my conflicts of interest on page 2 of this form.** x**I have declared my conflicts of interest in the AAOS database; my customer # is ____083774_____**
x**I understand that the AAOS will post my declared conflicts of interest with my comments concerning review of this guideline on the AAOS website.**

American Academy of Orthopaedic Surgeons
[The Treatment of Pediatric Supracondylar Fractures]
Guidelines Peer Review Form

REVIEWER CONFLICT OF INTEREST - The Orthopaedic Disclosure Program

Each item below requires an answer. Please report information for the last 12-months as required by the Accreditation Council for Continuing Medical Education (ACCME) guidelines.

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

American Academy of Orthopaedic Surgeons
[The Treatment of Pediatric Supracondylar Fractures]
Guidelines Peer Review Form

Reviewer Instructions

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

Please complete and return this form electronically in **WORD format** to wies@aaos.org; please contact Jan Wies at (847) 384-4311 if you have any questions. Thank you in advance for your time in completing this form and giving us your feedback. We value your input and greatly appreciate your efforts. Please return the completed form **in WORD format** by end of day **January 5, 2011**.

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

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

COMMENTS

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

Dear Dr. Frick,
We appreciate your thoughtful input. In order to address your concerns, please find below a point-by-point response that has been edited and approved by the AAOS Chair and Vice-Chair of the physician work group that developed this guideline. Based on your comments, Dr. Turkelson and the Guidelines Oversight Chairs have also reviewed this response.

Re 10 and 11 above - Without Dr Turkelson's guidance I wonder how many would collect and analyze this same data set and come to the same conclusions.

The AAOS uses the scientific method to develop its clinical practice guidelines. This method is well-known.

In the scientific method, one begins by asking questions, and by then using empirical data, collected according to scientific rules, to answer those questions. These answers are then converted into the guideline's final recommendations. The AAOS uses the scientific method because centuries of knowledge (the first clinical study that would have met our inclusion criteria was conducted by Daniel of Judea in about 600 BC, but see also the literature on the philosophy of science and, particularly the works of Karl Popper), shows that it is the most reliable way to separate that which is true from that which is not.

Granted, the AAOS does not rigorously apply this method when determining which studies to include. For example, prospective but uncontrolled studies are always included if they are the best available evidence. This means that those who apply the scientific method more stringently than the AAOS would be unlikely to make as many recommendations as were in this guideline. However, given that the hallmark of the scientific method is its ability to produce reproducible results, we are confident that anyone who adopted the same set of relatively lax rules used for the present guideline would come to the same conclusions.

My main criticism is about the structure of the CPG process and the lack of inclusion of retrospective case series that constitute the majority of the orthopaedic literature. It would be more helpful to clinicians if the staff could develop additional methodology to define the better level IV studies, review them and have the CPG panel then give summary statements (for example – the risk of ulnar nerve injury is higher with medial and lateral entry pins than with lateral entry alone; three weeks of pin fixation is supported by level IV studies and a lack of reports of refractures or nonunions following pin removal at three weeks, etc. The literature for SCH fractures in children that clinicians base practice on is largely retrospective, and the CPG process completely ignores this body of literature and the history of orthopaedics- the collective findings of these studies creates the principles and decision-making framework for clinical practice. Thus I disagree that the statistical methods employed are appropriate to the objectives of the CPG ("to help improve practice based on the current best evidence"- for many areas of orthopaedics the current best evidence is level IV studies that are not considered here).

You are correct in pointing out that the guideline did not include data from retrospective case series studies. Such studies lack virtually every component of a scientifically-conducted study, even a hypothesis. As Grimes and Schultz (2002) have noted (this article is also quoted in Carey and Boden (2003, pg. 1631), "The case series is one of a group of descriptive studies that by their very nature do not test the hypothesis of treatment efficacy." Carey and Boden go on to state, "That is, a case series is not the appropriate design to determine whether a treatment works or not."

It is not possible for staff to "develop methodology to define the better level IV studies." There is no such thing as a "better" retrospective case series. They do not constitute scientific evidence. One difficulty with retrospective studies are that because they lack an *a priori* hypotheses, one can see almost anything in their data that one wishes to see and, if

enough people go retrospectively looking for the same thing, somebody will find it. The best use of such studies is to generate a hypothesis that one will later test in a scientific study. However, the presence of a hypothesis is not sufficient for the AAOS to make practice recommendations that could have widespread implications. Since retrospective studies do not provide causally valid relationships, it is not clear that these studies are truly helpful to the practicing orthopaedic surgeon.

You state that these studies "constitute the majority of the orthopaedic literature" and imply that, based on volume and availability, the study design somehow gains precision, accuracy, reproducibility and increases its level of evidence. This is simply not correct. Whether you include 10 studies or 100 studies of weak quality, the overall strength of the recommendation will remain weak (please see the GRADE working group criteria) because one should not have confidence in the conclusions of these studies; they are too prone to bias. Their results are too unreliable to base clinical practice on. It is disconcerting that these studies "create the principles and decision-making framework for clinical practice" of pediatric supracondylar fractures.

Finally, even Level V evidence, consensus of the work group, is used in this guideline (see recommendations 7 and 8). The inclusion criteria for the literature for this guideline are more liberal than those of the JBJS system. The fact that we include any prospective case series studies make our inclusion criteria more liberal than that used by most methodologists. By not including retrospective case series, we are not considering those studies that are most likely to produce misleading results. We prefer to defer to the level V opinion of the experts on the work group to consider the evidence and evaluate the harms and the benefits associated with a given treatment as opposed to including such unreliable weak evidence as retrospective case series.

Reference: Carey T.S. and Boden S.D. (2003) *A Critical Guide to Case Series Reports*, *SPINE* Vol. 28 (15) pp. 1631-1634

The end result in my view of most of the CPGs released to this point is similar- we have very poor quality literature, and need more prospective randomized trials. This is take home message I got from reading this CPG also- I believe it would give someone (perhaps the press or a lay person/parent) the idea that we do not know what we are doing and clinical practice is not based on any knowledge base because we don't have any PRTs to assess all of the clinical decision points in managing a child with a SCH fracture. The reality is that all of those points cannot practically be studied- should you use a splint or a cast? Should you use 3 pins all the time or only 2? Does pin size matter? Does arm size matter? How important is it to obtain an anatomic reduction? Is it ok to take the pins out at 3 weeks every time? What are the risks of an extra week with the pins in? Do pins last longer if covered with sterile felt? As I ask more questions that may effect the outcome, the statisticians see problems with the power of any study, and the "quality" of the literature gets downgraded. A glaring example of level IV studies that are clinically important in the management of SCHF in children, and that are not discussed in this guideline, are those case series that emphasize the importance of recognizing medial column comminution and varus malalignment, and reducing it to prevent malunion.

1. We agree concerning the quality of the literature. Please note, however, that we did not (and are not) restricting the literature we would include to just randomized controlled trials. We include all prospective case series and, in doing so, we are merely asking people to think about the data they should be collecting before they collect it. This is not a very high bar.

2. Not every question can be answered in any guideline on all topics of interest. The attempt in the current AAOS guidelines is to avoid questions that are as granular as the ones you list. The physician work group determines the guideline's scope by constructing preliminary recommendations at a guideline introductory meeting. Due to time and budget constraints, the number of recommendations for a guideline is limited to those of greatest importance to the work group.

3. The recommendations that ultimately appear in the guideline are not limited based on the level of evidence; we address every recommendation formulated at the introductory meeting. This is to limit bias and increase transparency. Members cannot eliminate evidence they do not agree with.

4. If the level IV studies you refer to above were not included in this guideline, either they did not answer a recommendation in the guideline (These studies may report on diagnostic or fracture classification issues), there was 2 or more studies of higher level evidence available to address the recommendation (in this case, the studies should be listed in the excluded studies list) or the work group did not ask a question regarding these particular aspects. Varus malalignment was considered a critical outcome and is explicitly reported in five of the eleven studies included in recommendation two, and is incorporated in the other six studies by using accepted aggregate outcome criteria such as Flynn's criteria. We did not set out to describe the relationship between medial comminution and the potential for varus malalignment because the scope of the guideline is focused on evaluating evidence for statements regarding treatment, rather than statements regarding diagnosis.

The purpose of EBM (use of best available literature to support clinical decision-making) is primarily to maximize the opportunity for your patient to have a good outcome. I believe that the available literature on SCH fractures, understanding the limitations of retrospective studies, provides a good framework for a knowledgeable surgeon to understand the principles of care and achieve good outcomes for his or her patient. Interestingly these guidelines do not cover some of these basic principles of fracture care that can be gleaned from the level IV literature available; for example- 1) obtaining an acceptable reduction- there are no references to articles describing the best method of reducing SCHF, and there is no mention of how a clinician should assess the reduction or a definition of what is an acceptable reduction; 2) maintaining an acceptable reduction in a safe manner until fracture union- there is some discussion of pin fixation. There is no mention of how to best immobilize the arm safely- position of the elbow? Type of immobilization (splint, cast, plaster or fiberglass, split or not, padding over the anterior cubital fossa, etc)? How to manage pins (outside skin, under skin, cover with sterile felt, etc); What is the best way to monitor patients after surgery?

Please see the comments above. By design, Level IV studies cannot tell us whether or not a treatment works or the "best method" of treatment. To determine the "best method" of any treatment requires prospective comparative studies that clearly identify the critical outcomes of interest. These are not level IV case series (observational studies), but higher quality studies that have tried to limit bias and increase transparency in their methods. We have more confidence in the results of high quality studies designed to find causally valid relationships between the treatment(s) and the outcome.

I do not personally believe that the best utilization of resources in pediatric orthopaedics is a PRT to see if 3 weeks of pin fixation is better than or the same as 4 weeks - some of the recommendations to improve the literature that come from CPGs (a secondary aim) are "blue sky" ideas that I do not find practical.

Hence, the reason the work groups are limited to a defined set of preliminary recommendations that answer the most important questions for the treatment pathway.

I find the use of quality and applicability (after reading how this is measured not sure if it is reproducible/reliable) confusing.

"Applicability" and "generalizability" are synonyms. "Applicability" addresses the degree to which the results in the published literature are applicable to actual clinical practice.

Under the "rules of the game" that have been established thus far for creating CPGs, I think the review is thorough.
Thank you.

I think the two recommendations with moderate strength -1) immobilize type I fractures and reduce and 2) reduce and pin displaced fractures)- are good, but that most orthopaedic surgeons will say "of course" or "is that all?" that came from this large amount of work. The consensus opinion guidelines are reasonable.

The weak and inconclusive recommendations are not helpful and the practitioner will need to review the retrospective literature and level 4 and 5 evidence, and use clinical judgment.

I don't think these guidelines improve or will substantially change current clinical care of pediatric patients with SCH fractures.

We would not want to change clinical practice on weak evidence. We also agree that much of Orthopaedic practice is not currently based on evidence. In order to maintain and improve treatment options for pediatric patients with supracondylar fractures, the work group chair, vice-chair and members of the work group hope that this guideline will spur better high quality research to answer the important questions you and others have raised and are left unanswered. Please see the "Future Research Section" of the guideline. The Chair has cited nine specific trials that will be helpful to support improved patient care.

OVERALL ASSESSMENT

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

☐ Strongly recommend

☐ Recommend (with provisions or alterations)

X Would not recommend

☐ Unsure

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

American Academy of Orthopaedic Surgeons
[The Treatment of Pediatric Supracondylar Fractures]
Guidelines Peer Review Form

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

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

Please note that if you return a review:

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

Reviewer Information:

Name of Reviewer Lydia Futch Thurston

Address 1600 7th Ave. South Suite 402

City Birmingham State AL Zip Code 35216

Phone 205-914-0236 Fax 205-939-6109 E-mail lydia.futch@chsys.org

Specialty Area/Discipline: Orthopaedic Physical Therapy

Work setting: Children's Hospital based outpatient ortho PT Clinic Credentials: PT, DSC, ATC

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

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

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

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

Society Name: APTA

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

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

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

☒ **I have declared my conflicts of interest on page 2 of this form.**

☐ **I have declared my conflicts of interest in the AAOS database; my customer # is _____**

☒ **I understand that the AAOS will post my declared conflicts of interest with my comments concerning review of this guideline on the AAOS website.**

American Academy of Orthopaedic Surgeons
[The Treatment of Pediatric Supracondylar Fractures]
Guidelines Peer Review Form

REVIEWER CONFLICT OF INTEREST - The Orthopaedic Disclosure Program

Each item below requires an answer. Please report information for the last 12-months as required by the Accreditation Council for Continuing Medical Education (ACCME) guidelines.

Do you or a member of your immediate family receive royalties for any pharmaceutical, biomaterial or orthopaedic product or device? If YES, please identify product or device:	☐ Yes ☒ No
Within the past twelve months, have you or a member of your immediate family served on the speakers bureau or have you been paid an honorarium to present by any pharmaceutical, biomaterial or orthopaedic product or device company? If YES, please identify company:	☐ Yes ☒ No
Are you or a member of your immediate family a PAID EMPLOYEE for any pharmaceutical, biomaterial or orthopaedic device or equipment company, or supplier? If YES, please identify company or supplier:	☐ Yes ☒ No
Are you or a member of your immediate family a PAID CONSULTANT for any pharmaceutical, biomaterial or orthopaedic device or equipment company, or supplier? If YES, please identify company or supplier:	☐ Yes ☒ No
Are you or a member of your immediate family an UNPAID CONSULTANT for any pharmaceutical, biomaterial or orthopaedic device or equipment company, or supplier? If YES, please identify company or supplier:	☐ Yes ☒ No
Do you or a member of your immediate family own stock or stock options in any pharmaceutical, biomaterial or orthopaedic device or equipment company, or supplier (excluding mutual funds) If YES, please identify company or supplier: Pfizer, Tyco, Covidien <200 shares	☒ Yes ☐ No
Do you or a member of your immediate family receive research or institutional support as a principal investigator from any pharmaceutical, biomaterial or orthopaedic device or equipment company, or supplier? If YES, please identify company or supplier:	☐ Yes ☒ No
Do you or a member of your immediate family receive any other financial or material support from any pharmaceutical, biomaterial or orthopaedic device and equipment company or supplier? If YES, please identify company or supplier:	☐ Yes ☒ No
Do you or a member of your immediate family receive any royalties, financial or material support from any medical and/or orthopaedic publishers? If YES, please identify publisher:	☐ Yes ☒ No
Do you or a member of your immediate family serve on the editorial or governing board of any medical and/or orthopaedic publication? If YES, please identify:	☐ Yes ☒ No
Do you or a member of your immediate family serve on the Board of Directors or a committee of any medical and/or orthopaedic professional society? If YES, please identify:	☐ Yes ☒ No

American Academy of Orthopaedic Surgeons
[The Treatment of Pediatric Supracondylar Fractures]
Guidelines Peer Review Form

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

Please complete and return this form electronically in **WORD format** to wies@aaos.org; please contact Jan Wies at (847) 384-4311 if you have any questions. Thank you in advance for your time in completing this form and giving us your feedback. We value your input and greatly appreciate your efforts. Please return the completed form **in WORD format** by end of day **January 5, 2011**.

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

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

COMMENTS

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

Dear Dr. Futch-Thurston,

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

The guidelines presented reflect the findings from a thorough review of the literature. Some of the recommendations are limited in their ability to provide direction for clinical decisions because of the limited availability of quality/applicable research. What defines quality/applicable research in the area of pediatric supracondylar fractures is described, making this document useful for defining strategies for future research in this area. Due to the low quality/applicability of research available concerning physical therapy and treatment of individuals with pediatric supracondylar fractures, physical therapists will likely find this guideline most useful for designing studies. Future research can provide more clarity to recommendations related to physical therapy, such as recommendations 11 and 12 of this guideline.

Thank you.

The Keppler, et al. article referenced in recommendation eleven is unfortunately the only available article meeting the inclusion criteria that addresses the effectiveness of physical therapy for supracondylar fractures. According to the guideline, this article lacks details about study design that leaves the applicability of the study in question. Limited description of study design reduces the usefulness of this article in designing future studies.

We agree.

When describing the findings of the Keppler, et al. study, the use of the term “slightly” in draft page 133, line 1702, introduces unwarranted bias. The study found a statistically significant difference in range of motion between the groups at the 12 and 18 week follow-up examinations. If any judgment is to be made about the magnitude of difference, what defines a minimal clinically important improvement (MCII) in range of motion seems more appropriate and should be addressed as described in the guideline methods. If addressing MCCII for elbow range of motion is out of the scope of this guideline, I recommend in this context not using the term “slightly.”

We agree. There were no occurrences of validated MCII outcomes in the studies included in this clinical practice guideline and therefore, no evaluation of magnitude of the difference can be made. We have removed the word “*slightly*” from this sentence.

Function and return to activity were noted as critical outcomes for recommendation 11 and no evidence was found that addressed these outcomes. In the same way, recommendation 12 concerning optimal time to return to full activity lacks evidence for a definitive stance. As evidence emerges about treatment for individuals with

pediatric supracondylar fractures, it may be prudent to specify what measures of function and activities are considered critical outcomes.

We agree. This work group identified important critical outcomes *a priori* to the literature search for select recommendations. Based on your comments, we added text at line 1759 identifying the critical outcomes identified by the work group for Recommendation 12.
"Two critical outcomes were searched to answer this recommendation, incidence of refracture and timing of refracture."

This document is a useful tool for healthcare professionals and researchers in developing the best evidence based treatment for individuals with pediatric supracondylar fractures. Treatment of individuals with pediatric supracondylar fractures using physical therapy needs to be examined using quality studies that apply to the clinical setting. Minor changes in the wording of the rationale for recommendation eleven avoids bias and reflects the rigor of this document.

We agree and have edited this as previously indicated.

It may also be useful to determine what measures of function and what activities are considered critical outcomes for individuals with pediatric supracondylar fractures. As evidence emerges, the guideline can be refined to provide more definitive, stronger recommendations.

We agree and have edited.

Thank you for the opportunity to review this document by the American Academy of Orthopaedic Surgeons and provide input from the perspective of a physical therapist and member of the American Physical Therapy Association.

Dear Dr. Futch-Thurston,
We sincerely appreciate the time and expertise you have contributed to the review of this document. Your input has contributed to strengthening the final document we will present to the AAOS Board of Directors for approval.
Thank you.

OVERALL ASSESSMENT

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

☐ Strongly recommend

☒ Recommend (with provisions or alterations) Minor word change line 1702, draft page 133

☐ Would not recommend

☐ Unsure

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

American Academy of Orthopaedic Surgeons
[The Treatment of Pediatric Supracondylar Fractures]
Guidelines Peer Review Form

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

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

Please note that if you return a review:

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

Reviewer Information:

Name of Reviewer___Charles A. Goldfarb, MD_____

Address Washington University Department of Orthopaedic Surgery, Campus Box 8233

City__St Louis_____ State_____MO_____ Zip Code_____63105_____

Phone ___314-747-4705_____Fax _____E-mail__goldfarbc@wustl.edu

Specialty Area/Discipline: ____Upper extremity surgery_____

Work setting: ___academic_____Credentials: ____?_____

May we list you as a Peer Reviewer in the final Guidelines (GL)? x☐ Yes ☐ No
PLEASE READ: If you do not wish to be listed, your name will be removed for identification purposes. However, your review comments, our responses and your COI will still be available for public review on our website with the posted Guideline if you complete this review.

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

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

Society Name: _____American Society for Surgery of the Hand_____
(Listing the specialty society as a reviewing society does not imply or otherwise indicate endorsement of this guideline.)

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

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

x☐ **I have declared my conflicts of interest on page 2 of this form.**

x☐ **I have declared my conflicts of interest in the AAOS database; my customer # is _____**

x☐ **I understand that the AAOS will post my declared conflicts of interest with my comments concerning review of this guideline on the AAOS website.**

American Academy of Orthopaedic Surgeons
[The Treatment of Pediatric Supracondylar Fractures]
Guidelines Peer Review Form

REVIEWER CONFLICT OF INTEREST - The Orthopaedic Disclosure Program

Each item below requires an answer. Please report information for the last 12-months as required by the Accreditation Council for Continuing Medical Education (ACCME) guidelines.

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

American Academy of Orthopaedic Surgeons
[The Treatment of Pediatric Supracondylar Fractures]
Guidelines Peer Review Form

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

Please complete and return this form electronically in **WORD format** to wies@aaos.org; please contact Jan Wies at (847) 384-4311 if you have any questions. Thank you in advance for your time in completing this form and giving us your feedback. We value your input and greatly appreciate your efforts. Please return the completed form **in WORD format** by end of day **January 5, 2011**.

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

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

COMMENTS

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

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

I believe that workgroup did a good job asking the correct questions and providing salient explanations to their conclusions, albeit these conclusions are limited in scope. While the data is lacking, their conclusions and recommendations are helpful. Their recommendations for future research are also appropriate.
Thank you.

I have only a few, limited questions/ comments.
Recommendation 3
"The practitioner might use two or three laterally introduced pins to stabilize the reduction of displaced pediatric supracondylar fractures of the humerus."

This phrasing is curious to me. I assume this is related to the initial question posed but perhaps a different phrasing might make this (albeit weak) point better.

Please see "Table 6 AAOS Guideline Language" at line 801 of the guideline. If the overall strength of a recommendation is "*weak*" the corresponding language is "*The Practitioner might*". This language reflects the explicit link between the strength of the evidence and the language of the recommendation.

Table 1 AAOS guideline language

Guideline Language	Strength of Recommendation
We ***recommend***	Strong
We ***suggest***	Moderate
The Practitioner ***might***	Weak
We are ***unable to recommend for or against***	Inconclusive
In the absence of reliable evidence, the ***opinion*** of this work group is*	Consensus*

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

Line 567. ? 2009 rather than 2010

We agree and corrected this error. It now reads as follows:

"To develop this guideline, the work group held an introductory meeting on October 4, 2009 to establish the scope of the guideline and the systematic reviews. Upon completing the systematic reviews, the work group participated in a two-day recommendation meeting on October 2 and 3, 2010 at which the final recommendations and rationales were edited, written and voted upon. An initial draft was completed and submitted for peer review November 15, 2010."

Line 1166 typo- significant

We have corrected this typographical error.

Recommendation 5
"We are unable to recommend for or against a time threshold…" This is interesting phrasing to me. Is this based on how the research question was initially asked?

We use "*We are unable to recommend for or against*" to reflect the supporting evidence that is available to answer this recommendation. Please see Table 6 above.

Reference to a time threshold is in reference to the available supporting evidence. Please see the rationale at line 1363 in the guideline.

Because, the same data could lead the Recommendation to state that "We are unable to recommend early (<8/12 hrs) reduction…"

Based on the evidence concerning seven critical outcomes, the data does not support this statement. This is explained in the rationale.

1. The time of injury is often estimated; hence, there is uncertainty concerning the reported cut-offs of 8 (four studies) and 12 hours (two studies).
2. While there is no significant difference in "*early*" and "*late*" treatment groups for four *(compartment syndrome, cubitus varus, operative time, and need for reoperation)* critical outcomes, there was no evidence found for Baumann's angle and Malunion. The absence of evidence is not evidence of ineffectiveness; it means there are no data to address these critical outcomes in early **or** late treatment groups. In the absence of data, timing may or may not be critical to these outcomes. We do not know.
3. The evidence addressing the outcome "need for open reduction" was conflicting. As stated in the rationale, the indication for open reduction is subjective. Without additional details concerning the criteria used to determine the patient's need, better studies to eliminate selection bias and additional details concerning the patient injuries, we cannot decipher optimum timing for reduction of a pediatric supracondylar fracture of the humerus without neurovascular injury based on this outcome.
4. In summary, based on the uncertainty of the data for some outcomes, the lack of complete evidence for all critical outcomes, conflicting evidence for one outcome and the low quality of the evidence, we are unable to recommend for or against ***any time threshold*** for three of the seven critical outcomes.

Line 1699 "blind" should be "blinded"

We have corrected this typographical error.

Dear Dr. Goldfarb,
We sincerely appreciate the time and expertise you have contributed to the review of this document. Your input has contributed to strengthening the final document we will present to the AAOS Board of Directors for approval.
Thank you.

OVERALL ASSESSMENT

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

x☐ Strongly recommend

☐ Recommend (with provisions or alterations)

☐ Would not recommend

☐ Unsure

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

American Academy of Orthopaedic Surgeons
[The Treatment of Pediatric Supracondylar Fractures]
Guidelines Peer Review Form

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

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

Please note that if you return a review:

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

Reviewer Information:

Name of Reviewer_____William Hennrikus MD_____

Address_____30 Hope Drive_____

City____Hershey_____ State___PA_____ Zip Code_____17033_____

Phone __717.531-7006_____Fax ___717.531-0385_____E-mail____WLH5k@hotmail.com_____

Specialty Area/Discipline: ____Pediatric Orthopaedics_____

Work setting: ___ Penn State Medical School___Credentials: __Professor and Associate Dean, AAP representative_____

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

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

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

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

Society Name: ___American Academy of Pediatrics_____
(Listing the specialty society as a reviewing society does not imply or otherwise indicate endorsement of this guideline.)

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

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

x☐ **I have declared my conflicts of interest on page 2 of this form.**

x☐ **I have declared my conflicts of interest in the AAOS database; my customer # is ___24579____**

x☐ **I understand that the AAOS will post my declared conflicts of interest with my comments concerning review of this guideline on the AAOS website.**

American Academy of Orthopaedic Surgeons
[The Treatment of Pediatric Supracondylar Fractures]
Guidelines Peer Review Form

REVIEWER CONFLICT OF INTEREST - The Orthopaedic Disclosure Program

Each item below requires an answer. Please report information for the last 12-months as required by the Accreditation Council for Continuing Medical Education (ACCME) guidelines.

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

American Academy of Orthopaedic Surgeons
[The Treatment of Pediatric Supracondylar Fractures]
Guidelines Peer Review Form

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

Please complete and return this form electronically in **WORD format** to wies@aaos.org; please contact Jan Wies at (847) 384-4311 if you have any questions. Thank you in advance for your time in completing this form and giving us your feedback. We value your input and greatly appreciate your efforts. Please return the completed form **in WORD format** by end of day **January 5, 2011**.

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

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

COMMENTS

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

Dear Dr. Hennrikus,

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

P. iii, line 64. Type II SC fractures are lumped with Type III fractures for the purposes of this review. Many authors and surgeons perform selective surgical treatment of Type II injuries. By this report, some readers may conclude that the AAOS is suggesting that all Type II injuries should be treated like Type III injuries with surgical pin fixation. In my opinion, the literature does not support this.

The workgroup originally sought to stratify this recommendation by fracture type. Unfortunately, the available evidence did not support stratification. We state the following at line 1000 in the rationale for Recommendation 2:

"For this analysis Gartland Type II and III fractures were analyzed in aggregate since many of the studies combined the results from the two types. Similarly, the less common flexion type pediatric supracondylar fracture was included in this group."

It would be helpful if future studies stratified and reported results with fracture types delineated. This could be an opportunity for an esteemed member such as you to suggest this to journal editors, reviewers, and prospective authors. Doing so may improve the quality of the literature.

P. 1, line 494. Insurance payers, government bodies,…lawyers…etc. may find this guideline useful. I would suggest deleting this statement. (I realize that this suggestion will not be done. Please see below) Due to the lack of high level evidence on the topic of SC fractures in children, the guideline asks more questions than it answers and the information may possibly be harmful if mis-used by certain regulatory and legal groups. A more helpful statement would be that his guideline is very helpful for orthopaedic researchers in order to identify themes in the topic of pediatric supracondylar fractures that need additional higher level of evidence study.

Quite the contrary, Dr. Hennrikus, we have rewritten the "Intended User" section of this guideline to read as follows:

"This guideline is intended to be used by orthopaedic surgeons and all physicians managing children with supracondylar fractures of the humerus. Typically, orthopaedic surgeons will have completed medical training, a qualified residency in orthopaedic surgery, and some may have completed additional sub-specialty training.

The guideline is intended to both guide clinical practice and to serve as an information resource for medical practitioners. An extensive literature base was considered during the development of this guideline. In general, practicing clinicians do not have the resources necessary for such a large project. The AAOS hopes that this guideline will assist practitioners not only in making clinical decisions about their patients, but also in describing, to patients and others, why the chosen treatment represents the best available course of action.

This guideline is not intended for use as a benefits determination document. Making these determinations involves many factors not considered in the present document, including available resources, business and ethical considerations, and need.

Users of this guideline may also want to consider any appropriate use criteria (AUC) that the AAOS has developed on the topic of this guideline. The focus of AAOS guidelines is on the question "Does it work?" When an AAOS guideline or an AAOS-endorsed guideline

shows effectiveness, the AAOS may undertake development of AUC that ask the question "In whom does it work?" This dichotomy is necessary because the medical literature (both orthopaedic and otherwise) typically does not adequately address the latter question.

That having been said, evidence for the effectiveness of medical services is not always present. This is true throughout all areas of medicine. Accordingly, all users of this clinical practice guideline are cautioned that an absence of evidence is not evidence of ineffectiveness. An absence means just that; there are no data. It is the AAOS position that rigorously developed clinical practice guidelines should not seek to guide clinical practice when data are absent unless the disease, disorder, or condition in question can result in loss of life or limb. The AAOS incorporates expert opinion into a guideline under these circumstances, and only under these circumstances. Accordingly, when the AAOS states that it cannot recommend for or against a given intervention or service, it is stating that currently available data do not provide clear guidance on which course of action is best, and that it is therefore reluctant to make a recommendation that has potentially national ramifications. Although true in all circumstances, the AAOS believes that when evidence is absent, it is particularly important for the treatment for pediatric supracondylar fractures of the humerus in children to be based on the assumption that decisions are predicated on guardian and physician mutual communication with discussion of available treatments and procedures applicable to the individual patient. Once the patient's guardian has been informed of available therapies and has discussed these options with his/her child's physician, an informed decision can be made. Clinician input based on experience with conservative management and the clinician's surgical experience and skills increases the probability of identifying patients who will benefit from specific treatment options."

P 11 Line 806. Although no process is perfect, the described process of the committee meeting together and voting on the recommendations--resolutions almost sounds like service on a trial jury. My experience serving on juries enlightened me to how flawed our legal system is.

We agree that your participation on a guideline work group would probably enlighten you to the flaws in the Orthopaedic literature.

P 146 line 1884 1726 articles were identified, only 44 articles were kept for review for recommendations. This is an ambitious and rigorous deletion process. Although not level 1 or 2 evidence, some of the articles deleted may have helped to improve the strength of recommendations 10, 11, 12 and possibly 4. Are the articles deleted by the orthopaedic surgeons on the committee or by statisticians prior to the committee reviewing the articles?

The initial abstracts (1379) were excluded because they were not relevant to the recommendations (do not answer the question) or because the studies were not scientifically valid.

Based on the review of the abstracts for this guideline, 347 full text articles were recalled for in-depth review and 111 met the inclusion criteria. We evaluated the quality of these 111 articles. We use the "best available evidence, not all of the evidence to answer a recommendation. (See Line 631; Best Evidence Synthesis in the guideline) We use the "best available evidence" because we have more confidence in the results of these higher quality studies that we do in low quality studies. These studies have made attempts to limit bias and increase transparency in their methods; therefore we are more confident in the results. When the evaluation of all studies is complete, a teleconference is held with the physician work group. They audit all of the studies. All physician work groups are particularly diligent concerning exclusion of studies based on "not best available evidence". The statisticians and physicians review these studies together and discuss the flaws present that influence downgrading the quality of these studies when necessary.

At the final meeting, the physician work group reviews all included studies and, based on applicability and the information found in Table 5 "Strength of recommendation descriptions", Line 798, assigns the final overall strength of the recommendation. That said, including additional lower level evidence does not improve the strength of the recommendations. Weak evidence is weak evidence, whether you have 10 weak studies or 100 weak studies. Volume and availability does not improve the precision and accuracy of a study nor does volume and availability decrease the inherent bias present in weak studies. For AAOS guidelines we try to limit bias and maintain transparency. This guideline is not intended to be a collection of consensus or expert opinions but an evidence based document. Based on this goal, consensus opinion recommendations can only be made when there is no evidence identified by the systematic review (See Table 5) and the results of not issuing a recommendation will be catastrophic.

Specific to your comments:

Recommendations 4, 10 and 12 – there were no studies that answered these recommendations. We would have included level IV studies if they addressed the recommendation and met the inclusion criteria; however, we found no studies that answered the recommendations.

Recommendation 11 – one level II study was found that addressed this recommendation. If level III studies had been identified that answered the question and met the inclusion criteria, we would have included all such level III studies. Since no level III studies were found, we searched for level IV studies. We found no level IV studies that answered the recommendation and met the inclusion criteria. This left us with an inconclusive strength of recommendation since one study of limited applicability that is underpowered and not blinded was the only available evidence.

P 153, line 2015. Prior USPSTF task force summary recommendations on topics such as scoliosis screening, DDH screening, breast cancer screening and prostate cancer screening have met with negative public opinion due to the strict recommendations based on minimal high level evidence. I wonder a bit if we are eliminating the 'art' of medicine by defining our recommendations strictly based on high level only evidence literature. Government and regulatory agencies may use this evidence to deny payment in certain instances. Many physician's practices already involve multiple phone calls each week in order to obtain authorization for services after a government or regulatory agency employee has read a guideline and interpreted that guideline to allow denial of services.

Lower level evidence was used to address recommendations for this guideline including Levels III, IV and V. Recommendations 2, 5 and 6 are addressed with Level III evidence. Recommendations 7 and 8 were addressed with Level V evidence (consensus opinion of the work group). No level IV, prospective case series studies that met the inclusion criteria specified *a priori* to the literature search were found to answer the recommendations.

Actually, the inclusion criteria for the literature for this guideline are more liberal than those of the JBJS system. The only study design we did not include is retrospective case series. Further, the fact that we include any case series studies make our inclusion criteria more liberal than that used by most methodologists; hence we are not "defining the evidence for our recommendations strictly based on high level only evidence". Rather, we are not considering those studies that are most likely to produce misleading results.

P 154 2044. Litigation fear is a real issue. I an uncertain if the guideline improves this issue. Only recommendations 1 and 2 suggest moderate strength of the recommendation. At that, recommendation 1, in my opinion, should be high rather than moderate.

Recommendation 1 is based on one low quality study and one moderate quality study (see Quality Summary table 9, page 18). Based on quality and applicability (see Table 5 Strength of recommendation descriptions), the overall strength of the recommendation is moderate. This is consistent with the criteria we specified *a priori* to beginning guideline development. The work group did not adjust the overall strength of the recommendation based on harms and benefits associated with non-operative immobilization.

There is an explicit link in all AAOS guidelines between the strength of the recommendation and the body of evidence that supports it. Please see line 806 in the guideline "Defining the strength of the Recommendations". This is also why we have specified the criteria necessary for the work group to make opinion-based recommendations within an evidence-based guideline. Opinion-based recommendations can only be made in the absence of evidence when the results of NOT making a recommendation are catastrophic to the patient.

Recommendation 2, as previously described, in my opinion, may be better delineated by separating out Type 2 fractures for individual discussion.

American Academy of Orthopaedic Surgeons
[The Treatment of Pediatric Supracondylar Fractures]
Guidelines Peer Review Form

Please see our previous comments.

Physician practices evolve on a daily basis due to new knowledge and discoveries. The guidelines will be reviewed on a 5 year basis. Although not the intent, guidelines sometimes become biblical to those that may wish to mis-use them.

It is incumbent upon all readers of this material to understand the information held within, how the evidence is derived and how it should be used.

Thank you for allowing me to participate in the new and exciting endeavor.

Dear Dr. Hennikus,
We sincerely appreciate the time and expertise you have contributed to the review of this document. Your input has contributed to strengthening the final document we will present to the AAOS Board of Directors for approval.
Thank you.

OVERALL ASSESSMENT

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

☐ Strongly recommend

x☐ Recommend (with provisions or alterations)

☐ Would not recommend

☐ Unsure

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

American Academy of Orthopaedic Surgeons
[The Treatment of Pediatric Supracondylar Fractures]
Guidelines Peer Review Form

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

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

Please note that if you return a review:

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

Reviewer Information:

Name of Reviewer_____William Hennrikus MD_____

Address_____30 Hope Drive_____

City____Hershey_____ State___PA_____ Zip Code_____17033_____

Phone __717.531-7006_____Fax ___717.531-0385_____E-mail____WLH5k@hotmail.com_____

Specialty Area/Discipline: ____Pediatric Orthopaedics_____

Work setting: ___ Penn State Medical School___Credentials: __Professor and Associate Dean, AAP representative_____

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

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

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

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

Society Name: ___American Academy of Pediatrics_____
(Listing the specialty society as a reviewing society does not imply or otherwise indicate endorsement of this guideline.)

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

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

x☐ **I have declared my conflicts of interest on page 2 of this form.**

x☐ **I have declared my conflicts of interest in the AAOS database; my customer # is ___24579____**

x☐ **I understand that the AAOS will post my declared conflicts of interest with my comments concerning review of this guideline on the AAOS website.**

American Academy of Orthopaedic Surgeons
[The Treatment of Pediatric Supracondylar Fractures]
Guidelines Peer Review Form

REVIEWER CONFLICT OF INTEREST - The Orthopaedic Disclosure Program

Each item below requires an answer. Please report information for the last 12-months as required by the Accreditation Council for Continuing Medical Education (ACCME) guidelines.

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

American Academy of Orthopaedic Surgeons
[The Treatment of Pediatric Supracondylar Fractures]
Guidelines Peer Review Form

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

Please complete and return this form electronically in **WORD format** to wies@aaos.org; please contact Jan Wies at (847) 384-4311 if you have any questions. Thank you in advance for your time in completing this form and giving us your feedback. We value your input and greatly appreciate your efforts. Please return the completed form **in WORD format** by end of day **January 5, 2011**.

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

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

COMMENTS

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

Dear Dr. Hennrikus,

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

P. iii, line 64. Type II SC fractures are lumped with Type III fractures for the purposes of this review. Many authors and surgeons perform selective surgical treatment of Type II injuries. By this report, some readers may conclude that the AAOS is suggesting that all Type II injuries should be treated like Type III injuries with surgical pin fixation. In my opinion, the literature does not support this.

The workgroup originally sought to stratify this recommendation by fracture type. Unfortunately, the available evidence did not support stratification. We state the following at line 1000 in the rationale for Recommendation 2:

"For this analysis Gartland Type II and III fractures were analyzed in aggregate since many of the studies combined the results from the two types. Similarly, the less common flexion type pediatric supracondylar fracture was included in this group."

It would be helpful if future studies stratified and reported results with fracture types delineated. This could be an opportunity for an esteemed member such as you to suggest this to journal editors, reviewers, and prospective authors. Doing so may improve the quality of the literature.

P. 1, line 494. Insurance payers, government bodies,…lawyers…etc. may find this guideline useful. I would suggest deleting this statement. (I realize that this suggestion will not be done. Please see below) Due to the lack of high level evidence on the topic of SC fractures in children, the guideline asks more questions than it answers and the information may possibly be harmful if mis-used by certain regulatory and legal groups. A more helpful statement would be that his guideline is very helpful for orthopaedic researchers in order to identify themes in the topic of pediatric supracondylar fractures that need additional higher level of evidence study.

Quite the contrary, Dr. Hennrikus, we have rewritten the "Intended User" section of this guideline to read as follows:

"This guideline is intended to be used by orthopaedic surgeons and all physicians managing children with supracondylar fractures of the humerus. Typically, orthopaedic surgeons will have completed medical training, a qualified residency in orthopaedic surgery, and some may have completed additional sub-specialty training.

The guideline is intended to both guide clinical practice and to serve as an information resource for medical practitioners. An extensive literature base was considered during the development of this guideline. In general, practicing clinicians do not have the resources necessary for such a large project. The AAOS hopes that this guideline will assist practitioners not only in making clinical decisions about their patients, but also in describing, to patients and others, why the chosen treatment represents the best available course of action.

This guideline is not intended for use as a benefits determination document. Making these determinations involves many factors not considered in the present document, including available resources, business and ethical considerations, and need.

Users of this guideline may also want to consider any appropriate use criteria (AUC) that the AAOS has developed on the topic of this guideline. The focus of AAOS guidelines is on the question "Does it work?" When an AAOS guideline or an AAOS-endorsed guideline

shows effectiveness, the AAOS may undertake development of AUC that ask the question "In whom does it work?" This dichotomy is necessary because the medical literature (both orthopaedic and otherwise) typically does not adequately address the latter question.

That having been said, evidence for the effectiveness of medical services is not always present. This is true throughout all areas of medicine. Accordingly, all users of this clinical practice guideline are cautioned that an absence of evidence is not evidence of ineffectiveness. An absence means just that; there are no data. It is the AAOS position that rigorously developed clinical practice guidelines should not seek to guide clinical practice when data are absent unless the disease, disorder, or condition in question can result in loss of life or limb. The AAOS incorporates expert opinion into a guideline under these circumstances, and only under these circumstances. Accordingly, when the AAOS states that it cannot recommend for or against a given intervention or service, it is stating that currently available data do not provide clear guidance on which course of action is best, and that it is therefore reluctant to make a recommendation that has potentially national ramifications. Although true in all circumstances, the AAOS believes that when evidence is absent, it is particularly important for the treatment for pediatric supracondylar fractures of the humerus in children to be based on the assumption that decisions are predicated on guardian and physician mutual communication with discussion of available treatments and procedures applicable to the individual patient. Once the patient's guardian has been informed of available therapies and has discussed these options with his/her child's physician, an informed decision can be made. Clinician input based on experience with conservative management and the clinician's surgical experience and skills increases the probability of identifying patients who will benefit from specific treatment options."

P 11 Line 806. Although no process is perfect, the described process of the committee meeting together and voting on the recommendations--resolutions almost sounds like service on a trial jury. My experience serving on juries enlightened me to how flawed our legal system is.

We agree that your participation on a guideline work group would probably enlighten you to the flaws in the Orthopaedic literature.

P 146 line 1884 1726 articles were identified, only 44 articles were kept for review for recommendations. This is an ambitious and rigorous deletion process. Although not level 1 or 2 evidence, some of the articles deleted may have helped to improve the strength of recommendations 10, 11, 12 and possibly 4. Are the articles deleted by the orthopaedic surgeons on the committee or by statisticians prior to the committee reviewing the articles?

The initial abstracts (1379) were excluded because they were not relevant to the recommendations (do not answer the question) or because the studies were not scientifically valid.

Based on the review of the abstracts for this guideline, 347 full text articles were recalled for in-depth review and 111 met the inclusion criteria. We evaluated the quality of these 111 articles. We use the "best available evidence, not all of the evidence to answer a recommendation. (See Line 631; Best Evidence Synthesis in the guideline) We use the "best available evidence" because we have more confidence in the results of these higher quality studies that we do in low quality studies. These studies have made attempts to limit bias and increase transparency in their methods; therefore we are more confident in the results. When the evaluation of all studies is complete, a teleconference is held with the physician work group. They audit all of the studies. All physician work groups are particularly diligent concerning exclusion of studies based on "not best available evidence". The statisticians and physicians review these studies together and discuss the flaws present that influence downgrading the quality of these studies when necessary.

At the final meeting, the physician work group reviews all included studies and, based on applicability and the information found in Table 5 "Strength of recommendation descriptions", Line 798, assigns the final overall strength of the recommendation. That said, including additional lower level evidence does not improve the strength of the recommendations. Weak evidence is weak evidence, whether you have 10 weak studies or 100 weak studies. Volume and availability does not improve the precision and accuracy of a study nor does volume and availability decrease the inherent bias present in weak studies. For AAOS guidelines we try to limit bias and maintain transparency. This guideline is not intended to be a collection of consensus or expert opinions but an evidence based document. Based on this goal, consensus opinion recommendations can only be made when there is no evidence identified by the systematic review (See Table 5) and the results of not issuing a recommendation will be catastrophic.

Specific to your comments:

Recommendations 4, 10 and 12 – there were no studies that answered these recommendations. We would have included level IV studies if they addressed the recommendation and met the inclusion criteria; however, we found no studies that answered the recommendations.

Recommendation 11 – one level II study was found that addressed this recommendation. If level III studies had been identified that answered the question and met the inclusion criteria, we would have included all such level III studies. Since no level III studies were found, we searched for level IV studies. We found no level IV studies that answered the recommendation and met the inclusion criteria. This left us with an inconclusive strength of recommendation since one study of limited applicability that is underpowered and not blinded was the only available evidence.

P 153, line 2015. Prior USPSTF task force summary recommendations on topics such as scoliosis screening, DDH screening, breast cancer screening and prostate cancer screening have met with negative public opinion due to the strict recommendations based on minimal high level evidence. I wonder a bit if we are eliminating the 'art' of medicine by defining our recommendations strictly based on high level only evidence literature. Government and regulatory agencies may use this evidence to deny payment in certain instances. Many physician's practices already involve multiple phone calls each week in order to obtain authorization for services after a government or regulatory agency employee has read a guideline and interpreted that guideline to allow denial of services.

Lower level evidence was used to address recommendations for this guideline including Levels III, IV and V. Recommendations 2, 5 and 6 are addressed with Level III evidence. Recommendations 7 and 8 were addressed with Level V evidence (consensus opinion of the work group). No level IV, prospective case series studies that met the inclusion criteria specified *a priori* to the literature search were found to answer the recommendations.

Actually, the inclusion criteria for the literature for this guideline are more liberal than those of the JBJS system. The only study design we did not include is retrospective case series. Further, the fact that we include any case series studies make our inclusion criteria more liberal than that used by most methodologists; hence we are not "defining the evidence for our recommendations strictly based on high level only evidence". Rather, we are not considering those studies that are most likely to produce misleading results.

P 154 2044. Litigation fear is a real issue. I an uncertain if the guideline improves this issue. Only recommendations 1 and 2 suggest moderate strength of the recommendation. At that, recommendation 1, in my opinion, should be high rather than moderate.

Recommendation 1 is based on one low quality study and one moderate quality study (see Quality Summary table 9, page 18). Based on quality and applicability (see Table 5 Strength of recommendation descriptions), the overall strength of the recommendation is moderate. This is consistent with the criteria we specified *a priori* to beginning guideline development. The work group did not adjust the overall strength of the recommendation based on harms and benefits associated with non-operative immobilization.

There is an explicit link in all AAOS guidelines between the strength of the recommendation and the body of evidence that supports it. Please see line 806 in the guideline "Defining the strength of the Recommendations". This is also why we have specified the criteria necessary for the work group to make opinion-based recommendations within an evidence-based guideline. Opinion-based recommendations can only be made in the absence of evidence when the results of NOT making a recommendation are catastrophic to the patient.

Recommendation 2, as previously described, in my opinion, may be better delineated by separating out Type 2 fractures for individual discussion.

American Academy of Orthopaedic Surgeons
[The Treatment of Pediatric Supracondylar Fractures]
Guidelines Peer Review Form

Please see our previous comments.

Physician practices evolve on a daily basis due to new knowledge and discoveries. The guidelines will be reviewed on a 5 year basis. Although not the intent, guidelines sometimes become biblical to those that may wish to mis-use them.

It is incumbent upon all readers of this material to understand the information held within, how the evidence is derived and how it should be used.

Thank you for allowing me to participate in the new and exciting endeavor.

Dear Dr. Hennikus,
We sincerely appreciate the time and expertise you have contributed to the review of this document. Your input has contributed to strengthening the final document we will present to the AAOS Board of Directors for approval.
Thank you.

OVERALL ASSESSMENT

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

☐ Strongly recommend

x☐ Recommend (with provisions or alterations)

☐ Would not recommend

☐ Unsure

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

American Academy of Orthopaedic Surgeons
[The Treatment of Pediatric Supracondylar Fractures]
Guidelines Peer Review Form

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

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

Please note that if you return a review:

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

Reviewer Information:

Name of Reviewer__Scott H. Kozin MD_____

Address_____Shriner Hospital for Children 3551 N. Broad Street_

City_Philadelphia_____ State___PA_____ Zip Code__19140_____

Phone ____215-430-4288__Fax __215-430-4079___E-mail_skozin@shrinenet.org

Specialty Area/Discipline: _Pediatric Upper Extremity

Work setting: _____Credentials: _Professor, Dept of Orth Surgery Temple University

---

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

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

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

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

Society Name: __ASSH/ American Association for Hand Surgery_____
(Listing the specialty society as a reviewing society does not imply or otherwise indicate endorsement of this guideline.)

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

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

☒ **I have declared my conflicts of interest on page 2 of this form.**

☐ **I have declared my conflicts of interest in the AAOS database; my customer # is _____**

☒ **I understand that the AAOS will post my declared conflicts of interest with my comments concerning review of this guideline on the AAOS website.**

American Academy of Orthopaedic Surgeons
[The Treatment of Pediatric Supracondylar Fractures]
Guidelines Peer Review Form

REVIEWER CONFLICT OF INTEREST - The Orthopaedic Disclosure Program

Each item below requires an answer. Please report information for the last 12-months as required by the Accreditation Council for Continuing Medical Education (ACCME) guidelines.

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

American Academy of Orthopaedic Surgeons
[The Treatment of Pediatric Supracondylar Fractures]
Guidelines Peer Review Form

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

Please complete and return this form electronically in **WORD format** to wies@aaos.org; please contact Jan Wies at (847) 384-4311 if you have any questions. Thank you in advance for your time in completing this form and giving us your feedback. We value your input and greatly appreciate your efforts. Please return the completed form **in WORD format** by end of day **January 5, 2011**.

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

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

COMMENTS

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

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

I congratulate the work force on their effort to scrutinize the available data regarding Supracondylar fractures in children.

Thank you

I agree with the recommendations.

Thank you

I remain dismayed at the lack of evidence regarding such a common fracture in children.
More data would have allowed stronger recommendations.

We agree. We hope the "Future Research" section of the guideline will help identify areas that if investigated will help strengthen future guideline recommendations.

Dear Dr. Kozin,
We sincerely appreciate the time and expertise you have contributed to the review of this document. Your input has helped us strengthen the final document we will present to the AAOS Board of Directors for approval.

Thank you.

OVERALL ASSESSMENT

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

☐ Strongly recommend

☒ Recommend (with provisions or alterations)

☐ Would not recommend

☐ Unsure

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

American Academy of Orthopaedic Surgeons
[The Treatment of Pediatric Supracondylar Fractures]
Guidelines Peer Review Form

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

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

Please note that if you return a review:

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

Reviewer Information:

Name of Reviewer: Keith May PT, DPT, SCS, ATC, CSCS

Address: 3155 North Point Pkwy, Building A, Suite 100

City: Alpharetta State: GA Zip Code: 30005

Phone: 404-785-5701 Fax: 404-785-8576 E-mail: keith.may@choa.org

Specialty Area/Discipline: Physical Therapy

Work setting: Pediatric Sports Medicine Credentials: DPT, SCS, ATC, CSCS

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

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

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

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

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

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

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

x☐ **I have declared my conflicts of interest on page 2 of this form.**

☐ **I have declared my conflicts of interest in the AAOS database; my customer # is _____**

x☐ **I understand that the AAOS will post my declared conflicts of interest with my comments concerning review of this guideline on the AAOS website.**

American Academy of Orthopaedic Surgeons
[The Treatment of Pediatric Supracondylar Fractures]
Guidelines Peer Review Form

REVIEWER CONFLICT OF INTEREST - The Orthopaedic Disclosure Program

Each item below requires an answer. Please report information for the last 12-months as required by the Accreditation Council for Continuing Medical Education (ACCME) guidelines.

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

American Academy of Orthopaedic Surgeons
[The Treatment of Pediatric Supracondylar Fractures]
Guidelines Peer Review Form

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

Please complete and return this form electronically in **WORD format** to wies@aaos.org; please contact Jan Wies at (847) 384-4311 if you have any questions. Thank you in advance for your time in completing this form and giving us your feedback. We value your input and greatly appreciate your efforts. Please return the completed form **in WORD format** by end of day **January 5, 2011**.

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

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

COMMENTS

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

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

The guideline is concise, well written and through. The authors did an excellent job defining their intentions, boundaries, findings and their recommendations.

Thank you

As I am most qualified to comment on the physical therapy section; the body of information available to the authors was limited. This makes it difficult to make clear recommendations for or against the use of skilled therapy services. Anecdotally, therapists will claim necessity and benefit but according to the available literature there is no clear justification. There is clearly a need for the therapy community to research this point further.

We agree. We hope the "Future Research" section of the guideline will help identify areas that if investigated will help strengthen future guideline recommendations.

There appears to be a dating error in lines 567-572 under "Methods":

"Introductory meeting held 10/4/10" "2 day recommendation workshop held 10/2 and 10/3/10"

We agree and this error has been corrected:

*"To develop this guideline, the work group held an introductory meeting on October 4, **2009** to establish the scope of the guideline and the systematic reviews. Upon completing the systematic reviews, the work group participated in a two-day recommendation meeting on October 2 and 3, **2010** at which the final recommendations and rationales were edited, written and voted on. An initial draft was completed and submitted for peer review November 15, 2010.*

Dear Dr. May,
We sincerely appreciate the time and expertise you have contributed to the review of this document. Your input has helped us strengthen the final document we will present to the AAOS Board of Directors for approval. Thank you.

OVERALL ASSESSMENT

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

☐ X Strongly recommend

☐ Recommend (with provisions or alterations)

☐ Would not recommend

☐ Unsure

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

American Academy of Orthopaedic Surgeons
[The Treatment of Pediatric Supracondylar Fractures]
Guidelines Peer Review Form

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

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

Please note that if you return a review:

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

Reviewer Information:

Name of Reviewer___Mark Paterno _____

Address_____3333 Burnet Ave. MLC 10001_____

City___Cincinnati_____ State_____OH_____ Zip Code_____45229_____

Phone ____513-636-0517_____Fax __513-636-0516_____E-mail__mark.paterno@cchmc.org_____

Specialty Area/Discipline: _____Physical Therapy_____

Work setting: ____Cincinnati Children's Hospital Medical Center- Sports Medicine_Credentials: __ PT, PhD, MBA, SCS, ATC _____

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

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

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

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

Society Name: _____American Physical Therapy Association_____
(Listing the specialty society as a reviewing society does not imply or otherwise indicate endorsement of this guideline.)

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

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

X **I have declared my conflicts of interest on page 2 of this form.**

☐ **I have declared my conflicts of interest in the AAOS database; my customer # is _____**

☐ **I understand that the AAOS will post my declared conflicts of interest with my comments concerning review of this guideline on the AAOS website.**

American Academy of Orthopaedic Surgeons
[The Treatment of Pediatric Supracondylar Fractures]
Guidelines Peer Review Form

REVIEWER CONFLICT OF INTEREST - The Orthopaedic Disclosure Program

Each item below requires an answer. Please report information for the last 12-months as required by the Accreditation Council for Continuing Medical Education (ACCME) guidelines.

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

American Academy of Orthopaedic Surgeons
[The Treatment of Pediatric Supracondylar Fractures]
Guidelines Peer Review Form

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

Please complete and return this form electronically in **WORD format** to wies@aaos.org; please contact Jan Wies at (847) 384-4311 if you have any questions. Thank you in advance for your time in completing this form and giving us your feedback. We value your input and greatly appreciate your efforts. Please return the completed form **in WORD format** by end of day **January 5, 2011**.

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

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

COMMENTS

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

Dear Dr. Paterno,

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

Thank you for the opportunity to review this guideline. In general I think it is very well written and is representative of the current literature regarding the medical management of supracondylar humeral fractures in children. I believe the initial medical recommendations allowed for a robust and equitable evaluation of the current literature and as such, resulted in an adequate review of the medical management of this condition.

Thank you.

Conversely, in creating only one general, all encompassing rehabilitation recommendation there is potential that pertinent literature could be excluded. For example, the initial 3 recommendations very nicely asked questions about different variations of SCHF (i.e. fracture patterns, type of fractures etc.) to allow for independent analysis of variables which could inherently influence the medical intervention. Similarly, the next several recommendations look at different type of medical interventions to evaluate their efficacy (i.e. open vs. closed reduction, type of surgical fixations, etc.) This appropriately permitted an analysis of each specific intervention with a type of SCHF. At no time was a recommendation created that attempted to look at an intervention for “all SCHF” or were all interventions lumped together as “medical management” or simply “surgery” and this was appropriate. There is no way to fairly evaluate the efficacy of an intervention when it is discussed in too general terms. However, in the case of the rehabilitation intervention, there was only one initial recommendation, which simply asked the efficacy of “physical or occupational therapy” in all pediatric SCHF. This fatal flaw, of sorts, resulted in an inability to equitably evaluate the literature in respect to rehabilitation. Having said that, there is a paucity of evidence outside of case series or retrospective analysis on the efficacy of specific interventions in subsets of this population, however the reader is unable to appreciate the little credible literature that may exist, simply due to the *a priori* recommendation which was set up. I will give a more specific example in relation to recommendation 11 below in my specific comments.

We searched for any study concerning physical therapy. Only one study was found that addressed physical therapy and answered the recommendation. If we had found additional studies, they would be listed in an excluded study table with the reason for exclusion following Recommendation 11. (See Recommendation 3 or 7, Excluded Tables, for examples.)

Recommendations 1-6 were well written and representative of the current literature.

Thank you.

Recommendations 7-8 resulted in consensus statements, which in my opinion, were appropriately justified by the potential catastrophic outcome of a vascular injury left untreated. I was however, surprised there was no incidence data available.

We agree.

Recommendation 10: I agree there may be no material to support the optimal timing of pin removal and immobilization, however in the absence of this evidence, would it be wise to make a statement in the comments section regarding the use of basic science guidelines related to bone and tissue healing. I realize there is no evidence to support specific time frames to remove pins or how long to immobilize, but certainly a comment regarding healing rate of bone would be complimentary in the comments or future research direction statements.

New bone is radiographically evident as early as one week in these fractures. Most practitioners remove pins at three weeks plus or minus. Bone strengthening, remodeling, and maturation is still very active from a histological and radiographic standpoint at six weeks. One week of pinning is too early and risks redisplacement, and six weeks of pinning is too much, and risks elbow stiffness and pin site infection, according to current clinical practice. There is no high quality evidence to support this practice, and any statements about the biology of fracture healing are too broad to guide the clinical question. This topic is addressed in the future research of the document.

Recommendation 11: In addition to my comments above related to the limitations with grouping all Physical and occupational therapy interventions globally, I have a concern with the decision to downgrade the applicability to low. The comments stated the one article, which was included, had issues with generalizability as it only included subjects with an open reduction.

This is correct. The study is low applicability as indicated at line 1717 in the guideline:

"The included study has uncertain applicability. Specifically, if the treatment was delivered similarly to the way it would be delivered in the typical practice. There is also uncertainty if the patients enrolled in this study are like those seen in actual clinical practice, since only patients undergoing open reduction of the pediatric supracondylar fracture were enrolled. The strict compliance and adherence monitoring and subsequent exclusion of noncompliant patients from the analysis in this trial adds further uncertainty to the applicability of patients in this trial to those typically seen in clinical practice. Therefore, the applicability of this study's results to results that would be obtained in a typical practice is low. Results of the applicability domains analysis are available in Table 74."

Therefore, it was excluded, rather than making a statement that supervised PT may be indicated in a population of SCHF who requires open reduction. Rather, it was excluded based on generalizability due to the initial recommendation.

The study was not excluded. It was included; however, the work group chose to make an inconclusive recommendation because of the lack of evidence. The body of evidence consisted of one flawed study. This study was flawed because it was not sufficiently powered to find a difference in the treatment groups. It used a surrogate outcome measure (range of motion) and the trial was not blinded. The work group felt one flawed

study was insufficient evidence to base a recommendation on. (See Table 5; Strength of recommendation descriptions).

We agree that it is absolutely essential for both orthopaedic surgeons and physical therapists to do better high quality research to determine the efficacy of all treatments in order to sustain treatment options in the future. We believe that this is in the best interest of the patient.

The initial recommendation may have been inappropriately all inclusive of all types of SCHF. My recommendation would be to either state the current evidence suggests that supervised PT may be indicated in cases of SCHF that require open reduction OR simply change the final recommendation to state:

"We are unable to recommend for or against routine supervised physical or occupational therapy for **ALL** patients with **any type of** pediatric supracondylar fractures of the humerus.

Recommendation 11:
We are unable to recommend for or against routine supervised physical or occupational therapy for patients with pediatric supracondylar fractures of the humerus.

We respectfully decline your suggestions for the following reasons:

1. The work group determined at the final meeting that the single flawed study found does not constitute enough evidence to make a statement for patients with open reduction as indicated in the rationale and supporting evidence.
2. We believe "all" and "any type" is implied in the recommendation.

Future Recommendation:
There are many appropriate future research suggestions regarding medical management for SCHF. However, there were no recommendations related to PT/OT interventions. Considering the lack of evidence, which exists regarding recommendation 11, I would suggest some future research recommendation be made regarding this area. Such topics could include determination of what sub-group of SCHF may need PT, RCT's to validate specific PT interventions for these patient populations, what is the optimal timing of intervention after this injury, etc.

Based on your comments we have edited Line 1822 in the future research section from:

- *Prospective investigation comparing timing for removal of pins, timing for resumption of activities*

To:

- *Prospective investigation comparing timing for removal of pins, timing for resumption of activities, and results of physical therapy*.

Dear Dr. Paterno,
We sincerely appreciate the time and expertise you have contributed to the review of this document. Your input has helped us strengthen the final document we will present to the AAOS Board of Directors for approval. Thank you.

OVERALL ASSESSMENT

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

☐ Strongly recommend

x Recommend (with provisions or alterations)

☐ Would not recommend

☐ Unsure

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

Find Disclosure Records

Chad T Price, MD:

Submitted on: 05/17/2011 at 06:43 PM

Item 1 **Royalties from a company or supplier:**

- Biomet; Halo Innovations, Inc

Item 2 **Speakers bureau/paid presentations for a company or supplier:**
- No Conflict Reported

Item 3A **Paid employee for a company or supplier:**
- No Conflict Reported

Item 3B **Paid consultant for a company or supplier:**
- No Conflict Reported

Item 3C **Unpaid consultant for a company or supplier:**
- No Conflict Reported

Item 4 **Stock or stock options in a company or supplier:**
- No Conflict Reported

Item 5 **Research support from a company or supplier as a PI:**

- Wright Medical Technology, Inc.

Item 6 **Other financial or material support from a company or supplier:**
- No Conflict Reported

Item 7 **Royalties, financial or material support from publishers:**
- No Conflict Reported

Item 8 **Medical/Orthopaedic publications editorial/governing board:**

- Journal of Pediatric Orthopedics

Item 9 **Board member/committee appointments for a society:**
- No Conflict Reported

Find Disclosure Records

Harold J P Van Bosse, MD:

Submitted on: 04/07/2011 at 09:20 PM

Item 1. **Royalties from a company or supplier**
The following conflicts were disclosed

- No Conflict Reported

Item 2. **Speakers bureau/paid presentations for a company or supplier**
The following conflicts were disclosed

- No Conflict Reported

Item 3A. **Paid employee for a company or supplier**
The following conflicts were disclosed

- No Conflict Reported

Item 3B. **Paid consultant for a company or supplier**
The following conflicts were disclosed

- No Conflict Reported

Item 3C. **Unpaid consultant for a company or supplier**
The following conflicts were disclosed

- No Conflict Reported

Item 4. **Stock or stock options in a company or supplier**
The following conflicts were disclosed

- No Conflict Reported

Item 5. **Research support from a company or supplier as a PI**
The following conflicts were disclosed

- No Conflict Reported

Item 6. **Other financial or material support from a company or supplier**
The following conflicts were disclosed

- No Conflict Reported

Item 7. **Royalties, financial or material support from publishers**
The following conflicts were disclosed

- No Conflict Reported

Item 8. **Medical/Orthopaedic publications editorial/governing board**
The following conflicts were disclosed

- Orthopedics

Item 9. **Board member/committee appointments for a society**
The following conflicts were disclosed

- No Conflict Reported

Find Disclosure Records

Robert Murray Campbell Jr, MD:

There is no current disclosure data available for that person.

May 15, 2011

re: AAOS CPG: Treatment of Pediatric Supracondylar Humerus Fractures

Dear Jan and Charlie:

I am writing this letter in my capacity as Chair of the Evidence-Based Medicine Committee of the Pediatric Orthopaedic Society of North America (POSNA) regarding public commentary on the aforementioned AAOS CPG draft. I have cc'd Teri Stech (Executive Director of POSNA), Dr. Roach (President of POSNA), and Dr. Waters (current President of POSNA).

The CPG draft was posted on the member-only POSNA website. An email was sent to POSNA membership on April 25, 2011 encouraging the membership to review the draft CPG and provide commentary. Further commentary was solicited at the recent POSNA Annual Meeting on May 11-14, 2011, in Montreal, Canada.

Structured review forms with no additional comments were completed by Drs. McIntosh, Leet, Klingele, Gambacorta, and Crawford. These are attached to this email for your records.

Additional comments were provided by Drs. van Bosse, Price, and Campbell. These are summarized below.

Dr. Harold J.P. van Bosse (Philadelphia, PA):

1. Line 1231 of page 55: “significantl” (need to decide on whether you want “significant” or “significantly” – can’t choose the middle path!).

We have corrected this typographical error.

2. "My only issue is with the medial-lateral pinning vs. lateral only pinning (Recommendation 3). The combined rate of iatrogenic ulnar nerve injury is given as 6%, but I did not see an analysis of what percentage of those injuries recovered completely, and what percentage were incompletely recovered/permanent (I might have missed it, it is a lengthy document). Naturally, none of us wants to cause any harm to our patients. But, if the rate of lasting neurologic injury was extremely low, this might weaken the argument further against medial pinning.

The work group took considerable time to discuss this and agreed that the best available evidence is of low quality and as such the work group cannot have confidence that additional studies will not overturn this recommendation in the future. Also, regardless of recovery, the nerve injury has still occurred and therefore, does not weaken the argument against the use of medial pinning if we consider this from the patient’s perspective. Further, not all of the studies reported complications and number of patients who recovered. For your convenience, we have detailed the recovery rate data reported in the included studies for Recommendation 3. Please see below.

Author	Reported complication rate	Recovered	Time of recovery
France	Did not report complications	not reported	not reported
Altay	Medial pinning had 2 (8%) iatrogenic ulnar nerve injury	100%	Within 2-3 months
Bombaci	Four patients had neurologic complications. One median (group 1), one interosseous (group 2), and two radial nerve palsies (one group I, one group 2) were documented at the time of initial examination. Ulnar nerve palsy developed in one patient (group 1) postoperatively.	100%	not reported
Devkota	7 patients (6.86%) got ulnar nerve injury (no injury from lateral side)	6/7(86%)	3.5 months
Foead	Of the 55 patients,7 ulnar nerve injuries (5 patients in the medial-lateral fixation group and 2 patients in the 2-lateral pin fixation group) and one radial nerve injury (a patient in the 2-lateral pin fixation group) were detected after the treatment procedure.	100%	6 months
Gordon	Did not report complications	not reported	not reported
Kocher	No complications	not applicable	not applicable
Memisoglu	In group 1 (K-wires placed from the lateral condyle and lateral humerus towards the medial epicondyle) there was no postoperative iatrogenic nerve damage whereas in group 2 (Two cross-wires passed—one from medial and one from lateral)iatrogenic ulnar nerve damage developed in six (9%) patients. On statistical evaluation, a significant difference was seen between the two groups ($p<0.05$).	not reported	not reported
Shamsuddin	3 cases from crossed pin group and 2 from lateral pinning group	1/3 from crossed pin lateral pin patients was loss at follow up	not reported
Sibinski	5 ulnar nerve palsies occurred after closed reduction and medial pin insertion and were most probably iatrogenic. There were no ulnar nerve injuries in the lateral insertion group	4/5 80%	7 months
Skaggs	Seventeen (4.9%) of the 345 patients had an iatrogenic ulnar nerve injury. None of the 125 patients in whom only lateral pins were used had a nerve injury. Six (4%) of the 149 patients in whom a medial pin was placed without hyperflexion of the elbow and eleven (15%) of the seventy-one patients who had placement of the medial pin with hyperflexion of the elbow had an ulnar nerve injury. The difference among the three groups was significant ($p < 0.001$) .	16/17 (11 followed for 18 weeks after surgery and 1 did not recover)	4.5 months (18 weeks)
Solak	1 in two crossed K-wires group	All neurological deficits, except one postoperative ulnar nerve injury in group 1, showed a full recovery.	not reported
Topping	1 in crossed pin group	Fully recovered after replacing the pin	not reported
Tripuranein	1 transient ulnar neuritis in one medial and two lateral pins group	100%	7 months
Zamzam	4%	100%	not reported
Fahmy	Not reported	not reported	not reported
Lee	No complications	not applicable	not applicable

I agree with other reviewers' comments about steps that can be taken to decrease nerve injury, and understand the counter argument that these steps have not been vetted in the literature. A compromise might be to add to the end of the recommendation "…unless the practitioner well experienced in the operative care

of SCH fractures, and is keenly aware of techniques designed maximize the safety of the ulnar nerve during medial pin insertion."

Based on your comments a well as others, we have added the following statement to the Rationale for Recommendation 3:

"The risk of potential harm from a medial pin must be weighed against the potential advantages."

There is an explicit link between the strength of the supporting evidence and the language of the guideline. We believe the soft wording used with weak evidence conveys the confidence we have in the recommendation.

Dr. Charles Price (Orlando, FL):

1. "One remaining concern is our lack of agreement on the Gartland Classification when they say that all type II and III should be pinned. In fact that is true but many of us didn't (or don't know) that Gartland Type II is moderately displaced and type III is severely displaced. Thus, all Gartland II and III fractures are displaced and this may need to be communicated."

The work group discussed your comment in depth. Eleven studies provide the evidence for Recommendation 2. As stated in the rationale "For this analysis, Gartland Type II and III fractures were analyzed in aggregate since many of the studies combined the results from the two types. Similarly, the less common flexion type pediatric supracondylar fracture was included in this group." The authors of the studies may or may not have defined their individual interpretation of the Gartland classifications. The work group members suggest you refer to the authors for clarification as to the precise definition used within each study.

Dr. Robert Campbell (Philadelphia, PA):

1. "If I'm reading the AAOS recommendations correctly, the recommendation is that surgeons "might" consider 2-3 lateral pins, with no mention of medial pins.

As a direct result of the peer review process, this recommendation was changed to read as follows:

"The practitioner might use two or three laterally introduced pins to stabilize the reduction of displaced pediatric supracondylar fractures of the humerus. Considerations of potential harm indicate that the physician might avoid the use of a medial pin."

The message is clear that AAOS feels that with the roughly 500 cases in the literature, the rate of ulnar nerve injury by lateral pins (.53%?) vs medial pins (20%?) is so significant that they cannot support any consideration of medial pins. AAOS repeatedly cites that although some reviewers make the case for medial pins, AAOS can only consider the "available" published evidence. But as

they concede, the 15 reports addressing crossed pins vs lateral are mostly level III, except for Kocher's.

No, the recommendation does not say or imply that the AAOS "cannot support any consideration of medial pins." The best available evidence is weak and as such the work group cannot have confidence that additional studies will not overturn this recommendation in the future, hence the reason the recommendation is worded as "might avoid".

Data on 65 outcomes from 15 studies comparing pinning techniques using lateral pins only to a single lateral pin with a medial cross pin were found for this recommendation. Sixteen outcomes were of moderate quality and the remaining 49 were of low quality. Better quality evidence is needed to clarify the use of medial pins and it is incumbent on the proponents of this technique to illustrate its usefulness while balancing the benefits and harms associated with its use.

In my opinion, that evidence is even weaker, because the highest rates of ulnar nerve injury have occurred at academic institutions, where level of experience of house staff, and their level of supervision are unknown (some studies, I believe, do look at level of training, but that may be misleading since I've known some junior residents with better skills with SC fX than more senior ones). Also these studies don't really tell us the experience levels of the supervising staff. Also a lot of type III fxs differ in complexity, some atypical, maybe comminuted, and are more of a challenge, even to the greatly experienced like us. So the studies differ widely in ulnar complication rate for all these reasons. Seems like this evidence is so weak and limited, this recommendation is way too overreaching, especially compared to the other recommendations.

We agree that the best available evidence is weak. The issues you raise address the applicability of the studies and not the quality of this evidence. We do correct for applicability flaws, however, there is no consensus in the methodological world for how and how much we should correct.

Recommendation 3 is supported by weak evidence and, therefore, the recommendation is worded as "The physician might avoid the use of a medial pin." This is very soft wording. Please see table 6 on page 11 of the guideline. Also as indicated above, the data reported is from 15 studies and 65 outcomes; sixteen were of moderate quality.

And if AAOS want to endorse lateral pins only for this injury (yes,I know, some say guidelines are not an endorsement, but the public and the attorneys will say otherwise), there may be liability for AAOS and POSNA later when lateral pins go badly, (remember the liability of SRS in the pedicle screw law suits?) And those of us who occasionally feel for the best of a patient we need to add a medial pin, then we are placed in unnecessary liability. And realistically, most of the common injury problems, like supracondylar fxs, are not reported(my only ulnar nerve injury was due to a lateral pin, and that remained unreported) , so AAOS is going way out on a limb making recommendations based on a very small percentage of the total US practice experience. The ideal study to quote for practice guidelines would be a prospective randomized single expert surgeon study in which the same person, treating a very rigorously defined type of SC Fx , either with

crossed or lateral pins only , with enough power to see neurologic issues, if any, happen, but I'm not aware of that one."

We agree that what is best for the patient should always be the first consideration and you are also correct that the AAOS is not endorsing the use of lateral pins. That said, and not surprisingly, we would hope for documentation of the statements you make above including correlations to academic institutions, surgeon experience, fracture complexity, type and added complications. We would also appreciate documentation that changes due to technical and other modifications are, indeed, improvements.

Recommendation 3 is based on weak evidence and also considers the harms and benefits associated with lateral and medial introduction of pins. The work group wrote the recommendation indicating preference for laterally introduced pins. We believe surgeons have the option to treat the patient as necessary, including using the option of medial pinning. Please remember that the recommendation says "might", it does not say "must."

The guidelines, as currently written, permit the clinician to apply a medial pin if judged necessary. The work group does come down in favour of lateral pinning because of the potential for harm. Literature substantiating the assertion that a medial pin can be placed safely in such circumstances would be a contribution. The present state of the literature suggests a higher chance of ulnar nerve injury with a medial pin, at about 6%, and little clinically important loss of reduction with all lateral pinning.

Dear Dr. Kocher, as always thank you for your time in collating these responses. We appreciate the support, time and effort of all POSNA members.

Thank you for your consideration of these comments during the commentary period. We look forward to your response.

Sincerely,
Min Kocher

Mininder S. Kocher, M.D., M.P.H.
Associate Director, Division of Sports Medicine Children's Hospital Boston
Associate Professor of Orthopaedic Surgery Harvard Medical School

clinical: (781) 216-1328
surgical scheduling: (617) 355-8931
fax: (617) 730-0178
administrative: (617) 355-8423
administrative assistant:
mandy.wong@childrens.harvard.edu<mailto:mandy.wong@childrens.harvard.edu>

American Academy of Orthopaedic Surgeons
[The Treatment of Pediatric Supracondylar Fractures]
Guidelines Peer Review Form

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

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

Please note that if you return a review:

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

Reviewer Information:

Name of Reviewer_____Charles T. Price, M.D._____

Address__83 W. Columbia St_____

City__Orlando_____ State_____Florida_____ Zip Code_32806_____

Phone _321-843-5271_____Fax _321-843-5298____E-mail_charles.price@orlandohealth.com

Specialty Area/Discipline: ____Pediatric Orthopedic Surgery_____

Work setting: __Academic/Hospital_____Credentials: ___M.D._____

May we list you as a Peer Reviewer in the final Guidelines (GL)? x☐ Yes ☐ No
PLEASE READ: If you do not wish to be listed, your name will be removed for identification purposes. However, your review comments, our responses and your COI will still be available for public review on our website with the posted Guideline if you complete this review.

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

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

Society Name: __Pediatric Orthopedic Society of North America_____
(Listing the specialty society as a reviewing society does not imply or otherwise indicate endorsement of this guideline.)

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

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

x☐ **I have declared my conflicts of interest on page 2 of this form.**

x☐ **I have declared my conflicts of interest in the AAOS database; my customer # is 00012037_____**

x☐ **I understand that the AAOS will post my declared conflicts of interest with my comments concerning review of this guideline on the AAOS website.**

American Academy of Orthopaedic Surgeons
[The Treatment of Pediatric Supracondylar Fractures]
Guidelines Peer Review Form

REVIEWER CONFLICT OF INTEREST - The Orthopaedic Disclosure Program

Each item below requires an answer. Please report information for the last 12-months as required by the Accreditation Council for Continuing Medical Education (ACCME) guidelines.

Do you or a member of your immediate family receive royalties for any pharmaceutical, biomaterial or orthopaedic product or device? If YES, please identify product or device: Biomet Spine and Trauma (Array Spinal Deformity, Peanut Growth Modulation Plate, Submscular Femoral Locking Plate, Pediatric Radius Fracture Brace)	x☐ Yes ☐ No
Within the past twelve months, have you or a member of your immediate family served on the speakers bureau or have you been paid an honorarium to present by any pharmaceutical, biomaterial or orthopaedic product or device company? If YES, please identify company: Yes, Biomet Spine	x☐ Yes ☐ No
Are you or a member of your immediate family a PAID EMPLOYEE for any pharmaceutical, biomaterial or orthopaedic device or equipment company, or supplier? If YES, please identify company or supplier:	☐ Yes x☐ No
Are you or a member of your immediate family a PAID CONSULTANT for any pharmaceutical, biomaterial or orthopaedic device or equipment company, or supplier? If YES, please identify company or supplier: Biomet spine	x☐ Yes ☐ No
Are you or a member of your immediate family an UNPAID CONSULTANT for any pharmaceutical, biomaterial or orthopaedic device or equipment company, or supplier? If YES, please identify company or supplier:	☐ Yes ☐ No
Do you or a member of your immediate family own stock or stock options in any pharmaceutical, biomaterial or orthopaedic device or equipment company, or supplier (excluding mutual funds) If YES, please identify company or supplier: I do not manage my investments or have any knowledge of our investments. Our account managers manage these without my review or knowledge.	x☐ Yes ☐ No
Do you or a member of your immediate family receive research or institutional support as a principal investigator from any pharmaceutical, biomaterial or orthopaedic device or equipment company, or supplier? If YES, please identify company or supplier: Wright Medical	x☐ Yes ☐ No
Do you or a member of your immediate family receive any other financial or material support from any pharmaceutical, biomaterial or orthopaedic device and equipment company or supplier? If YES, please identify company or supplier:	☐ Yes x☐ No
Do you or a member of your immediate family receive any royalties, financial or material support from any medical and/or orthopaedic publishers? If YES, please identify publisher:	☐ Yes x☐ No
Do you or a member of your immediate family serve on the editorial or governing board of any medical and/or orthopaedic publication? If YES, please identify: Journal of Pediatric Orthopedics, Journal of Orthopedic Trauma	x☐ Yes ☐ No
Do you or a member of your immediate family serve on the Board of Directors or a committee of any medical and/or orthopaedic professional society?	x☐ Yes ☐ No

If YES, please identify: **Annual Meeting Committee of AAOS and Education Council of AAOS**	

American Academy of Orthopaedic Surgeons
[The Treatment of Pediatric Supracondylar Fractures]
Guidelines Peer Review Form

Reviewer Instructions

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

Please complete and return this form electronically in **WORD format** to wies@aaos.org; please contact Jan Wies at (847) 384-4311 if you have any questions. Thank you in advance for your time in completing this form and giving us your feedback. We value your input and greatly appreciate your efforts. Please return the completed form **in WORD format** by end of day **January 5, 2011**.

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

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

COMMENTS

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

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

2. There is not a link between the recommendations and the supporting evidence for Recommendations 2 and 6.

Recommendation #2 cites the Gartland classification as the guideline for surgery for supracondylar fractures. The Gartland Classification has poor reliability, and was not used by several of the publications that were cited as evidence for application of that classification. An erroneous assumption may have been made that the reviewers understood this Gartland classification without actually reviewing the original article. As Mark Twain said, “It ain’t what you don’t know that gets you into trouble. It’s what you know for sure that just ain’t so.” This assumption of knowledge can lead to treatment guidelines that are erroneous or inappropriate, as they are in the case of Recommendation #2.

We did not intend to recommend the Gartland classification system per se. Rather, we used it as a description that we thought most orthopaedic surgeons would understand. Based on your comments, we have added a section at line 695 to the methods section of the guideline as well as text to the rationale for Recommendation 2. The work group chose to use the Gartland system for classification of fractures as a frame of reference. We are confident that a qualified Orthopaedic surgeon will be able to associate the characteristics of a Gartland Type I, II, or III fracture to the patient before them, also considering the limitations of any classification system.

The work group spent considerable time during the final meeting discussing the classification systems used in the supporting studies for Recommendations 1 and 2. All classification systems have flaws. Use of any system requires the interpretation of the surgeon, who also incorporates the characteristics and presentation of the specific patient presenting for treatment, the circumstances, and the available resources in order to diagnose and determine type of fracture and treatment. As stated in several places throughout this guideline, clinician input based on experience increases the probability of identifying patients who will benefit from specific treatment options. The individual patient’s circumstances will also influence treatment decisions; therefore, discussion of available treatments and procedures applicable to the individual patient rely on mutual communication between the patient’s guardian and physician, weighing the potential risks and benefits for that patient. Once the physician has informed the patient’s guardian of available therapies and has discussed these options with his/her child’s physician, an informed decision can be made.

Recommendation #3 did not account for current techniques for avoiding ulnar nerve injury. Only one method of lateral pinning was evaluated and the voting on this recommendation may reflect inadvertent bias by reviewers who believe that lateral pinning is the only way to prevent ulnar nerve injury.

The technique of medial pin introduction that you espouse, and that Kocher reported, reflects the anatomical and technical considerations that many of us have used when performing and teaching dozens if not hundreds of medial pin insertions over the past fifteen years. We may all be right that this is a safe way to insert a medial pin. However, the empirical patient results recorded in the orthopaedic literature as of 2010 are insufficient to support this position. The guideline can only reflect what is known based on conscientiously applied rules of evidence which are explicitly defined beforehand. Careful documentation of current techniques may change the balance of evidence in the future.

We performed a comprehensive, systematic search to support Recommendation 3. If there are studies that met the *a priori* inclusion criteria and were not included, please supply the references and we will be happy to review and consider for inclusion. We believe our searches would have captured current techniques for avoiding ulnar nerve injury if published data were available and posted prior to this date. In general, it is not prudent to assume that something is better just because it is new. Accordingly, we are particularly interested in well-designed studies that establish that current techniques that have reduced ulnar injury rates.

Also, clinical knowledge of fractures requires that medial pinning remain an option for unstable fractures. Limiting surgeons to lateral pinning by guideline recommendations is detrimental to patient care. An article in Lancet (374:273-5, 2009) noted that guidelines are being used by third-party insurers to influence payment, by litigating attorneys to hold physicians accountable in malpractice cases, and by companies to promote sales. It is essential that surgeons have the option of using medial pinning when fracture stability dictates medial and lateral pinning. It remains to be determined whether three, four, or five lateral pins are as safe as one medial and one lateral pin with two lateral pins are unstable.

1. It is incumbent upon all users and readers of this guideline to understand the recommendations made and the supporting evidence. This includes third party payors and attorneys.

2. Based on weak evidence, and considering the harms and benefits associated with lateral and medial introduction of pins, the work group wrote the recommendation indicating preference for laterally introduced pins. It is a weak recommendation as indicated by the language "The practitioner might…" This leaves the option of medial pinning open.

3. We believe surgeons have the option to treat the patient as necessary, including using the option of medial pinning. This recommendation should be an indication to surgeons that if they chose to use medial pinning there is a 1 in 22 chance of harm (see the rationale for this recommendation, line 1177 in the guideline.)

4. There is an inherent link between the strength of the evidence and the language of the guideline [see tables 5 and 6]. The fact that this recommendation is based on weak evidence reflects the confidence that the work group members have that this recommendation *could* be overturned by future higher quality evidence.

5. The basis for this recommendation includes 65 outcomes derived from 15 low or moderate quality studies. This body of evidence also represents the *best available evidence*.

   This recommendation states:

The practitioner might use two or three laterally introduced pins to stabilize the reduction of displaced pediatric supracondylar fractures of the humerus. In the absence of strong evidence, considerations of potential harm indicate that the physician might avoid the use of a medial pin.

The rationale for Recommendation 3 summarizes the evidence and the work group's reasoning (see the rationale for this recommendation) in the guideline:

Critical outcomes investigated were iatrogenic ulnar nerve injury, loss of reduction, malunion, and reoperation rate. This recommendation is based on data on 65 outcomes from 15 studies comparing pinning technique using lateral only pin entry to lateral and medial crossed pin technique.

We understand that, in the absence of considering ulnar nerve injury, two of the six studies that were sufficiently powered for loss of reduction were statistically significant in favor of medial pins. The remaining four studies reported no statistically significant difference between lateral and medial pins. However, when all studies are taken together, their results are tempered.

Meta-analysis of low and moderate quality studies found no statistically significant difference between lateral and medial pin configurations with respect to Baumann's angle, Baumann's angle change, Flynn's Criteria and infection.

A meta-analysis of these studies also demonstrated a statistically significant effect in favor of lateral pinning (Number Needed to Harm = 22, Odds ratio = 0.27). This suggests a 1 in 22 chance of harm resulting from the medial pinning techniques used in these studies.

6. The criteria used to select articles were inappropriate in my opinion.

Studies from developing countries should not be used to determine guidelines for medical care in the USA. Cultural, social, and resource issues in those countries may bias the outcomes of surgery or out-patient care in follow-up of operative or non-operative care. Being published in English is not an adequate filter for guiding care in the USA.

The criterion of publication in a peer-reviewed journal is a low hurdle for many of the articles that were selected for inclusion. There is a reason why articles in English are published in the *Kathmandu University Medical Journal* (reference #30), in the *Journal of Ayub Medical College* Abbottabad (ref.#28). Also citations from the *Journal of the Nepal Medical Association* or the *Saudi Medical Journal* and other similar journals were probably rejected by the JBJS, JPO, CORR, JOT, and several other journals before they finally emerged in regional or local publications. I would suggest the added criteria of regions of general distribution of English-language journals, or perhaps circulation volume, or perhaps eliminate all journals that are distributed primarily to members of the society that publishes the journal or journals that are provided at no cost to the reader. In this day of easy publication it is necessary to have a filter that is broader than publication in the English language.

1. We are all developing countries (see gapminder.org). Countries exist along a continuum of social and economic and health care indicators with no clear cutpoints.
2. Although wealth and education are positively correlated both within and across countries, excluding information from outside the US would be a difficult position to defend. In addition, the study criteria are determined *a priori* to the literature search to minimize bias.

3. Excluding all studies from outside the US would exclude the Pirone study from Canada. This is silly. Any other cutpoint is arbitrary.
4. Given the complexity of the country of origin question (publications from around the globe in JBJS A and B, American publications in foreign based journals), it would be difficult to quantify how country of origin or publication affects study quality. There may be some effect. We are unaware of a scientifically rigorous technique for evaluating this effect. We believe that the best position to take is an explicit evaluation of the quality of the full publication according to current scientific and reporting standards.
5. As an aside, distraction osteogenesis, one of the biggest orthopaedic advances in the last half century, was developed by Ilizarov working independently in a Siberian operating room reputedly heated by a woodstove.

Please understand that we subject all articles to a rigorous quality evaluation. Accordingly, if these articles were indeed that poor, they would have been excluded. Evidence-based medicine demands substantial critical evaluation of information sources. Assuming that a study is good (or bad) because it appeared (or did not appear) in a certain journal is not in keeping with these demands.

Thus, this and all other guidelines must be viewed with skepticism in their entirety until appropriate citations are selected.

This guideline, like all others the AAOS develops, is the product of an intellectually rigorous evaluation of the data.

8. Several important studies that met criteria were not included. These are indicated in some of the attached documents.

We addressed these studies where you listed them in the attached documents; none of these studies met the inclusion criteria, principally because they were not performed on living people or because they were of low quality. Reasons for exclusion are noted with the citations.

Finding only one would represent the tip of the iceberg because I did not have the time or resources to search more than 10-15 articles in my efforts to identify excluded articles that should have been considered.

Please see the preceding comments.

Even some of the basic assumptions such as the Gartland Classification were not included in the development of these criteria and those articles should have been reviewed and included.

The work group discussed this and felt the citation was “common knowledge” within the Orthopaedic Community. Based on your comments, it will be added to bibliographic list for references in the guideline because it was recalled, reviewed, excluded for the recommendations and used for reference.

Gartland JJ. *Management of Supracondylar Fractures of the humerus in children*. Surgery, Gynecology and Obstetrics, 1959 (PMID: 13675986)

Why wasn't Flynn's original article cited?

This study was cited and listed in the excluded study list (see line 2498 in the guideline):

Flynn JC, Matthews JG, Benoit RL. *Blind pinning of displaced supracondylar fractures of the humerus in children. Sixteen years' experience with long-term follow-up*. J Bone Joint Surg Am 1974;56(2):263-272.

That article was the first full publication of pinning of supracondylar fractures. Prior to that, only an abstract had been published. Flynn's criteria are used in many of the subsequent papers that are cited as outcome measures in the included articles. Do the reviewer's know Flynn's criteria and whether the outcomes were reported accurately or whether Flynn's criteria was loosely applied as was the Gartland classification? Flynn's paper forever changed the way this injury is treated. As Flynn's partner, I was privileged to witness the improvements in treatment for this injury without statistical methodology to develop clinical practice guidelines Dr. Flynn's nurse of many years, had a withered arm from Volkmann's ischemic contracture. As a child, she had been treated in a flexed arm cast. Her story was horrifying and represented the practice guidelines of the period before he developed pinning. Flynn's persistence and the publication by Pirone were the two seminal events in changing practice patterns. Everything that has followed regarding two pins vs. three pins, medial vs. lateral, type II vs.Type III is only fluff and meaningless trivia that should be left up to the surgeon to decide. Only pinning of displaced fractures and extension of the elbow following pinning should be emphasized. That is the true advancement in care in the past 20 years. Ulnar nerves are rarely injured accidentally, can be protected by current techniques, and recover more than 95% of the time. That is a small price to pay for prevention of compartment syndrome by stable fixation that allows elbow extension following pinning.

Elbow extension and cast splitting should be the emphasis of these guidelines instead of quibbling about trivia when there is not enough evidence to support current trivia.

We believe that the physician work group that volunteered their time and expertise to this guideline captured the important clinical process for treatment of supracondylar fractures. When they asked the preliminary recommendations concerning the treatment pathway for this injury, they did not know what evidence would be available.

The work group volunteers adhered to the rigorous AAOS evidence-based processes, attended the Introductory and Final Meetings and are participating in the dissemination of this guideline. They have provided a valuable service to the mission and goals of the Academy.

9. The validity of some studies may have been inappropriately analyzed due to hidden fears and biases. The reviewers may not have analyzed the studies of ulnar nerve injury to account for spontaneous recovery. The number injured by medial pinning is too small to be statistically valid and only one case in the citations had residual deficit. Lateral pinning in unskilled hands may be more hazardous than medial pinning in skilled hands. It is not possible to make statistical assumptions on basis of one case that did not recover when hundreds of cases have been included in this entire report. One case is anecdotal information. I would encourage the reviewer's to read the book, *The Science of Fear*, by Daniel Gardner to see how rare events can have overwhelming influence on human behavior.

1. The physician work group consisted of nine surgeons and we are confident that applicability was not "inappropriately analyzed due to hidden fears and biases." The physician work group considered the external validity (generalizability or applicability) of the included studies. We have indicated this for each recommendation in a summary table immediately following the Strength of Recommendation. This table also indicates if the strength of the recommendation was adjusted when the work group considered harms and benefits. Perhaps you skipped over these tables in the guideline? We have copied the table for Recommendation 3 below following our response for your convenience.

2. The number injured by medial pinning is statistically significant, not made on the basis of one case, and we believe important to the patient. In addition, the rationale addresses the number injured from medial pinning. This information is copied below for your convenience. Further, the numbers would not change concerning the "harms" associated with ulnar nerve injuries if "spontaneous recovery" was included. The injury (complication) still occurred, although we agree that patient recovery is a desired outcome. Please see Line 1171 in the guideline for the following text,

"The ulnar nerve was injured in 3 of 557 (0.53%) cases with laterally introduced pins. Medially introduced pins resulted in 49 of 808 (6%) cases of ulnar nerve injury. Iatrogenic ulnar nerve injury was noted to be statistically significant in favor of lateral pinning in 6 of 11 studies. A meta-analysis of these studies and three additional underpowered studies (1 moderate quality and 13 low quality) also demonstrated a statistically significant effect in favor of lateral pinning (Number Needed to Harm = 22, Odds ratio = 0.27). This suggests a 1 in 22 chance of harm resulting from the medial pinning techniques used in these studies. Based on weak evidence, the practitioner might use two or three laterally introduced pins to stabilize the reduction of displaced pediatric supracondylar fractures of the humerus."

Included Studies	Number of Outcomes	Level of Evidence	Quality	Applicability	Critical Outcome(s)	Benefits and Harms Adjustment
Altay[34]	1	III	Low	Moderate	iatrogenic ulnar nerve injury. loss of reduction, malunion, reoperation rate	None
Bombaci[35]	3	III	Low	Moderate		
Devkota[36]	3	II	Low	Moderate		
Foead[37]	9	II	Low/ Moderate	Moderate		
France[26]	1	III	Low	Moderate		
Gordon[38]	2	III	Low	Moderate		
Kocher[39]	14	II	Moderate	Moderate		
Memisoglu[40]	5	III	Low	Moderate		
Shamsuddin[41]	7	III	Low	Moderate		

Sibinski[42]	4	III	Low	Moderate
Skaggs[43]	3	III	Low	Moderate
Solak[44]	3	III	Low	Moderate
Topping[45]	3	III	Low	Moderate
Tripuraneni[46]	4	II	Low/ Moderate	Moderate
Zamzam[47]	3	III	Low	Moderate
Fahmy[48] *	3	III	Low	Moderate
Lee[49] **	6	III	Low	Moderate

*Intrafocal pinning techniques compared, **Divergent vs. parallel configurations

13. The side effects and health benefits have not been adequately addressed. The parameter of instability from lateral pinning has been under-emphasize and the parameter of transient ulnar symptoms has been over-emphasized.

The AAOS guideline development process is strictly structured to minimize such bias. If a parameter is "under or over-emphasized" it is a reflection of the available evidence rather than bias by the work group. The physician work group defines the scope of the guideline by specifying the preliminary recommendations at the Introductory Meeting. The preliminary recommendations follow the treatment pathway; this is intentional.

Health benefits of stable fixation by medial pinning have been overlooked because biomechanical studies have not been included.

We are not certain how the health benefits and treatment efficacy of stable fixation can be determined using cadavers. Biomechanical studies do not provide patient-oriented outcomes. These studies *may* provide a tight set of data; however, the difference may be clinically negligible. We focus our guidelines on outcomes that matter to patients. Please see "Outcomes Considered", line 649 in the guideline:

"Clinical studies often report many different outcomes. For this guideline, patient-oriented outcomes are included wherever possible. If patient-oriented outcomes were not available surrogate/intermediate outcomes were considered. Surrogate outcome measures are laboratory measurements or another physical sign used as substitutes for a clinically meaningful end point that measures directly how a patient feels, functions, or survives.[5]

Crossed pinning is technically easier to perform as evidenced by specific techniques of lateral pinning that must be understood to achieve equal stability. Loss of fixation from lateral pinning is more common than long term ulnar neuropathy. Several authors added medial pins when lateral pinning was deemed unstable in the operating room. Thus it is clear that medial pinning is more stable and is actually recommended for many supracondylar fractures. Any surgeon should have healthy respect

for the ulnar nerve, and I have switched to lateral pinning for the majority of supracondylar fractures because lateral pins can stabilize most of these fractures. However, my bias for lateral pinning does not mean that medial pinning is a poor technique in the hands of a good surgeon.

We agree, please see all of our previous comments.

15. For the reasons cited above some of the grades assigned to the recommendations are inappropriate.

The grades of the recommendations are based on the supporting evidence that met the inclusion criteria for this guideline as a result of a comprehensive review. The reasons you cite above as "inappropriate" suggest/ require that the inclusion criteria and recommendations for this guideline be changed to reflect your *opinions*. Unfortunately, we cannot accommodate your opinions as this is an evidence-based guideline.

Dear Dr. Price,
We sincerely appreciate the time and expertise you have contributed to the review of this document. Your input has helped us strengthen the final document we will present to the AAOS Board of Directors for approval.

Thank you.

OVERALL ASSESSMENT

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

☐ Strongly recommend

☐ Recommend (with provisions or alterations)

x☐ Would not recommend

☐ Unsure

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

Recommendation #2 cannot be supported because the evidence used to support pinning of Type II supracondylar fractures is flawed and confusing in some of the citations. The evidence for closed reduction and pinning of Type III supracondylar fractures is clearly established, but it is inappropriate to lump both types of supracondylar fractures in the same recommendation on the strength of evidence reported in the studies that were cited, or in any studies for that matter. The evidence in the literature supports reduction and pinning of displaced supracondylar fractures.

The work group initially stratified the recommendations by type of fracture but, as you point out, the reporting of the published results did not permit this. However, because the authors of these studies combined data from the fracture types, they, the peer-reviewers of these articles clearly felt that this "lumping" was appropriate. We followed their lead. Line 1000 in the guideline implies this by saying:

"Data on 48 outcomes from 11 studies formed the basis of this recommendation. For this analysis Gartland Type II and III fractures were analyzed in aggregate since many of the studies combined the results from the two types. Similarly, the less common flexion type pediatric supracondylar fracture was included in this group."

Given your stature in the field, it may be possible for you to talk to journal editors, reviewers, and prospective authors about this issue. Doing so may improve the quality of the literature.

I would encourage the panel of experts to review Gartland's original description if they haven't done so. That paper does not meet the criteria for inclusion so perhaps it was used as a guide based on general perceptions that may be erroneous.

The work group felt this classification system was so common that we did not need to include the reference. However, based on your comments, and because the guideline is not evaluating the effectiveness of this system, we have now included the citation for it as a reference.

Examples and concerns:

In several of your comments below, you mention the conclusions reached by the authors of published studies. To avoid confusion, we would like to take this opportunity to note that , as a general rule, one should not rely on authors conclusions. The data they report is more important and, often, more accurate. We are not unique in employing this kind of critical reading of the literature. It has been suggested by others (see Montori VM, Jaeschke R, Schunemann HJ et al. Users' guide to detecting misleading claims in clinical research reports. *BMJ* 2004;329:1093-1096) and is fundamental to the critical evaluation of a published paper.

1. The article by Ababneh, et.al. (Intl. Orthop. 22:263, 1998) compared three types of treatment for displaced supracondylar extension fractures. They concluded that "Closed reduction and wire fixation is recommended as the treatment for grades II and III supracondylar fractures". It should be noted that these authors used the classification system of Liang and not the classification system of Gartland. Thus,

that publication is not relevant to the evidence and should be eliminated from further consideration if the Gartland classification is used for decision-making.

The work group did not intend to specifically recommend the use of the Gartland classification system. Rather, their mention of it is by way of describing the kinds of fractures they are discussing in any given recommendation. This is obviously preferable to not providing any sort of description, and also to devising their own classification system. We have changed the language in the guideline to reflect this.

Based on your comments, as well as those of others, we have added a paragraph called "Classificaton Systems" to the guideline at line 581. The intent of the work group as to the use of classification systems is detailed here as follows:

CLASSIFICATION OF THE FRACTURE

TIMING

Based on the evidence, acute fracture we defined patients with "acute" fractures as those patients who presented for treatment within fourteen days of injury. Please see the supporting evidence for Recommendation 1 for additional information.

SYSTEMS OF CLASSIFICATION

There are numerous fracture classification systems employed by surgeons to help evaluate, plan and standardize treatment. Classification systems communicate the displacement, comminution and rotation of the fracture being treated but no single classification system has perfect inter and intra observer reliability. Further, no classification system can precisely classify all fractures without consideration of additional clinical factors including the mechanism of injury, time and duration since injury, soft tissue damage and swelling and/or presence of neurovascular compromise. Hence, within the guideline we reference the Gartland classification system as a point of reference and not a standard for fracture classification.

The Gartland classification system also applies only to extension and not flexion fractures. However, within our guideline all recommendations that address a displaced fracture refer to both extension and flexion fractures. The ultimate goal of treatment is to achieve optimal outcomes for the patient. As stated throughout the guideline, treatments and procedures applicable to the individual patient rely on mutual communication between the patient's guardian and physician, weighing the potential risks and benefits for that patient based on their individual circumstances, injury and presentation.

2. PIrone, et.al. is also included as a valid study. These authors found a high proportion of poor outcomes when Type II fractures were treated closed. However these authors used their own classification system that was modified from Wilkins' modification of the Gartland's Classification. They included minimally displaced fractures as Gartland Type IIb, but also identified a Type IIa which would be qualified as a Gartland Type I fracture. Pirone, et.al. did not separately analyze their type IIa and type IIb so it is impossible to determine whether some of the Gartland Type I fractures were included in their

surgical group. This should invalidate the use of Prione, et.al. as evidence for use of Gartland's classification

As noted above, the guideline is not evaluating the Gartland system. Rather, it is using it as a way to describe fracture types. The revised version should make this clearer.

3. Pandey, et.al conducted a randomized trial of pinning vs. slab application. They concluded that pinning produced improved outcomes compared to plaster slab after reduction. However, they only included supracondylar fractures classified as Type IIb and Type III. This is the Wilkins classification although it is not identified as such.

As noted above, the guideline is not evaluating the Gartland system. Rather, it is using it as a way to describe fractures. The revised version should make this clearer.

4. Eleven papers were cited as evidence for pinning of Type II supracondylar fractures. Two included only Type III fractures, at least three (including the one from Kathmandu) did not use the Gartland classification as noted previously. Five papers were published in local journals in Nepal, Saudi Arabia(2), Kathmandu University Medical Journal, or the Journal of Ayub Medical College. Even though these are noted as peer-reviewed journals and published in English, one must question the applicability of methods of management in those countries compared to methods of management in the USA. Perhaps closed treatment is not as satisfactory based on ability to follow patients closely, availability of resources or cultural issues that are not applicable to surgeons in the USA for whom these guidelines are intended. The remaining two papers made the following statements: Kennedy, et.al., "We conclude that pin fixation has no advantages over simple immobilization in certain Gartland II and III type injuries." Padman, et.al. stated, "Closed reduction followed by plaster immobilization **or** percutaneous pinning resulted in a better outcome than open reduction." Thus it seems that two valid papers concluded that pinning is not required for all Gartland II and III fractures.

<u>How then did the panel find that pinning is recommended for all Gartland Type II fractures?</u>

The panel suggested pinning for displaced fractures based on data from 48 outcomes and 11 studies that met the inclusion criteria for this guideline. We came to a different conclusion than the authors in #4 above because we did our own *de novo* analysis of the data reported in ***all*** of the referenced studies. (please note the above comments about using author's conclusions).

5. Three reports specifically address Gartland Type II supracondylar fractures that were not included in development of these guidelines even though they seem to meet the stated criteria.

a. A report from Cincinnati Children's Hospital by Parikh, et.al. (JPO 24:380-84, 2004) is titled, "Displaced Type II extension supracondylar humerus fractures: do they all need pinning?" These authors concluded that pinning is not necessary for all type II fractures. They stated, "An attempt at closed reduction and casting, … appears justified if close follow-up can be maintained."

This study is a retrospective case series medical records review. Such studies do not meet any of the criteria required of a scientifically valid study.

b. An earlier report by Hadlow, et.al. (JPO 16:104-6, 1996) noted , "…Of Type II fractures 77% would be needlessly pinned if such a policy [routine pinning] was applied to Type II fractures."

From the abstract the study description is as follows: "The results of a 'selective treatment' policy applied to 176 patients with supracondylar fracture of the humerus are analyzed. As initial treatment 148 patients from this study underwent closed reduction and casting, 7 closed reduction and pinning, 17 olecranon traction, and 4 open reduction and pinning."

The main comparison group in this study (148 patients) could not be compared to other groups in the study that were considered for the guideline because the comparison groups contained too few patients to provide reliable data.

c. The third report is from Ireland by Kennedy, et.al. (Injury 31:163-7, 2000). These authors concluded "…that pin fixation has no advantages over simple immobilization in certain Gartland II and III type injuries." Thus there is evidence that pinning is not needed for the some Gartland Type II supracondylar fractures.

Again, seven patients with Gartland Type II injuries had closed reduction and percutaneous pinning. This is too few to yield reliable data. Similarly, for the patients with Gartland Type III injuries, there are too few patients to yield reliable results. There were only 5 patients in the open reduction and pinning group. This study did contain data that was included for patient complications and non-operative treatment. Flynn's score, however, could not be deciphered due to the author's incomplete reporting (see Table 1 in the study).

Again, please see line 613 in the guideline for inclusion criteria.

6. It should also be noted that reviews of surgical management may have selection bias because only fractures that are admitted to the hospital or operating room are included in the study. Patients with Gartland Type II fractures that are treated in an office or Emergency Department not be included in some of the studies that have been selected for analysis. Thus, the severity of Gartland Type II fractures may be skewed in the direction of treatment of more severely displaced fractures that are treated in the hospital or operating room.

You are correct. This is an applicability issue and is addressed in our quality evaluation. All studies for this recommendation had moderate applicability as noted in Line 1112, Table 18 in the document. Please also see Applicability Line 744, Table 3 Line 757, and Table 4 line 764 for all of the questions asked and method for scoring.

7. Heal, et.al. evaluated the reproducibility and reliability of the Gartland classification for supracondylar fractures. (J. Orthopedic Surgery 15:12-4, 2007). These authors found that Type II fractures showed fair to moderate agreement, but Type III fractures showed good to very good agreement. Thus, orthopedic surgeons are able to agree on displaced Type III fractures. Another study of reliability was published by Mallo, et.al. (Orthopedics 33:19, 2010). These authors reported the use of the Gartland classification for supracondylar fractures and also noted full agreement for Type III fractures, but moderate agreement for Type II fractures.

This guideline did not evaluate the utility of the Gartland Classification system. If it had, we would have done a comprehensive search and analyzed all studies that provided data on the validity (face, convergent and divergent), reliability, and reproducibility of the instrument.

Conclusions and Recommendations for Recommendation #2.

It is my opinion that Recommendation #2 should state:

"We suggest closed reduction with pin fixation for patients with Gartland Type III supracondyar fractures of the humerus."

The evidence does not support this. As indicated in the summary tables [Table 17, Table 31, and Table 33], the authors of the included studies routinely mix Type II and Type III fracture types.

Displaced fractures are displaced and that is definition enough for orthopedic surgeons. The type II b of Wilkins is displaced as is the Type IIb of Pirone. Expert opinion would conclude that pinning is recommended for displaced fractures even thought the evidence is not really conclusive in view of the numerous classifications and the confusion and unreliability of the Gartland Classification. The Gartland Type II fracture is a displaced fracture, but it cannot be supported by the evidence that is cited. Also there will be little agreement on the differences in Type II fractures when other surgeons confuse the Prione IIa and the Wilkins IIa or the Liang Classification. The term Type II is too confusing for guidelines to be accurately applied and may lead to unnecessary pinning of Wilkins Type IIa fractures in the belief that this represents a Gartland Type II fracture.

There is ample evidence to support pinning of displaced supracondylar fractures and there is also reliable agreement regarding completely displaced supracondylar humerus fractures (Gartland Type III).

This is what the work group said in Recommendation 2.

There is also evidence that even Gartland Type II fractures do not all need to be pinned.

We looked for this evidence but because the authors combined fracture types we did not identify any studies that support this conclusion.

It is my expert opinion that they do, but that is only an expert opinion that is refuted by at least two of the eleven cited papers and three more that seemed to meet the inclusion criteria but were not presented to the panel.

For clarification, all studies are presented to the work group. The AAOS process incorporates time for the physician work group to audit every study evaluated for this guideline if they so choose.

It is my opinion that Recommendation #3 should be changed to state:

"Two or three pins are recommended to stabilize the fracture following reduction of displaced type III fractures. We are unable to recommend for or against fixation with only lateral pins."

To reduce the possibility of bias in how recommendations are worded, the AAOS uses specific, predetermined wording for each of its recommendations [see table 5 and 6, page 11]. This wording is determined by the strength of the recommendation. The specific rules we use determining the wording is shown in the table below. Accordingly, recommendation three is worded the way it is because the strength of the recommendation is weak.

Table 16 AAOS guideline language

Guideline Language	Strength of Recommendation
We ***recommend***	Strong
We ***suggest***	Moderate
The Practitioner ***might***	Weak
We are ***unable to recommend for or against***	Inconclusive
In the absence of reliable evidence, the ***opinion*** of this work group is*	Consensus*

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

In some cases medial pinning is necessary for fracture stability. Although biomechanical studies have been excluded, it is known that crossed pinning is more stable than lateral pinning unless the lateral pin configuration is carefully followed. Thus teaching of technique is essential regardless of medial or lateral pinning. One of the purposes of retrospective review of clinical practice is to identify complications that occur from standard treatments. When those complications are identified, then strategies are implemented to avoid those complications. Thus, review of older literature in comparison to current methods can distort guidelines based on statistical methodology.

We agree that complications can be identified by retrospective case series. However, due to the inherent limitations in such studies, they cannot be used to determine the frequency with which these events occur. This is one reason we have excluded them from consideration. Further, "more stable" may be of little relevance; lateral pinning is stable enough given rapid healing and has low complications. The measurable data are provided in the guideline.

We also note that in the presence of older literature showing complications, it is difficult to assert that these complications do not occur when there are no newer data. The older literature represents the best available information.

Lateral pinning is one strategy that has been identified to prevent iatrogenic ulnar nerve injury during pinning. Initial teaching of pinning included full flexion of the elbow during medial and lateral pin insertion (see Flynn, 1974). Current methods using medial pin entry teach that the lateral pin is inserted first. Then, the elbow is partially extended. A small incision is then made and a hemostat is used to dissect to the medial epicondyle. Then, the pin is inserted into the medial column. This method is taught in AAOS courses and reported in publications by several authors. (Kocher, 2007, Skaggs, 2001, Gordon 2001) Crossed pinning is also essential in some cases of very unstable fractures.

Suggesting that surgeons only use lateral pinning is unnecessarily restrictive and represents expert opinion that is not supported by the literature.

As stated previously, this recommendation is based on weak evidence (not expert opinion), and includes consideration of the harms and benefits associated with lateral and medial introduction of pins. It is based on 65 outcomes from 15 low or moderate quality studies. The work group wrote the recommendation indicating preference for laterally introduced pins based on the entire body of evidence weighing the harms and benefits.

That recommendation also does not account for lessons learned from incorrect medial pinning. Thus, recommendation #3 as written selects only one preferred strategy for avoiding ulnar nerve injury and does not recognize the advancing nature of medical practice that is based upon current knowledge and technical modifications. Nor does that recommendation recognize that almost all authors advocate crossed pinning in certain circumstances when lateral pinning is unstable (Gordon, et.al. for example).

Not surprisingly, we would hope for documentation of the fact that the changes due to technical and other modifications are, indeed, improvements.

The Gordon study is one of 15 studies included to support this recommendation. That said, Recommendation 3 is based on weak evidence and also considers the harms and benefits associated with lateral and medial introduction of pins. The work group wrote the recommendation indicating preference for laterally introduced pins. We believe surgeons have the option to treat the patient as necessary, including using the option of medial pinning. Please remember that the recommendation says “might”, it does not say “must.”

1. The same objections are raised regarding literature from developing countries that do not have access to technology or training that exist in the United States where these guidelines are intended to be used. Western countries could be included but countries with limited resources should not be included.

We are all developing countries. (see gapminder.org). Although wealth and education are positively correlated both within and across countries, excluding information from outside the US would be a difficult position to defend since our inclusion criteria were determined *a priori* to the literature search. Excluding countries according to arbitrary criteria could diminish the reproducibility of the guidelines process as there is not a clear way to decide about the quality of a country. Further, excluding all studies from outside the US would mean excluding the Pirone study, which was done in Canada.

You correctly point out that the 1974 Flynn paper on blind percutaneous pinning reflected a substantial change in practice in the US. Diffusion of this technique and its modifications across US was quicker than diffusion to the remainder of the world. Accordingly, papers with explicit comparisons between older and newer techniques are more likely to come from countries where the knowledge diffusion is occurring last. It would be wrong to ignore a paper explicitly comparing casting to pinning of displaced fractures provided it meets basic quality criteria. The broadest range of patients and comparators is available if we keep countries along all points of the knowledge diffusion curve.

As an aside, distraction osteogenesis, one of the biggest orthopaedic advances in the past fifty years, was developed by Ilizarov working independently in Siberia, away from academic centres in an operating room reputedly heated by a woodstove.

2. Reports from the USA include Gordon, et.al. These authors compared three types of pin configurations including medial and lateral pinning. The only patient that showed marked rotational instability was pinned using two lateral pins. The authors recommend two lateral pins but addition of a medial pin if there is rotational instability after lateral pinning. They also noted, "If a medial pin is necessary, and the ulnar nerve cannot be identified by palpation, a small incision should be made and the pin placed under direct vision." This recommendation illustrates my comment in the opening paragraph and also indicates that medial pinning is sometimes necessary and can be safely performed based on current surgical technique.

   The AAOS does not use the results of only one study when drawing conclusions. Rather, it uses the entire body of evidence. Also, please note that the recommendation says "might", not "must."

   Recommendation 3:

   Data on 65 outcomes from 15 studies comparing pinning techniques using lateral pins only to a single lateral pin with a medial cross pin were found for this recommendation. Sixteen outcomes were of moderate quality and the remaining 49 were of low quality (Table 28). Three of the studies were randomized controlled trials.

The guidelines as currently written permit the clinician to apply a medial pin if judged necessary. They do come down in favour of lateral pinning because of the potential for harm. Literature substantiating the assertion that a medial pin can be placed safely in such circumstances would be a contribution. The present state of the literature suggests a higher chance of ulnar nerve injury with a medial pin, at about 6%, and little clinically important loss of reduction with all lateral pinning.

3. The randomized trial of Kocher, et.al. compared medial and lateral pins to only lateral pins. Both methods produced equal outcomes and there were no nerve injuries in either group. These authors used the technique that is currently taught for medial and lateral pinning. They stated, "For the medial and lateral pin entry technique, one pin was inserted from the lateral aspect of the elbow across the lateral cortex to engage the medial cortex with the elbow in hyperflexion. The elbow was then extended to less than a 90° position to avoid injury to an anteriorly subluxating ulnar nerve. A small medial incision of 1.5-3.0 cm was made over the medial epicondyle. Superficial dissection was performed to ensure that the pin was placed in the medial epicondyle and that the ulnar nerve was not subluxated anteriorly over the medial epicondyle." These authors concluded that "both lateral entry pin fixation and medial and lateral entry pin fixation are effective in the treatment of completely displaced (type-III) extension supracondylar fractures of the humerus in children."

   The numbers of patients treated in this well designed trial was too small for it to be powered to detect differences in ulnar nerve injury at usual rates. Further, the correct approach to evaluating a body of literature is to consider the results of all studies that are of equal quality. Accordingly, recommendation three is based on *"data on 65 outcomes from 15 studies comparing pinning techniques using lateral pins only to a single lateral pin with a medial cross pin were found for this recommendation."*

4. Iatrogenic ulnar nerve injury is rare even when incorrect methods are used for medial pinning. Also, persistent neurological deficits are even more rare and may be less common than instability after only lateral pinning for unstable fractures as reported by Gordon, et.al. Advocating against medial pinning may increase the frequency of iatrogenic rotational instability without significantly reducing the frequency of iatrogenic ulnar nerve injury. Inadequate fixation from lateral pinning has been identified by several authors who indicated that unstable lateral pinning is a reason to add medial pins to avoid loss of reduction. <u>So, the surgeon rather than the statistical analyst should weigh the risk of transient nerve injury versus the reality of unstable lateral fixation.</u>

   The published data suggest a 6% (or 1 in 22 chance) of harm. We believe it is important for Orthopaedic Surgeons to know the likelihood of both harms and benefits when performing such a procedure if such data is available. In addition, treatment decisions should be made in light of all circumstances presented by the patient. Treatments and

procedures applicable to the individual patient rely on mutual communication between guardian and physician as well as other healthcare practitioners.

Please see line 1171 in the guideline for the data and the following text:

"*The ulnar nerve was injured in 3 of 557 (0.53%) cases with laterally introduced pins. Medially introduced pins resulted in 49 of 808 (6%) cases of ulnar nerve injury. Iatrogenic ulnar nerve injury was noted to be statistically significant in favor of lateral pinning in 6 of 11 studies. A meta-analysis of these studies and three additional underpowered studies (1 moderate quality and 13 low quality) also demonstrated a statistically significant effect in favor of lateral pinning (Number Needed to Harm = 22, Odds ratio = 0.27). This suggests a 1 in 22 chance of harm resulting from the medial pinning techniques used in these studies. Based on weak evidence, the practitioner might use two or three laterally introduced pins to stabilize the reduction of displaced pediatric supracondylar fractures of the humerus*."

5. Recommendation #3 as written is also in conflict with recommendation #4. It is inconsistent to recommend lateral pin fixation and then note inconclusive evidence for or against a method for inserting a medial pin. Recommendation #3 should be consistent with recommendation #4. This is another reason why recommendation #3 be neutral with regard to medial or lateral pinning. It is not surprising that there is no evidence for open insertion of a medial pin. Skaggs, et.al. are the only ones who attempted to evaluate this technique. These authors noted 6% risk with the nerve was visualized and 8% risk when the nerve was not visualized, but they did not correlate this with position of the elbow in hyperflexion which is known to increase the risk of ulnar nerve injury. Even visualizing the nerve when the elbow is flexed does not protect it when the elbow is extended in the cast. The correct study should evaluate the entirely correct method of medial pinning as recommended by Kocher. Kocher noted no difference between medial and lateral pinning and also reported no ulnar nerve injuries with medial pinning. Perhaps training is important. Training is necessary whether only lateral pins are used because the configuration is technically important and clinical evaluation of stability is required following only lateral pinning. Thus either method has its drawbacks based on the best available evidence.

Thank you for your comment. We agree. Accordingly, recommendation #3 has been written to more clearly express the weak preference for lateral pinning over medial pinning. It now reads as follows:

The practitioner might use two or three laterally introduced pins to stabilize the reduction of displaced pediatric supracondylar fractures of the humerus. In the absence of strong evidence, considerations of potential harm indicate that the physician might avoid the use of a medial pin.

In summary, recommendation #3 is unnecessarily restrictive and could lead to improper fixation when fractures are unstable. This recommendation should be modified to accommodate surgeons who practice correct techniques and use medial pins judiciously.

We believe that your suggestion is consistent with the recommendations of the guideline. The wording of recommendation three is consistent with the fact that it is a weak recommendation. Further, the definition of what we mean by a "weak" recommendation is also provided in the guideline. Please see Page 11, Tables 5 and 6.

Recommendation #6 should be changed to the following:

"The practitioner might perform open reduction for displaced pediatric supracondylar fractures of the humerus with varus or other malposition after attempted closed reduction. "

As stated in the guideline, Recommendation 6 reads:

> *The practitioner might perform open reduction for displaced pediatric supracondylar fractures of the humerus with varus or other malposition after closed reduction.*

We believe that you are trying to convey that the closed reduction was unsuccessful. Based on your comments, we have reworded the recommendation as follows:

> *The practitioner might perform open reduction for displaced pediatric supracondylar fractures of the humerus following closed reduction if varus or other malposition of the bone occurs.*

STRUCTURED PEER REVIEW FORM

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

Reviewer Information:
Name of Reviewer____J. Andy Sullivan, M.D._____

Address__915 NW 17th St_____

City__Okla. City, _____ State___OK_ Zip Code_73106__

Phone _405 271-6458_FAX 405 271-1502_E-mail andy-sullivan2ouhsc.edu

Specialty Area/Discipline: _ped ortho_____

Work setting: _OUHSC Dept of Ortho
hospital_Children's Hosp of OK__Credentials: 35 year's of pinning these fractures, 5 years of residency using traction and everything else_____

May we list you as a Peer Reviewer in the final Guidelines (GL)? Yes
If you do not wish to be listed, your name will be removed for identification purposes. However, your COI will still be available for review with the comments you have made.
Are you reviewing this guideline as a representative of a professional society? No

If yes, may we list your society as a reviewer of this guideline? Yes No
Society Name: _____
(Listing the specialty society as a reviewing society does not imply or otherwise indicate endorsement of this guideline.)

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

I have declared my conflicts of interest in the AAOS database; my customer # is ___none_____

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

Find Disclosure Records

J Andy Sullivan, MD:

Submitted on: 04/07/2011 at 09:42 AM

Item 1 **Royalties from a company or supplier:**
- No Conflict Reported

Item 2 **Speakers bureau/paid presentations for a company or supplier:**
- No Conflict Reported

Item 3A **Paid employee for a company or supplier:**
- No Conflict Reported

Item 3B **Paid consultant for a company or supplier:**
- No Conflict Reported

Item 3C **Unpaid consultant for a company or supplier:**
- No Conflict Reported

Item 4 **Stock or stock options in a company or supplier:**
- No Conflict Reported

Item 5 **Research support from a company or supplier as a PI:**
- No Conflict Reported

Item 6 **Other financial or material support from a company or supplier:**
- No Conflict Reported

Item 7 **Royalties, financial or material support from publishers:**
- No Conflict Reported

Item 8 **Medical/Orthopaedic publications editorial/governing board:**

- Journal of Pediatric Orthopedics

Item 9 **Board member/committee appointments for a society:**
- No Conflict Reported

Public Comments: The Treatment of Pediatric Supracondylar Fractures of the Humerus
Dr. J. Andy Sullivan
May 9, 2011

Dear Dr. Sullivan,

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

I understand the difficulty of doing this. I was on committees for the AAOS where we tried to craft position statements (school screening for scoliosis) and know we walk a fine line. Having said that I offer only a few comments.

I have reviewed cases of compartment syndrome and testified to defend doctors. There is a lot of AAOS literature that you have to defend that plaintiff's attorneys use. I always am able to read them the disclaimers and say this is only one author's opinion. While the same may be said for these recommendations, I think by the very fact that they are "guidelines" and "recommendations" will carry more weight with a jury so that wording is very important.

Recommendation Number 1

I do not think anyone at this time treats Type III supracondylar fractures by any means other than pinning, whether that is open or closed. I think to state that the strength of recommendation number 2 is "moderate" defies common sense.

The "Strength of the Recommendation" reflects the evidence that supports Recommendation 2. In point of fact, the studies that address this recommendation are not as well-designed as they could be. Our wording, and the manner in which it is used, is in keeping with wording commonly used in guidelines.

Public Comments: The Treatment of Pediatric Supracondylar Fractures of the Humerus
Dr. J. Andy Sullivan
May 9, 2011

Recommendation number 4.

We believe you are referring to Recommendation 3.

Like all of my vintage, I started out using crossed pins. We pin 100-200 of these a year. I have never done a formal review of all I have pinned in 35 years. I know of one in which I pinned an ulnar nerve and there were certainly more if I could do a formal review. I recognized it in the PACU and removed the pin. We have reviewed supracondylar fractures in our institution and I know ulnar nerve injury occurs if you do enough medial pins. I also know they recover and don't recall a median nerve that did not recover. If the incidence you quote of 1 in 22 injuries of the median nerve if you use a medial pin were to occur in our institution we would not be using medial pins. [This value was calculated based on the results reported in 14 studies; one moderate and thirteen weak quality studies.] We have had radial nerves that did not recover, usually injured at the time of injury.

You state "in the absence of strong evidence" which to me means you have none.

No, the phrase, "in the absence of strong evidence" means exactly that, we do not have strong evidence not that we have NO evidence. We also consider moderate and weak evidence to answer our recommendations. The evidence that addresses this recommendation consists of 14 studies; one moderate and thirteen weak quality studies. Please refer to Table 5 on pages 11 and 12 in the guideline.

That said, we have removed "in the absence of strong evidence" from the recommendation to avoid further misinterpretation.

It is very common for us to use 2 lateral pins and a medial pin in very unstable cases. It is hard in the best of hands to achieve the same stability

with lateral pins that you obtain with crossed pins. I read all the articles about pin placement and configuration and now use only lateral pins in most of my cases. I have ended up with more fractures that rotate using lateral only pins. A medial pin is necessary in some cases to correct and maintain varus deformity. There are times when there is not enough cortex laterally for 2-3 lateral pins. If you state "in the absence of strong evidence" you need to re-state the second part after the comma. These could include:

"The risk of potential harm from a medial pin must be weighed against the potential advantages. "

Based on your comments as well as those of others, we have added this statement to the rationale of the recommendation at line 1283. We added this statement to the rationale because good recommendations take the form of [what] should be done in [whom] and [when] and specify an action. This statement does not specify an action but adds clarification and was therefore, added to the rationale.

"Despite potential risk of harm, a medial pin may be necessary in clinical conditions such as varus deformity or instability not held securely with lateral pins "

The use of the word "might" that corresponds with the "weak" supporting evidence leaves the option of using a medial pin open if the physician documents the clinical need for medial pinning as you have described above.

Recommendation number 6.

I do not find anywhere in here that you state that open reduction is indicated if you cannot achieve satisfactory position after attempted

closed reduction. Satisfactory is in the eyes of the beholder but that is what clinical judgment is all about.

"When satisfactory position cannot be achieved by closed manipulation, open reduction and fixation may be indicated"

In Recommendation 6 the recommendation does state the practitioner might perform "open reduction" following closed reduction if varus or other malposition of the bone occurs so it appears that the only word you wish to add is "*satisfactory*". We are not certain this adds significantly to the recommendation because as you state, this is dependent on clinical judgment.

Recommendation number 8.

'if the hand remains under perfused after reduction" the hand remains under perfused after reduction"

Based on your comments, we have reworded Recommendation 8 from:

In the absence of reliable evidence, the opinion of the work group is that open exploration of the antecubital fossa be performed in patients with absent wrist pulses and decreased perfusion, if the hand remains underperfused after reduction and pinning of displaced pediatric supracondylar humerus fractures.

To the following:

In the absence of reliable evidence, the opinion of the work group is that open exploration of the antecubital fossa be performed in patients who have absent wrist pulses and underperfusion after reduction and pinning of displaced pediatric supracondylar humerus fractures.

This is the recommendation. Immediately below you define under perfused as a hand with an absent radial pulse and a cold, pale hand. This definition needs to bee a part of the recommendation. I know you can't put a time frame on it but we all know there are cases where the hand

will pink up in the OR if you wait a bit. Are you talking about a palpable pulse or a Doppler pulse?

The work group is referring to a palpable pulse.

Will all the rationale and evidence be published along with the guidelines?

The full guideline will be published on the AAOS website. The recommendations and the rationales will be published in JAAOS. JBJS will publish only the recommendations.

I did not read all the comments but found that those by Chad Price were in more detail than mine and I agreed with him on the points he made.

We hope you also read the detailed responses that we made and sent back to Dr. Price during the peer review process. In some cases, his comments did result in changes to the guideline. All of the review process comments will be available on the website as soon as the guideline is approved by the AAOS Board of Directors.

I appreciate the difficulty of developing guidelines in a surgical specialty and thank you for your time.

We sincerely appreciate your comments and the time you have given us in reviewing this document. Thank you.