AAOS
American Academy of Orthopaedic Surgeons

Review Period Report

Evidence-Based Clinical Practice Guideline on Limb Salvage or Early Amputation

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Overview of Review Period

The reviews and comments related to this clinical practice guideline are reprinted in this document and posted on the AAOS website. All peer reviewers and public commenters are required to disclose their conflict of interests. Names are removed from the forms of reviewers who requested that they remain anonymous; however, their COI disclosures still accompany their response.

Review Period

AAOS contacted 8 organizations with content expertise to review a draft of the clinical practice guideline during the three-week peer review period between October and November 2019.

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

Reviewer Key

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

Table 1. Reviewers

Reviewer Number	Name of Reviewer	Society Being Represented
1	Felasfa Wodajo, MD	Musculoskeletal Tumor Society (MSTS)
2	Andrew Chen, MD	American Society of Plastic Surgeons (ASPS)
3	Neal Barshes, MD, MPH	Society for Vascular Surgery (SVS)
4	Ruth Bush, MD, JD, MPH	Society for Vascular Surgery (SVS)
5	Nelson Kennedy, MD	Orthopaedic Trauma Association (OTA)
6	Bradley Deafenbaugh, MD	Society of Military Orthopaedic Surgeons (SOMOS)
7	Selina Poon, MD	American Academy of Orthopaedic Surgeons (AAOS)

Reviewer Demographics

Table 2. Reviewer Demographics

Reviewer Number	Name of Reviewer	Society you are representing	Please list your primary specialty	Please list your work setting
1	Felasfa Wodajo, MD	Musculoskeletal Tumor Society (MSTS)	Ortho/Oncology	Private Group or Practice
2	Andrew Chen, MD	American Society of Plastic Surgeons (ASPS)	Plastic Surgery	Academic Practice
3	Neal Barshes, MD, MPH	Society for Vascular Surgery (SVS)	Vascular surgery	
4	Ruth Bush, MD, JD, MPH	Society for Vascular Surgery (SVS)	Vascular surgery	Non-Military Government or Public
5	Nelson Kennedy, MD	Orthopaedic Trauma Association (OTA)	Trauma	Military
6	Bradley Deafenbaugh, MD	Society of Military Orthopaedic Surgeons (SOMOS)	Trauma	Military
7	Selina Poon, MD	American Academy of Orthopaedic Surgeons (AAOS)	Pediatric Orthopaedics	

Reviewer's Disclosure Information

Table 3. Disclosure Question Key

Disclosure Question	Disclosure Question Details
A	A) Do you or a member of your immediate family receive royalties for any pharmaceutical, biomaterial or orthopaedic product or device?
B	B) Within the past twelve months, have you or a member of your immediate family served on the speakers bureau or have you been paid an honorarium to present by any pharmaceutical, biomaterial or orthopaedic product or device company?
C	C) Are you or a member of your immediate family a PAID EMPLOYEE for any pharmaceutical, biomaterial or orthopaedic device or equipment company, or supplier?
D	D) Are you or a member of your immediate family a PAID CONSULTANT for any pharmaceutical, biomaterial or orthopaedic device or equipment company, or supplier?
E	E) Are you or a member of your immediate family an UNPAID CONSULTANT for any pharmaceutical, biomaterial or orthopaedic device or equipment company, or supplier?
F	F) Do you or a member of your immediate family own stock or stock options in any pharmaceutical, biomaterial or orthopaedic device or equipment company, or supplier (excluding mutual funds)?
G	G) Do you or a member of your immediate family receive research or institutional support as a principal investigator from any pharmaceutical, biomaterial or orthopaedic device or equipment company, or supplier?
H	H) Do you or a member of your immediate family receive any other financial or material support from any pharmaceutical, biomaterial or orthopaedic device and equipment company or supplier?
I	I) Do you or a member of your immediate family receive any royalties, financial or material support from any medical and/or orthopaedic publishers?
J	J) Do you or a member of your immediate family serve on the editorial or governing board of any medical and/or orthopaedic publication?

Table 4. Reviewer's Disclosure Information

Reviewer Number	Name of Reviewer	Disclosure Available via AAOS Disclosure System	A	B	C	D	E	F	G	H	I	J
1	Felasfa Wodajo, MD	Yes										
2	Andrew Chen, MD	No	No	No	No	No	No	No	No	No	No	No
3	Neal Barshes, MD, MPH	No	No	No	No	No	No	No	No	No	No	No
4	Ruth Bush, MD, JD, MPH	No	No	No	No	No	No	No	No	No	No	No
5	Nelson Kennedy, MD	Yes										
6	Bradley Deafenbaugh, MD	Yes										
7	Selina Poon, MD	Yes										

Reviewer Responses to Structured Peer Review Form Questions

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

Table 5. Reviewer Responses Questions 1-4

Reviewer Number	Name of Reviewer	Society you are representing	1. The overall objective(s) of the guideline is (are) specifically described.	2. The health question(s) covered by the guideline is (are) specifically described.	3. The guideline's target audience is clearly described.	4. There is an explicit link between the recommendations and the supporting evidence.
1	Felasfa Wodajo, MD	Musculoskeletal Tumor Society (MSTS)	Strongly Agree	Strongly Agree	Agree	Strongly Agree
2	Andrew Chen, MD	American Society of Plastic Surgeons (ASPS)	Agree	Agree	Agree	Agree
3	Neal Barshes, MD, MPH	Society for Vascular Surgery (SVS)	Strongly Agree	Strongly Agree	Strongly Agree	Agree
4	Ruth Bush, MD, JD, MPH	Society for Vascular Surgery (SVS)	Strongly Agree	Strongly Agree	Strongly Agree	Agree
5	Nelson Kennedy, MD	Orthopaedic Trauma Association (OTA)	Strongly Agree	Agree	Agree	Agree
6	Bradley Deafenbaugh, MD	Society of Military Orthopaedic Surgeons (SOMOS)	Strongly Agree	Strongly Agree	Strongly Agree	Strongly Agree
7	Selina Poon, MD	American Academy of Orthopaedic Surgeons (AAOS)	Strongly Agree	Strongly Agree	Strongly Agree	Strongly Agree

Table 6. Reviewer Responses Questions 5-8

Reviewer Number	Name of Reviewer	Society you are representing	5. Given the nature of the topic and the data, all clinically important outcomes are considered.	6. The patients to whom this guideline is meant to apply are specifically described.	7. The criteria used to select articles for inclusion are appropriate.	8. The reasons why some studies were excluded are clearly described.
1	Felasfa Wodajo, MD	Musculoskeletal Tumor Society (MSTS)	Agree	Strongly Agree	Strongly Agree	Strongly Agree
2	Andrew Chen, MD	American Society of Plastic Surgeons (ASPS)	Agree	Agree	Neutral	Agree
3	Neal Barshes, MD, MPH	Society for Vascular Surgery (SVS)	Strongly Agree	Strongly Agree	Strongly Agree	Strongly Agree
4	Ruth Bush, MD, JD, MPH	Society for Vascular Surgery (SVS)	Agree	Strongly Agree	Strongly Agree	Strongly Agree
5	Nelson Kennedy, MD	Orthopaedic Trauma Association (OTA)	Agree	Agree	Agree	Neutral
6	Bradley Deafenbaugh, MD	Society of Military Orthopaedic Surgeons (SOMOS)	Agree	Strongly Agree	Strongly Agree	Strongly Agree
7	Selina Poon, MD	American Academy of Orthopaedic Surgeons (AAOS)	Strongly Agree	Strongly Agree	Strongly Agree	Strongly Agree

Table 7. Reviewer Responses Questions 9-12

Reviewer Number	Name of Reviewer	Society you are representing	9. All important studies that met the article inclusion criteria are included.	10. The validity of the studies is appropriately appraised.	11. The methods are described in such a way as to be reproducible.	12. The statistical methods are appropriate to the material and the objectives of this guideline.
1	Felasfa Wodajo, MD	Musculoskeletal Tumor Society (MSTS)	Agree	Strongly Agree	Strongly Agree	Strongly Agree
2	Andrew Chen, MD	American Society of Plastic Surgeons (ASPS)	Neutral	Agree	Neutral	Agree
3	Neal Barshes, MD, MPH	Society for Vascular Surgery (SVS)	Strongly Agree	Strongly Agree	Strongly Agree	Strongly Agree
4	Ruth Bush, MD, JD, MPH	Society for Vascular Surgery (SVS)	Strongly Agree	Strongly Agree	Strongly Agree	Agree
5	Nelson Kennedy, MD	Orthopaedic Trauma Association (OTA)	Neutral	Agree	Agree	Agree
6	Bradley Deafenbaugh, MD	Society of Military Orthopaedic Surgeons (SOMOS)	Strongly Agree	Strongly Agree	Strongly Agree	Strongly Agree
7	Selina Poon, MD	American Academy of Orthopaedic Surgeons (AAOS)	Strongly Agree	Strongly Agree	Strongly Agree	Strongly Agree

Table 8. Reviewer Responses Questions 13-16

Reviewer Number	Name of Reviewer	Society you are representing	13. Important parameters (e.g., setting, study population, study design) that could affect study results are systematically addressed.	14. Health benefits, side effects, and risks are adequately addressed.	15. The writing style is appropriate for health care professionals.	16. The grades assigned to each recommendation are appropriate.
1	Felasfa Wodajo, MD	Musculoskeletal Tumor Society (MSTS)	Strongly Agree	Agree	Strongly Agree	Agree
2	Andrew Chen, MD	American Society of Plastic Surgeons (ASPS)	Agree	Disagree	Agree	Disagree
3	Neal Barshes, MD, MPH	Society for Vascular Surgery (SVS)	Strongly Agree	Strongly Agree	Strongly Agree	Strongly Agree
4	Ruth Bush, MD, JD, MPH	Society for Vascular Surgery (SVS)	Agree	Agree	Strongly Agree	Strongly Agree
5	Nelson Kennedy, MD	Orthopaedic Trauma Association (OTA)	Agree	Agree	Strongly Agree	Agree
6	Bradley Deafenbaugh, MD	Society of Military Orthopaedic Surgeons (SOMOS)	Strongly Agree	Agree	Strongly Agree	Strongly Agree
7	Selina Poon, MD	American Academy of Orthopaedic Surgeons (AAOS)	Strongly Agree	Strongly Agree	Strongly Agree	Strongly Agree

Reviewer's Recommendation for Use of this Guideline in Clinical Practice

Table 9. Would you recommend these guidelines for use in clinical practice?

Reviewer Number	Name of Reviewer	Society you are representing	Would you recommend these guidelines for use in clinical practice?	Additional Comments regarding this CPG?
1	Felasfa Wodajo, MD	Musculoskeletal Tumor Society (MSTS)	Recommend	Some editorial comments are below. Feel free to include or ignore: Page 6: the first recommendation refers to Time 0 and Time 1, but these are not defined until page 11. The definition should be shown on page 6 also. Page 6: the sub headers "Non-Limb Specific Injury" and "Limb Specific Injury" are shown but it is not clear to this reader what they mean in this context (the entire CPG is about limb injuries) Page 16: The following sentence is unclear: "Recommendations were approved and adopted in instances where a simple majority (60%) of the guideline development group voted to approve; however, the guideline development group had consensus (100% approval) when voting on every recommendation for this guideline." When did 60% suffice and when was 100% required ? Page 28: "Cost data clearly show a successful limb salvage patient incurs significantly lower lifetime medical costs compared to amputation." This is an important statement, which I didn't realize was so clear. I would consider including this in the introduction as it is highly relevant.
2	Andrew Chen, MD	American Society of Plastic Surgeons (ASPS)		

3	Neal Barshes, MD, MPH	Society for Vascular Surgery (SVS)	Strongly Recommend	
4	Ruth Bush, MD, JD, MPH	Society for Vascular Surgery (SVS)	Recommend	
5	Nelson Kennedy, MD	Orthopaedic Trauma Association (OTA)	Recommend	I like the format and how this addresses subsets of the various problems you tend to encounter in this topic, effectively dispelling many persistent myths. I think the references and tables should be in a different pdf from the straight cpg, as opening a 169 page document can be quite intimidating and I think you will have a significant number of surgeons who see that number and immediately close the file where they would look through it if it were 20 pages.
6	Bradley Deafenbaugh, MD	Society of Military Orthopaedic Surgeons (SOMOS)		
7	Selina Poon, MD	American Academy of Orthopaedic Surgeons (AAOS)	Strongly Recommend	

Reviewer Detailed Responses

Reviewer #1

Reviewer Number	Name of Reviewer	Society you are representing	Please provide a brief explanation of both your positive and negative answers in the preceding section. If applicable, please specify the draft page and line numbers in your comments. Please feel free to also comment on the overall structure and content of the Guideline:
1	Felasfa Wodajo, MD	Musculoskeletal Tumor Society (MSTS)	No real negative answers/comments The goals of the CPG and the reason why it was initiated are clear and appropriate, specifically in the literature there are conflicting recommendations as to when to attempt limb salvage vs amputation. Furthermore, prospective randomized studies will not be forthcoming, thus it was reasonable for a group of clinical experts to analyze the literature and make evidence based recommendations. Not surprisingly, the paucity of high quality evidence left many of the recommendations at limited or moderate strength. One important and potentially provocative recommendation was "Physicians should not utilize extremity specific scores to select limb salvage vs. amputation, or to predict outcomes for patients with high energy lower extremity trauma." which was upgraded to a moderate strength recommendation. This may have the most long term impact. Page 7: The recommendation starts with "Clinicians should screen all patients..." but does not say how they should be screened or how the findings from screening should be used. In the rationale, four references were cited but the instruments, whether they are clinically validated, etc was not specified. Given that this recommendation had am assigned strength of "strong", it would seem that the clinician should be given more guidance on how to act on this recommendation The various recommendations were prefaced with different phrases, including: - no preface, i.e directly state the recommendation (for example "The Physician team should evaluate overall burden of injury and patient ...") - "In the absence of reliable evidence ...." - "The evidence suggests..." - "Limited evidence suggests..." This is confusing to the reader. It is not obvious that the various phrases correlate with the provided strength of recommendation. Nor is it clear whether "The evidence suggests..." and "Limited evidence suggests..." imply there was not enough high quality evidence to support the recommendation and thus what follows is a consensus statement. (I assume "In the absence of reliable evidence ...." would imply that). This should be clarified to the reader.

Workgroup Responses to Reviewer #1

A.
B.
C.
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F.
G.
H.
I.

Reviewer Detailed Responses

Reviewer #2

Reviewer Number	Name of Reviewer	Society you are representing	Please provide a brief explanation of both your positive and negative answers in the preceding section. If applicable, please specify the draft page and line numbers in your comments. Please feel free to also comment on the overall structure and content of the Guideline:
2	Andrew Chen, MD	American Society of Plastic Surgeons (ASPS)	1) Rehabilitation Recommendation (p. 7) - evidence seems to be "strong" not moderate which may have been impacted by potential managed care impact but should be re-examined since voting process described may not have captured enough studies 2)Amputation/Limb Salvage Recommendation (p. 35)-statement supporting amputation seems overly strong would modify as follows, "injury patterns requiring ankle arthrodesis/free tissue may have worse long-term outcomes and the decision to amputate in the non-acute phase requires shared decision-making with the patient 3) Injury Patterns Recommendation (p. 35)- confusing wording on nerve injury would suggest the following," absence of plantar sensation to presence of observed nerve transection/tibial nerve injury", (is there any interest in distinguishing between different nerves and why this may only be applicable to acute/immediate setting. Also, should the word "immediate" be added before amputation? Rather than saying it is "not a factor" which implies it doesn't matter at all, perhaps state it is "not an absolute, major or unique factor"- perhaps need to add this within the scope of the recommendation on cumulative burden of injury to the limb under Recommendation 1C along with the known injury at presentation 4) Smoking Recommendation (p. 31)-while this would not affect the reconstructive teams to salvage a limb or not, perhaps add some verbiage on shared decision making such as, "physicians should recommend nicotine education/cessation (abstinence of nicotine) for all patients with high energy lower limb trauma and engage in shared decision-making with patients as there is moderate evidence to suggest that smoking/nicotine has a detrimental effect"

Workgroup Responses to Reviewer #2

A.
B.
C.
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F.

Reviewer Detailed Responses

Reviewer #3

Reviewer Number	Name of Reviewer	Society you are representing	Please provide a brief explanation of both your positive and negative answers in the preceding section. If applicable, please specify the draft page and line numbers in your comments. Please feel free to also comment on the overall structure and content of the Guideline:
3	Neal Barshes, MD, MPH	Society for Vascular Surgery (SVS)	Overall, excellent guidelines that are well written. I like the emphasis on the practical aspects of limb salvage vs. amputation decision making. A few comments: Major points: Page 11: "High energy" (first used on page 11) is used throughout the document but never defined. Is this defined by the mechanism (i.e. only high-velocity [military-grade] weapons) or by the extent of tissue destruction? Page 21: It would be hard for anyone to disagree with this statement, emphasizing life over limb. Yet for this recommendation to have any practical application, the writing committee should be more specific on "when further attempts at definitive salvage will increase mortality" by either provide criteria or at least examples (with references). Otherwise concern for mortality could be the trump card played by surgeons who don't feel as comfortable with limb salvage efforts. The "Rationale" paragraph makes this no clearer. In particular, many of the studies cite relatively-poorer outcomes, but seem to support the feasibility of limb salvage (ex. for calcaneal fractures: poorer AAOS F&A scores isn't ideal, but not associated with mortality == support for attempting limb salvage). Page 27: Not clear how the presence of these factors should be factored into the decision making. In all the citations provided throughout the guideline, the ideal comparison should not be to persons without some specific injury but rather to persons with that injury who undergo leg amputation. For example, "volumetric muscle loss" was associated with worse SIP scores four years later. Does this mean that an amputation would be better? If so, this needs to be justified, as simply saying outcomes are worse compared (to persons without volumetric muscle loss) would not suffice. As written, I could imagine surgeons pointing to this recommendation to support being very conservative toward limb salvage. Also: should the increased risk of PE/DVT push someone toward amputation? Literature on non-traumatic leg amputations suggest PE is among the most common causes of perioperative mortality. So simply stating that PE/DVT incidence is higher with a certain injury type should not necessarily weight into the decision-making process. Likewise, for increased pain and osteoarthritis scores (fifth paragraph in this section) -- how would this consideration factor in? Last paragraph in this section (on degloving injury) seems like a non sequitur, as there is no mention of any worse outcomes. Listing "blunt" as among the characteristics associated with "increased risk of adverse events" also seems very non-specific here. All blunt injuries? Blunt injuries resulting in a certain amount of

			tissue destruction? Minor points: Page 22: "Wasn't" (last line of first paragraph on this page) should be expanded to "was not" to avoid having the writing style seem informal.

Workgroup Responses to Reviewer #3

A.
B.
C.
D.
E.

Reviewer Detailed Responses

Reviewer #4

Reviewer Number	Name of Reviewer	Society you are representing	Please provide a brief explanation of both your positive and negative answers in the preceding section. If applicable, please specify the draft page and line numbers in your comments. Please feel free to also comment on the overall structure and content of the Guideline:
4	Ruth Bush, MD, JD, MPH	Society for Vascular Surgery (SVS)	1. Page 29. Section on Vascular Injury or Vascular Ischemia - the outcomes for vascular injury in extremity trauma need a few details about patients age and the existence of pre-existing atherosclerosis. Young person in military trauma or civilian accidents have poorer limb outcomes as they have no collateral vessels established which occur as a result of chronic PVD. Most of the references are from wartime data. There is no mention of autogenous versus prosthetic implant use, especially important to consider with soft tissue damage. What about co-existing bony injuries and vascular injuries - what is the preferred order of repair? Who/ what determines? 2. There is existing data suggesting a strong correlation between duration of injury and limb salvage. While duration should not be a hard and fast rule, there is a point at which limb salvage is futile, painful, and costly. These data should be referenced. 3. Page 42. Co-morbidities. There are many accepted and validated risk prediction scoring systems to evaluate patients comorbidities and their potential impact on surgical risk and outcomes. These should be mentioned here to aid in the clinical decision-making process. Overall - This appears to have followed a rigorous protocol and process. The recommendations appear sound and the supporting documentation, while not in depth, thoroughly vetted by the organizing group.

Workgroup Responses to Reviewer #4

A.
B.
C.
D.
E.

Reviewer Detailed Responses

Reviewer #5

Reviewer Number	Name of Reviewer	Society you are representing	Please provide a brief explanation of both your positive and negative answers in the preceding section. If applicable, please specify the draft page and line numbers in your comments. Please feel free to also comment on the overall structure and content of the Guideline:
5	Nelson Kennedy, MD	Orthopaedic Trauma Association (OTA)	I think that this is a well done summary of the thought processes I go through when assessing the salvage vs amputation question. I suspect I know several of the authors / reviewers as friends and mentors who have shaped my own experiences with this topic. I think they were a little harsh on the included/excluded articles, but I did not have time to run through the hundreds of listed articles to get more than a general impression of that or give specific examples, though I do think there are more than 36 well done articles out there on the topic. page 22 1st paragraph 'talar' instead of 'talal' page 29 1st line 'injuries' instead of 'injury' page 39 is there indication to believe (other than common sense; I truly enjoyed seeing that phrase invoked as justification) that well fitting and maintained prostheses make a difference in patient satisfaction or outcome? Some people don't maintain anything in their lives.... page 40-41. There is little to no difference in this section vs the previous soft tissue section. Why the repeat? Doesn't seem to add anything to me.

Workgroup Responses to Reviewer #5

A.
B.
C.
D.
E.

Reviewer Detailed Responses

Reviewer #6

Reviewer Number	Name of Reviewer	Society you are representing	Please provide a brief explanation of both your positive and negative answers in the preceding section. If applicable, please specify the draft page and line numbers in your comments. Please feel free to also comment on the overall structure and content of the Guideline:
6	Bradley Deafenbaugh, MD	Society of Military Orthopaedic Surgeons (SOMOS)	The authors are to be commended on the thorough review of available research and their commitment to including only studies that offer sufficient usable data. The body of evidence for limb salvage versus amputation is conflicting and the set of CPGs proposed here offer as much clarity on decision-making and management as can be reasonably expected. In my opinion, factors such as burden of injury, psychosocial issues, nerve injury and extremity severity scores are appropriately addressed and the recommendations set forth are balanced. They are neither too specific nor too vague given the body of literature available at this time. The authors' have highlighted areas that are important for further research, particularly regarding rehabilitation and psychosocial issues, as further high quality research into these topics will hopefully specify useful pathways that will optimize outcomes in both amputation and limb salvage.

Workgroup Responses to Reviewer #6

A.
B.
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Appendix A – Structured Review Form

Review Questions (REQUIRED)

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

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:

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

- ○ Strongly Recommend
- ○ Recommend
- ○ Would Not Recommend
- ○ Unsure

Additional Comments regarding this clinical practice guideline?