AAOS

American Academy of Orthopaedic Surgeons

Peer Review & Public Comment Report and AAOS Responses

Clinical Practice Guideline on *Detection and Nonoperative Management of Pediatric Developmental Dysplasia of the Hip in Infants up to Six Months of Age*

Table of Contents

Detection and Nonoperative Management of Pediatric Developmental Dysplasia of the Hip in Infants up to Six Months of Age Evidence-Based Guideline

Summary of Changes to Guideline Draft after Peer Review

Recommendation: Stable Hip with Ultrasound Imaging Abnormalities - Added the following language to the rationale "…supports observation without treatment for infants".

Recommendation: Imaging of the Infant Hip – Original recommendation language changed from "Limited evidence supports the use of an AP pelvis radiograph instead of an ultrasound to assess DDH in infants between 4 and 6 months." To "Limited evidence supports the use of an AP pelvis radiograph instead of an ultrasound to assess DDH in infants beginning at 4 months of age."

Recommendation: Type of Brace for the Unstable Hip – Original recommendation language changed from "Limited evidence supports the use of rigid brace over soft brace for initial treatment of an unstable hip" to "Limited evidence supports use of the von Rosen splint over Pavlik, Craig, or Frejka splints for initial treatment of an unstable hip".

Recommendation: Type of Brace for the Unstable Hip – The following sentence was added to the rationale "This recommendation is based on the braces that were studied, but other similar fixed-position braces may or may not work as well as the braces mentioned in the evidence."

Future Research - Added to Future Research, "Future studies should standardize follow-up times after bracing to improve objective testing of outcomes."

Attrition chart was moved from the appendix to the beginning of the guideline document.

Line 382 revised to be consistent and now reads "developmental dysplasia of the hip".

Line 475. Added "In clinically normal hips imaging evaluation would be the only viable method to assess for hip problems that could have a potential to evolve into a future pathologic condition with adverse impact upon an individual's quality of life."

Line 1085 added "ultrasound"

Line 1131, "Examination of other quoted risk factors was done. Evidence was not found to include foot abnormalities, gender, oligohydramnios, torticollis as risk factors for DDH."

Summary of Changes to Guideline Draft after Public Comment

Introduction: Burden of Disease/Incidence and Prevalence Section, removed “In the US in 2010, there were 332,000 hip replacements performed.”

Overview of Peer Review and Public Comment Responses

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

Peer Review

AAOS contacted 13 organizations with content expertise to review a draft of the clinical practice guideline during the peer review period in April 2014.

- Fifteen individuals provided comments via the electronic structured peer review form. Three reviewers asked to remain anonymous.
- Of the 15 submissions, seven were on behalf of a society and six have given consent to be listed as a reviewer.
- The work group considered all comments and made some modifications when they were consistent with the evidence.

Public Comment

The new draft was then circulated for a 30-day public comment period ending on July 31, 2014.

- AAOS received five comments including one representing specialty society, four from individuals, and none from industry.
- If warranted and based on evidence, the guideline draft s modified by the work group members in response to the public comments.

PEER REVIEW RESPONSES

Peer Reviewer Key

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

Table 1. Peer Reviewer Key

Reviewer #	Name of Reviewer	What is the name of the society that you are representing?
1	Boaz Karmazyn, MD	American College of Radiology
2	Anonymous	American Academy of Family Physicians
3	John W Harrington, MD	N/A
4	Joy Guthrie, PhD., RDMS, RDCS, RVT	N/A
5	Lawrence Wasser, MD	N/A
6	Lisa Gilmer, MD	N/A
7	Anonymous	N/A
8	Minna Saslaw, MD	Academic Pediatric Association (APA)
9	Nicholas M P Clarke, ChM, DM, FRCS	N/A
10	Panagiotis Kratimenos, MD	N/A
11	Anonymous	AAP
12	Suhas Nafday, MD, MRCP (Ireland), FAAP	Academic Pediatric Association
13	Kelly Bradley-Dodds, M.D., F.A.A.P.	N/A
14	Brian Brighton, MD, MPH	Pediatric Orthopaedic Society of North America
15	Charles T. Price, MD	International Hip Dysplasia Institute

Peer Reviewer Demographics

Reviewer #	Name of reviewer	Please list your primary specialty (Required):	Please list your secondary specialty (if applicable):	Please list your work setting (Required):
1	Boaz Karmazyn, MD	Pediatric radiology		Academic Practice
2	Anonymous	Family Medicine		Administrative - American Academy of Family Physicians
3	John W Harrington, MD	General Academic Pediatrics		Academic Practice
4	Joy Guthrie, PhD., RDMS, RDCS, RVT	Pediatric Sonography		Clinical Hospital
5	Lawrence Wasser, MD	Pediatrics		Academic Practice
6	Lisa Gilmer, MD	Pediatrics		Academic Practice
7	Anonymous	General Pediatrics		Academic Practice
8	Minna Saslaw, MD	General Pediatrics		Academic Practice
9	Nicholas M P Clarke, ChM, DM, FRCS	Pediatric Orthopaedics	Pediatric hip	Clinical Hospital
10	Panagiotis Kratimenos, MD	Pediatrics, Neonatal-Perinatal Medicine		Academic Practice
11	Anonymous	Pediatrics		Clinical Hospital
12	Suhas Nafday, MD, MRCP (Ireland), FAAP	Pediatrics	Neonatal-Perinatal Medicine	Academic Practice
13	Kelly Bradley-Dodds, M.D., F.A.A.P.	Pediatrics		Academic Practice
14	Brian Brighton	Pediatric Orthopaedics		Academic Practice
15	Charles T. Price	Pediatric Orthopaedics		Academic Practice

Peer Reviewers' Disclosure Information

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

Table 2. Disclosure Question Key

Disclosure Question	Disclosure Question Details
A	A) Do you or a member of your immediate family receive royalties for any pharmaceutical, biomaterial or orthopaedic product or device?
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 3. Peer Reviewer's Disclosure Information

Reviewer Number	Name of Reviewer (Required)	Please list your AAOS Customer # below (Required):	A	B	C	D	E	F	G	H	I	J
1	Boaz Karmazyn, MD		No	No	No	No	No	No	Yes	No	No	No
2	Anonymous		No	Yes	No	No	No	No	No	No	No	No
3	John W Harrington, MD		No	No	No	No	No	No	No	No	No	No
4	Joy Guthrie, PhD., RDMS, RDCS, RVT		No	No	No	No	No	No	No	No	No	No
5	Lawrence Wasser, MD		No	No	No	No	No	No	No	No	No	No
6	Lisa Gilmer, MD		No	No	No	No	No	No	No	No	No	No
7	Anonymous		No	No	No	No	No	No	No	No	No	No
8	Minna Saslaw, MD		No	No	No	No	No	No	No	No	No	No
9	Nicholas M P Clarke, ChM, DM, FRCS	189331	.	.	.	.	.	.	.	.	.	.
10	Panagiotis Kratimenos, MD		No	No	No	No	No	No	No	No	No	No
11	Anonymous		No	No	No	No	No	No	No	No	No	No
12	Suhas Nafday, MD, MRCP (Ireland), FAAP, MD		No	No	No	No	No	No	Yes	No	No	No
13	Kelly Bradley-Dodds, M.D., F.A.A.P.	1437374										
14	Brian Brighton	371653										
15	Charles T. Price	12037										

Table 4. Peer Reviewer Detailed Disclosure Information

Reviewer Number	Name of Reviewer (Required)	B.1) You indicated that within the past twelve months, 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.	G.1) You indicated that 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.
1	Boaz Karmazyn, MD	N/A	Philips
2	Anonymous	I previously provided Nexplanon training on behalf of Merck. I no longer serve in this capacity. Last training I provided was 6 months ago.	N/A
12	Suhas Nafday, MD, MRCP (Ireland), FAAP, MD	N/A	Innara Health, 10900 S Clay Blair Blvd, Suite 900 Olathe, Kansas 66061 U.S.A.

Peer Reviewer Responses to Structured Peer Review Form Questions

All peer reviewers are asked 16 structured peer review questions which have been adapted from the AGREE II Criteria*. Their responses to these questions are listed on the next few pages.

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

Reviewer #	Name of Reviewer (Required)	What is the name of the society that you are representing?	1. The overall objective(s) of the guideline is (are) specifically described.	2. The health question(s) covered by the guideline is (are) specifically described.	3. The guideline's target audience is clearly described.	4. There is an explicit link between the recommendations and the supporting evidence.
1	Boaz Karmazyn, MD	American College of Radiology	Strongly Agree	Strongly Agree	Strongly Agree	Strongly Agree
2	Anonymous	American Academy of Family Physicians	Strongly Agree	Strongly Agree	Strongly Agree	Agree
3	John W Harrington, MD	N/A	Agree	Agree	Neutral	Neutral
4	Joy Guthrie, PhD., RDMS, RDCS, RVT	N/A	Strongly Agree	Strongly Agree	Strongly Agree	Agree
5	Lawrence Wasser, MD	N/A	Agree	Agree	Agree	Agree
6	Lisa Gilmer, MD	N/A	Neutral	Strongly Agree	Strongly Agree	Agree
7	Anonymous	N/A	Strongly Agree	Strongly Agree	Strongly Agree	Agree
8	Minna Saslaw, MD	Academic Pediatric Association (APA)	Agree	Agree	Agree	Neutral
9	Nicholas M P Clarke, ChM, DM, FRCS	N/A	Agree	Agree	Agree	Disagree
10	Panagiotis Kratimenos, MD	N/A	Strongly Agree	Strongly Agree	Agree	Agree
11	Anonymous	AAP	Strongly Agree	Agree	Neutral	Agree
12	Suhas Nafday, MD, MRCP (Ireland), FAAP, MD	Academic Pediatric Association	Strongly Agree	Strongly Agree	Strongly Agree	Strongly Agree
13	Kelly Bradley-Dodds, M.D., F.A.A.P.	N/A	Strongly Agree	Strongly Agree	Strongly Agree	Strongly Agree
14	Brian Brighton, MD, MPH	Pediatric Orthopaedic Society of North America	Agree	Agree	Agree	Agree
15	Charles T. Price, M.D.	International Hip Dysplasia Institute	Strongly Agree	Strongly Agree	Strongly Agree	Strongly Agree

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

Reviewer #	Name of Reviewer (Required)	What is the name of the society that you are representing?	5. 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	Boaz Karmazyn, MD	American College of Radiology	Strongly Agree	Strongly Agree	Strongly Agree	Strongly Agree
2	Anonymous	American Academy of Family Physicians	Agree	Strongly Agree	Disagree	Strongly Agree
3	John W Harrington, MD	N/A	Neutral	Agree	Agree	Agree
4	Joy Guthrie, PhD., RDMS, RDCS, RVT	N/A	Strongly Agree	Strongly Agree	Agree	Strongly Agree
5	Lawrence Wasser, MD	N/A	Agree	Agree	Agree	Agree
6	Lisa Gilmer, MD	N/A	Agree	Strongly Agree	Strongly Agree	Agree
7	Anonymous	N/A	Agree	Agree	Agree	Agree
8	Minna Saslaw, MD	Academic Pediatric Association (APA)	Disagree	Agree	Neutral	Agree
9	Nicholas M P Clarke, ChM, DM, FRCS	N/A	Neutral	Agree	Disagree	Disagree
10	Panagiotis Kratimenos, MD	N/A	Agree	Agree	Agree	Agree
11	Anonymous	AAP	Agree	Strongly Agree	Neutral	Strongly Agree
12	Suhas Nafday, MD, MRCP (Ireland), FAAP, MD	Academic Pediatric Association	Agree	Strongly Agree	Strongly Agree	Strongly Agree
13	Kelly Bradley-Dodds, M.D., F.A.A.P.	N/A	Strongly Agree	Strongly Agree	Strongly Agree	Strongly Agree
14	Brian Brighton, MD, MPH	Pediatric Orthopaedic Society of North America	Neutral	Agree	Agree	Agree
15	Charles T. Price, M.D.	International Hip Dysplasia Institute	Agree	Strongly Agree	Strongly Agree	Agree

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

Reviewer #	Name of Reviewer (Required)	What is the name of the society that you are representing?	9. 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	Boaz Karmazyn, MD	American College of Radiology	Strongly Agree	Strongly Agree	Strongly Agree	Strongly Agree
2	Anonymous	American Academy of Family Physicians	Neutral	Agree	Agree	Agree
3	John W Harrington, MD	N/A	Agree	Neutral	Agree	Agree
4	Joy Guthrie, PhD., RDMS, RDCS, RVT	N/A	Strongly Agree	Strongly Agree	Agree	Agree
5	Lawrence Wasser, MD	N/A	Agree	Agree	Agree	Agree
6	Lisa Gilmer, MD	N/A	Agree	Agree	Strongly Agree	Strongly Agree
7	Anonymous	N/A	Agree	Agree	Neutral	Neutral
8	Minna Saslaw, MD	Academic Pediatric Association (APA)	Neutral	Agree	Agree	Agree
9	Nicholas M P Clarke, ChM, DM, FRCS	N/A	Disagree	Agree	Agree	Agree
10	Panagiotis Kratimenos, MD	N/A	Agree	Agree	Strongly Agree	Agree
11	Anonymous	AAP	Agree	Strongly Agree	Agree	Agree
12	Suhas Nafday, MD, MRCP (Ireland), FAAP, MD	Academic Pediatric Association	Agree	Strongly Agree	Strongly Agree	Strongly Agree
13	Kelly Bradley-Dodds, M.D., F.A.A.P.	N/A	Strongly Agree	Strongly Agree	Strongly Agree	Strongly Agree
14	Brian Brighton, MD, MPH	Pediatric Orthopaedic Society of North America	Agree	Agree	Agree	Agree
15	Charles T. Price, M.D.	International Hip Dysplasia Institute	Strongly Disagree	Agree	Agree	Agree

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

Reviewer #	Name of Reviewer (Required)	What is the name of the society that you are representing?	13. 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	Boaz Karmazyn, MD	American College of Radiology	Strongly Agree	Strongly Agree	Strongly Agree	Strongly Agree
2	Anonymous	American Academy of Family Physicians	Agree	Agree	Agree	Disagree
3	John W Harrington, MD	N/A	Neutral	Agree	Agree	Agree
4	Joy Guthrie, PhD., RDMS, RDCS, RVT	N/A	Agree	Agree	Agree	Agree
5	Lawrence Wasser, MD	N/A	Agree	Agree	Agree	Agree
6	Lisa Gilmer, MD	N/A	Strongly Agree	Strongly Agree	Agree	Agree
7	Anonymous	N/A	Agree	Agree	Neutral	Agree
8	Minna Saslaw, MD	Academic Pediatric Association (APA)	Agree	Disagree	Agree	Agree
9	Nicholas M P Clarke, ChM, DM, FRCS	N/A	Agree	Neutral	Neutral	Disagree
10	Panagiotis Kratimenos, MD	N/A	Neutral	Neutral	Neutral	Agree
11	Anonymous	AAP	Strongly Agree	Strongly Agree	Strongly Agree	Strongly Agree
12	Suhas Nafday, MD, MRCP (Ireland), FAAP, MD	Academic Pediatric Association	Strongly Agree	Strongly Agree	Strongly Agree	Strongly Agree
13	Kelly Bradley-Dodds, M.D., F.A.A.P.	N/A	Strongly Agree	Strongly Agree	Agree	Strongly Agree
14	Brian Brighton, MD, MPH	Pediatric Orthopaedic Society of North America	Agree	Agree	Neutral	Agree
15	Charles T. Price, M.D.	International Hip Dysplasia Institute	Agree	Agree	Neutral	Disagree

Peer Reviewers' Recommendation for Use of this Guideline in Clinical Practice

Would you recommend these guidelines for use in clinical practice?

Reviewer #	Name of Reviewer	What is the name of the society that you are representing?	Would you recommend these guidelines for use in clinical practice?
1	Boaz Karmazyn, MD	American College of Radiology	Strongly Recommend
2	Anonymous	American Academy of Family Physicians	Recommend With Revisions
3	John W Harrington, MD	N/A	Recommend With Revisions
4	Joy Guthrie, PhD., RDMS, RDCS, RVT	N/A	Strongly Recommend
5	Lawrence Wasser, MD	N/A	Recommend
6	Lisa Gilmer, MD	N/A	Recommend
7	Anonymous	N/A	Recommend
8	Minna Saslaw, MD	Academic Pediatric Association (APA)	Recommend With Revisions
9	Nicholas M P Clarke, ChM, DM, FRCS	N/A	Recommend
10	Panagiotis Kratimenos, MD	N/A	Recommend
11	Anonymous	AAP	Recommend
12	Suhas Nafday, MD, MRCP (Ireland), FAAP, MD	Academic Pediatric Association	Strongly Recommend
13	Kelly Bradley-Dodds, M.D., F.A.A.P.	N/A	Strongly Recommend
14	Brian Brighton, MD, MPH	Pediatric Orthopaedic Society of North America	Recommend With Revisions
15	Charles T. Price, M.D.	International Hip Dysplasia Institute	Would Not Recommend

Peer Reviewer Detailed Responses

Reviewer #1, Boaz Karmazyn, MD, ACR

Reviewer #	Name of Reviewer	Please provide a brief explanation of both your positive and negative answers in the preceding section
1	Boaz Karmazyn, MD	The patients population is well defined, the questions covers well most aspects of management, the methods and analysis make these guidelines very strong.

Workgroup Response

Dear Dr. Boaz Karmazyn,

Thank you for your expert review of the Clinical Practice Guideline on the Detection and Nonoperative Management of Pediatric Developmental Dysplasia of the Hip in Infants up to Six Months of Age.

Respectfully,

2014 DDH CPG Workgroup

Reviewer #2, Anonymous, AAFP

Reviewer #	Name of Reviewer	Please provide a brief explanation of both your positive and negative answers in the preceding section
2	Anonymous	A. I appreciate the AAOS' commitment to evidence. I do question the use of a priori recommendations as this has the potential to result in bias when reviewing the evidence. B. 7 - Concern that unpublished articles were not considered. This presents the potential of publication bias. 16 - The use of "limited" recommendation is confusing as at first glance in implies recommendation.

Workgroup Response

Dear Anonymous Reviewer,

Thank you for your expert review of the Clinical Practice Guideline on the Detection and Nonoperative Management of Pediatric Developmental Dysplasia of the Hip in Infants up to Six Months of Age. We will address your comments by guideline section in the order that you listed them.

- Point A. Thank you for your comments. The use of a priori recommendations is part of the AAOS guidelines process to reduce bias by setting strict article inclusion criteria before reviewing the literature. If guidance for the literature review is not established a priori, choosing relevant articles may be prone to guideline members' biases. The methodology of the AAOS guideline question development has recently changed and guideline work groups now define the scope of the literature search using a priori parameters in a PICOT format (i.e. Population, Intervention, Comparison, Outcome, and Time).
- Point B. AAOS guideline development procedure only allows inclusion of evidence from published, peer-reviewed literature. Unpublished, non-peer-reviewed literature is prone to severe risks of bias.

Respectfully,

2014 DDH CPG Workgroup

Reviewer #3, John W Harrington, MD

Reviewer #	Name of Reviewer	Please provide a brief explanation of both your positive and negative answers in the preceding section
3	John W Harrington, MD	A. The major issue is the actual diagnosis of DDH. Essentially if a disorder has a 10-20 fold variance of 0.1/1000 to 2/1000 then it is likely there is disagreement amongst clinicians as to what constitutes clinically significant. For the primary care practitioner who examines 1000's of children per year it seems likely that they would see children with this disorder, however many only see infants with this disorder in the nursery 1 or 2 times in their career. Once children are sent home from the nursery it is likely a single practitioner may see several children with concerning physical exams and send them for ultrasound. Therefore some guidelines related to a positive history (family or breech) along with physical exam findings of an unstable hip beyond a clicking noise, makes sense to evaluate with ultrasound. Outside of that, I think other recommendations appear fairly flimsy B. 1. Universal US screening Agree with recommendation since this would really be likely to chaff the infant's skin then they can decide. It is likely that the softer braces require a little more expertise and skill to keep in the appropriate position and therefore is subject to variability and failure. C. 9. Monitoring of patient during brace treatment Limited evidence that serial exams or follow up while in brace is helpful. Other than checking for skin breakdown it is unlikely to be helpful to do more exams and radiographs. Having a set time after bracing where objective testing can be done should be studied over time

Workgroup Response

Dear Dr. John W Harrington,

Thank you for your expert review of the Clinical Practice Guideline on the Detection and Nonoperative Management of Pediatric Developmental Dysplasia of the Hip in Infants up to Six Months of Age. We will address your comments by guideline section in the order that you listed them.

- Point A. Thank you for your comments. We share your impression that the evidence supporting many practices related to the early detection and management of DDH is limited. The issue of defining the terms related to DDH is an important point and one that limits the effectiveness of the published literature. This is an important item which needs to be addressed by future research in this area.
- Point B. Thank you for your comment.
- Point C. Your comment about setting time for testing after application of brace is appropriate for future research.

Respectfully,

2014 DDH CPG Workgroup

Reviewer #4, Joy Guthrie, PhD., RDMS, RDCS, RVT

Reviewer #	Name of Reviewer	Please provide a brief explanation of both your positive and negative answers in the preceding section
4	Joy Guthrie, PhD., RDMS, RDCS, RVT	I felt that there was sufficient literature review and statistical analysis to support the recommendations and guidelines in this material. Well done.

Workgroup Response

Dear Dr. Joy Guthrie,

Thank you for your expert review of the Clinical Practice Guideline on the Detection and Nonoperative Management of Pediatric Developmental Dysplasia of the Hip in Infants up to Six Months of Age.

Respectfully,

2014 DDH CPG Workgroup

Reviewer #5, Lawrence Wasser, MD

Reviewer #	Name of Reviewer	Please provide a brief explanation of both your positive and negative answers in the preceding section
5	Lawrence Wasser, MD	Guideline is clear and well documented.

Workgroup Response

Dear Dr. Lawrence Wasser,

Thank you for your expert review of the Clinical Practice Guideline on the Detection and Nonoperative Management of Pediatric Developmental Dysplasia of the Hip in Infants up to Six Months of Age.

Respectfully,

2014 DDH CPG Workgroup

Reviewer #6, Lisa Gilmer, MD

Reviewer #	Name of Reviewer	Please provide a brief explanation of both your positive and negative answers in the preceding section
6	Lisa Gilmer, MD	A. The objectives of the guideline are described in the introduction (provide practice recommendations for the early screening and detection of hip instability and dysplasia) however it also details gaps in the literature. It is these gaps which result in a set of guidelines where the highest level of support is only moderate and that is only for two of nine recommendations. So although the guideline is intended to improve my ability to detect and manage hip instability and hip dysplasia (line 377) after reading the guidelines, as a practicing pediatrician in a nursery setting, I am still left with many clinical questions and unsure how this guideline changes my current clinical practice. B. Q2: The guidelines sought to answer the clinical questions I encounter- who to screen, do you screen infants with just risk factors, how do you image, etc...And the questions were covered specifically. C. Q3: The guidelines clearly describe target audiences and cover recommendations would have provided a clearer picture of the extent of the literature review used for the guidelines. Given my comment to Q1, with guidelines that leave me with continued clinical questions, seeing the extent of the literature review made it clear that the answers just weren't found yet in the literature. Being able to see that without reading all of Appendix 11 would be helpful. D. Q14: Addressed concisely and thoroughly. E. Q16: The grades appear to have been assigned appropriately based on the criteria provided. From a clinical perspective, I would have liked to have seen stronger recommendations but the methodology is described well enough that I am able to follow the conclusion that there isn't strong evidence to support any of the 9 recommendations or even moderate evidence to support 7 of them. F. When reading a new set of guidelines, my hope each time is that either my current clinical practices will be validated or a new, strongly recommended clinical practice will be described. These guidelines were disappointing in that the literature did not strongly support any of the 9 recommendations for clinical practice. Without strong recommendations for change, providers may not even read these new guidelines past the summary section. The guidelines clearly support NOT doing universal ultrasound screening as well as evaluation for infants with risk factors that are clarified as a result of literature review. After that, however, I am still left with questions about what to do with these infants including when to do it, what to do and in particular guidance for when to refer to a pediatric orthopedic surgeon; a question not addressed by any of the recommendations. I would recommend the guidelines in that they provide some guidance for clinical practice but even more as a call for future research in this area that is of high quality in order to provide stronger recommendations for practice in the future.

Workgroup Response

Dear Dr. Lisa Gilmer,

Thank you for your expert review of the Clinical Practice Guideline on the Detection and Nonoperative Management of Pediatric Developmental Dysplasia of the Hip in Infants up to Six Months of Age. We will address your comments by guideline section in the order that you listed them.

- Point A. Thank you for your comments. We agree that we would like to see more evidence to support practices in this area and hope that future research will continue in this area.
- Point B. Thank you for your comment.
- Point C. Thank you for your comment. The work group agrees with your suggestion and has moved the study attrition chart to the beginning of the guideline.
- Point D. Thank you for your comment.
- Point E. Thank you for your comment.
- Point F. Thank you for your comment.

Respectfully,

2014 DDH CPG Workgroup

Reviewer #7, Anonymous

Reviewer #	Name of Reviewer	Please provide a brief explanation of both your positive and negative answers in the preceding section
7	Anonymous	A. Physical examination remains the most significant and cost effective screening tool for this condition. This examination should continue at all well visits until the child's gait is regarded as normal. B. Ultrasonography is operator dependent and so its use in cases where the examination is positive remains questionable as the primary care provider would still make a referral to the orthopedic specialist. Having said that, this guideline by AAOS puts in further clarity to this condition whose evaluation has been rife with conflicting advice to the primary care provider.

Workgroup Response

Dear Anonymous Reviewer,

Thank you for your expert review of the Clinical Practice Guideline on the Detection and Nonoperative Management of Pediatric Developmental Dysplasia of the Hip in Infants up to Six Months of Age. We will address your comments by guideline section in the order that you listed them.

- Point A. The work group agrees that physical examination should continue and have included that information in the introduction. Unfortunately, there is not a well-designed study to show the impact of physical screening, although it is widely accepted that it is of benefit. We do have limited evidence to support serial examinations as noted in recommendation 5.
- Point B. The work group agrees that ultrasound is operator dependent. If exam positive as in recommendation 3, limited evidence suggests that US may be of use in guiding when to initiate brace treatment.

Respectfully,

2014 DDH CPG Workgroup

Reviewer #8, Minna Saslaw, MD, APA

Reviewer #	Name of Reviewer	Please provide a brief explanation of both your positive and negative answers in the preceding section
8	Minna Saslaw, MD	A. As written currently not much is changing. We would still be doing clinical exams from birth at each well child visit, referring for US if risk factors or abnl exam and referring to orthopedics before 6 weeks. As a pediatrician would like to see a recommendation that we do not start clinical screening until an infant is 2-4 weeks of age based on the data presented: B. 1. Unstable hip exams seem to normalize in many infants by 1 week 2. sonographically abnl hips mostly resolve by 4 weeks 3. C. Rec 7 acknowledges there is conflicting evidence about immediate or delayed bracing. D. 4. These guidelines excluded studies which support lower levels of morbidity with DDH e.g. Engesaeter 2008 than the wording of the current guidelines suggest. E. 5. we are probably doing more harm by raising the anxiety level of new parents and ordering unnecessary tests by examining infants at a time where they have more laxity in their hips

Workgroup Response

Dear Dr. Minna Saslaw,

Thank you for your expert review of the Clinical Practice Guideline on the Detection and Nonoperative Management of Pediatric Developmental Dysplasia of the Hip in Infants up to Six Months of Age. We will address your comments by guideline section in the order that you listed them.

- Point A. Thank you for your comment. Unfortunately, we do not have information to suggest that screening of all types be delayed until 2-4 weeks of age. Taken in aggregate, the optimal timing of the initial evaluation is unknown. Early versus late application of a brace for a clinically unstable hip were both supported by low strength articles as noted in recommendation 7.
- Point B. We agree with your comments. Recommendation 6 incorporates some of this information, as do recommendations 3 and 7.
- Point C. Your comment is correct.
- Point D. The Engesaeter 2008 article did not meet the inclusion criteria for this guideline, as it is a retrospective case series.
- Point E. Thank you for your comment.

Respectfully,

2014 DDH CPG Workgroup

Reviewer #9, Nicholas MP Clarke, ChM, DM, FRCS

Reviewer #	Name of Reviewer	Please provide a brief explanation of both your positive and negative answers in the preceding section
9	Nicholas M P Clarke, ChM, DM, FRCS	A. I have reviewed the detection and non-operative management of pediatric developmental dysplasia of the hip in infants up to six months of age document. I am not surprised about the moderate evidence in relation to comprehensive ultrasound screening and the moderate evidence and recommendation for evaluation for risk factors. I am surprised at the conclusion in respect of limited recommendations for treatment of clinical hip instability, for monitoring a patient during brace treatment. Overall the document gives a rather pessimistic picture of the treatment of infantile DDH. There is not enough emphasis on early diagnosis and treatment before 3 months. B. I have looked at the number of articles per recommendation per strength of study. There are 14 articles in respect of universal (comprehensive) ultrasound screening and only a handful of articles in relation to recommendations 2-9. C. Under recommendation 2 there is literature which has been overlooked which I published in 2012 (Clarke NMP, Reading IC, Corbin C, Taylor CC, Bochmann T. Twenty years' experience of selective secondary ultrasound screening for congenital dislocation of the hip. Arch Dis of Child 2012;97:423-9) as a result of screening over 100,000 infants and I am sure that this is an oversight. D. There is also a paper published in 1994 (Boeree, N.R., Clarke, N.M.P. Ultrasound Imaging and Secondary Screening for Congenital Dislocation of the Hip. J Bone Joint Surg Br. 1994 Jul;76(4):525-33) and this should also be included. In all other respects I do not have any further comments to make. Overall however, I cannot support the recommendation that hip instability should not be treated.

Workgroup Response

Dear Dr. Nicholas MP Clarke,

Thank you for your expert review of the Clinical Practice Guideline on the Detection and Nonoperative Management of Pediatric Developmental Dysplasia of the Hip in Infants up to Six Months of Age. We will address your comments by guideline section in the order that you listed them.

- Point A. Included studies did not parse out evaluation and treatment.
- Point B. The list of included articles found for universal screening is more robust, as there were more published articles meeting the guideline inclusion criteria that were relevant to this recommendation.
- Point C. Thank you for the suggestion. The paper was assessed for Recommendation 1, but was excluded as not best available evidence (refer to Table 50). A description of the best available evidence methodology can be found in Section III of the guideline.
- Point D. The paper was considered for recommendation 3, but as the age at ultrasound was not confined to neonates, it did not meet the inclusion criteria.

Respectfully,

2014 DDH CPG Workgroup

Reviewer #10, Panagiotis Kratimenos, MD

Reviewer #	Name of Reviewer	Please provide a brief explanation of both your positive and negative answers in the preceding section
10	Panagiotis Kratimenos, MD	Well described objectives. Questions accurately answered. All important studies were included and their validity was determined including the parameters that could have affected their outcomes. A. A specific section summarizing what is new in the new guidelines would be very helpful for the readers.

Workgroup Response

Dear Dr. Panagiotis Kratimenos,

Thank you for your expert review of the Clinical Practice Guideline on the Detection and Nonoperative Management of Pediatric Developmental Dysplasia of the Hip in Infants up to Six Months of Age. We will address your comments by guideline section in the order that you listed them.

- Point A. The AAOS methodology uses preliminary recommendations that are then supported or not supported by the literature review. The recommendations reflect practices rather than a list of specific recommendations. Hence, unlike other guidelines there is not a list of specific do's and don'ts. However, for the convenience of users, a brief summary of recommendations will be available as well as the full guideline document.

Respectfully,

2014 DDH CPG Workgroup

Reviewer #11, Anonymous, AAP

Reviewer #	Name of Reviewer	Please provide a brief explanation of both your positive and negative answers in the preceding section
11	Anonymous	A. Overall structure of this guideline appropriately delineates and addresses specific questions regarding surveillance and treatment of DDH. Content overall is very good in light of the limited evidence based research available for analysis and review. This guideline should help guide practitioners in the surveillance and non-surgical management of DDH with some exceptions as outlined below. B. There is no mention of target audience with respect to screening (done primarily by pediatricians, physician extenders and orthopedists) versus management (done primarily by orthopedists). C. Recommendation 2 - There is no clear definition of family history. Perhaps this is purposely vague for screening purposes to capture a larger cohort but this could be clarified (for example first and second degree relatives with history of hip pathology). D. In addition, the recommendation suggests an imaging study prior to 6 months for all risk factors but the time frame for imagine should be more specific for each risk factor. For example, US between 2-6 weeks for the clinically unstable hip and imagining at 6 weeks to 6 months for breech presentation as DDH may present later in this population. E. Recommendation 5 - This recommendation is for infants without risk factors and a stable exam and should be stated explicitly for clarity. F. Recommendation 8 - This recommendation conflicts with common practice and consensus on the treatment of the unstable hip with Pavlik harness. With such limited evidence comparing rigid versus soft brace this recommendation will be a less helpful guideline for practitioners and perhaps cause confusion.

Workgroup Response

Dear Anonymous Reviewer,

Thank you for your expert review of the Clinical Practice Guideline on the Detection and Nonoperative Management of Pediatric Developmental Dysplasia of the Hip in Infants up to Six Months of Age. We will address your comments by guideline section in the order that you listed them.

- Point A. Thank you for your comment.
- Point B. Intended users of this material is highlighted on page 1 in the Introduction section. The work group has added in line 402 “medical evaluation and treatment of typically developing children….” and Line 410 “There are not established standards as to what type of practitioner may diagnose and what type of practitioners may treat DDH. Each practitioner is advised to assess their own background and training and the resources available in their communities to determine the optimal care team for children under their care.”

- Point C. Your point is noted. Studies that were included and excluded for this study do not identify what "family history" is in the majority of cases and as such we cannot specify what practitioners should be looking for. The work group has added the following language into Recommendation 2 line 1143. "No study that evaluated the question of family history as a risk factor defined what a positive family history was." The question of family history as a risk factor was not sufficiently addressed within the studies found for this guideline to define "positive family history".
- Point D. Line 1165 does indicate that none of the studies are able to indicate the optimal timing of imaging to occur.
- Point E. The work group agrees that this applies to infants without risk factors.
- Point F. Thank you for your comment.

Respectfully,

2014 DDH CPG Workgroup

Reviewer #12, Suhas Nafday, MD, MRCP (Ireland), FAAP, APA

Reviewer #	Name of Reviewer	Please provide a brief explanation of both your positive and negative answers in the preceding section
12	Suhas Nafday, MD, MRCP (Ireland), FAAP, MD	A. Overall a great report and it was exhaustive reading, but it has been written really well. B. 2. Page 13, line 382: The initial definition of DDH is labeled 'Developmental dislocation of hip', whereas subsequently term used is 'Developmental dysplasia of hip'. I suggest, we use the latter term consistently throughout the report. C. I have some comments about the overall structure of these guidelines: a. Clarification on conflicting terminology in definition needs to be explained, esp. clarity on 'clunk', 'click' etc. would be helpful. D. Clarity on identification of criteria used for diagnosis, definition of appropriate cutoff points for dividing the continuous spectrum of acetabular morphology at US into prognostic subgroups, the disagreement on how to define substantial risk for the predicted harm would be helpful. In particular, the terms sonographically depicted dysplasia and radiographically depicted dysplasia should be distinguished because they provide different inform emphasizes that the great majority of hips that are unstable at birth (positive Ortolani/Barlow) resolve spontaneously. E. When should a pediatrician refer these infants to an Orthopedist? F. It is important to emphasize that maldevelopments of the acetabulum alone (primary acetabular dysplasia) can be determined only by imaging. Abnormal physical findings may be absent in an infant with acetabular dysplasia where subluxation or dislocation has not yet occurred.

Workgroup Response

Dear Dr. Suhas Nafday,

Thank you for your expert review of the Clinical Practice Guideline on the Detection and Nonoperative Management of Pediatric Developmental Dysplasia of the Hip in Infants up to Six Months of Age. We will address your comments by guideline section in the order that you listed them.

- Point A. Thank you for your comment.
- Point B. Thank you. The work group has revised line 382 to be consistent and now reads "developmental dysplasia of the hip".
- Point C. Thank you. This point was acknowledged in the Introduction under the Burden of Disease section. We hope the reviewer will find this reference to be sufficient.
- Point D. Thank you for your comment.
- Point E. The timing and rate of resolution of these abnormalities is not well defined making specific recommendations as to the timing of treatment not possible.
- Point F. The work group agrees with your comment and has added the following language into line 475. "In clinically normal hips imaging evaluation would be the only viable method to assess for hip problems that could have a potential to evolve into a future pathologic condition with adverse impact upon an individual's quality of life."

Respectfully, 2014 DDH CPG Workgroup

Reviewer #13, Kelly Bradley-Dodds, M.D., F.A.A.P.

Reviewer #	Name of Reviewer	
13	Kelly Bradley-Dodds, M.D., F.A.A.P.	Overall this was an excellent and comprehensive review of the available evidence that addressed key questions a pediatrician would have when considering the evaluation of an infant. specific comments: A. Page 21, line 1085: Recommend adding "ultrasound" so that the line reads, "There is moderate evidence to not do universal ultrasound screening of all infants for DDH." Although it should be clear from the recommendation's headline, a reader could confuse this sentence to mean any universal screening, such as physical examination. B. Page 28: Recommend that the authors consider mention of the infant's gender, such as, "Moderate evidence suggests performing an imaging study before 6 months of age in infants with one or more of the following risk factors regardless of gender..." Earlier guidelines from the American Academy of Pediatrics contained different recommendations for male vs. female infants, as females were believed to have higher risk of DDH. We teach that anything making the uterus a tight fit can increase risk for DDH -- oligohydramnios, LGA infant, maternal fibroids, etc. Not seeing mention of these factors, I presume there is no evidence in the literature relating to them. The authors could consider mention of the absence of data relating to these factors in the literature. I was very appreciative of the authors' discussion of what "breech" means. This is a common and often disagreed-upon topic of discussion in pediatrics. C. Page 70: Does Recommendation 6 suggest that for an infant with risk factors and a normal physical exam, we should wait to perform a screening ultrasound until 6 weeks of age?

Workgroup Response

Dear Dr. Kelly Bradley-Dodds,

Thank you for your expert review of the Clinical Practice Guideline on the Detection and Nonoperative Management of Pediatric Developmental Dysplasia of the Hip in Infants up to Six Months of Age. We will address your comments by guideline section in the order that you listed them.

- Point A. The work group has added “ultrasound” to line 1085.
- Point B. The work group agrees with your comments and has added the following language into line 1131, “Examination of other quoted risk factors was done. Evidence was not found to include foot abnormalities, gender, oligohydramnios, torticollis as risk factors for DDH. “
- Point C. The work group agrees with your comments and has added the following language into the rationale on line 1131, “The optimal time to obtain an ultrasound within this 2-6 weeks of age period is not defined by the available literature.”

Respectfully, 2014 DDH CPG Workgroup

Reviewer #14, Brian Brighton, MD, MPH, POSNA

14	Brian Brighton	Comprehensive review of the detection and management of DDH in infants up to 6 months of age highlights the gaps in the evidence to make strong recommendations in the management of this clinical problem. A. Part of the potential uncertainty of gaining acceptance of these guidelines among pediatricians and non-pediatric orthopaedic surgeons, lies in the stem language regarding limited evidence as to what a clinician might or might not do. In these cases the rationale needs to be highlighted to clarify the message and intent of the guideline recommendation. B. Recommendations 4 and 5 need to be resolved with current AAP practice guidelines suggesting screening with physical exam up to a year and x-rays around 6 months. C. Recommendation 6 supports observation without a brace with clinically stable hip with US abnormalities but without following through the recommendations in the rationale, this only applies up to 6 weeks but that is not clearly stated in the recommendation if that is the intention. In summary, I do not feel these guidelines would change the practice of many practicing pediatric orthopaedic surgeons however it provides an opportunity to develop and study some clinical care pathways along these scenarios under the guidelines.

Workgroup Response

Dear Dr. Brian Brighton,

Thank you for your expert review of the Clinical Practice Guideline on the Detection and Nonoperative Management of Pediatric Developmental Dysplasia of the Hip in Infants up to Six Months of Age. We will address your comments by guideline section in the order that you listed them.

A. Thank you for your comment.
B. Current AAP guidelines are 14 years old. This guideline is based on current literature.
C. We hope that these guidelines will help with a research agenda for management of DDH.

Respectfully,

2014 DDH CPG Workgroup

Reviewer #15, Charles T. Price, MD, IHDI

15	Charles T. Price, M.D.	A. Rec. 3. Doesn't this support newborn ultrasound whenever the pediatrician thinks there is instability? The American College of Radiology guidelines say, "Preferably at the age of 4-6 weeks" B. Rec. 4. Consider change to "…AP radiograph instead of an ultrasound to assess DDH in infants older than 4-6 months of age." Or, "…in infants beginning at 4 to 6 months of age." C. Rec. 5. The wording takes me a while to figure out and I still may not have this correct. The first sentence of the Rationale on p. 67 is much clearer. Perhaps, "Limited evidence supports subsequent clinical screening of children up to 6 months of age for infants previously found to have a normal hip examination." Mine is convoluted too, but maybe there's a clearer way than the summary recommendation so it's similar to the rationale. D. Rec. 6. This specifies a brace but what about splints and bulky diapers? Should this say, "…supports observation without treatment for infants…". Perhaps the literature only supports avoidance of a brace and doesn't say anything about other treatments? E. Rec. 8. – This is a bit of a conundrum that obviously needs more research as you've suggested on page 104. This recommendation is supported by the Rationale but the two studies cited showed specifically that the von Rosen splint was superior. An RCT was presented at POSNA comparing plastizote abduction orthosis to Pavlik. Of course, that hasn't been published and could not be included. Mainly the plastizote abduction orthosis is a poor brace compared to von Rosen. Other types of rigid braces have not been studied. Is there a different way to define rigid brace, or clarify that "Limited evidence supports use of the von Rosen splint over Pavlik, Craig, or Frejka splints for initial treatment of an unstable hip"? F. #8 is not supported by the literature. A significant research study was not included even though it meets criteria for inclusion. The paper is published in English by Azzoni R, Babitza P, A comparative study of the effectiveness of two different devices in the management of developmental dysplasia of the hip in infants. Minerva Pediatr 2011;63:355-61. Azzoni's study is a blinded randomized trial comparing a rigid brace (Teuffel-Mignon) and a brace (Cora-Flex). The authors describe the Teuffel-Mignon brace as more rigid and the Cora-Flex as a harness. There were 59 patients in each group and no differences in outcome were noted regardless of Graf classification. The recommendation submitted by the panel relies on two retrospective studies that found the von Rosen splint superior when applied by various orthopedic surgeons. Wilkinson30 states, "The management is determined by the orthopaedic consultant in charge of the patient, and this depends on which suggest adding benefits in the last objective that indicates future research should define the harms of early diagnosis and treatment." Benefits should also be included in that statement. Recommendation 8 needs to be corrected before I could use this in my practice.

		G. **Definitions:** Is a table of definitions needed? If it's there, I couldn't find it. Your Future Research calls for improved terminology so maybe it's too difficult to have definitions. In lieu of definitions, some areas may need some clarification or elaboration. Unstable – I'm assuming this means everything from mild instability to complete irreducible dislocation at rest. That seems OK in most instances, but may not distinguish between mild and severe for recommendation #8. Screening – I'm always confused between screening as a general term. It may be preferable to state ultrasound screening or clinical screening to clarify type of screening. This distinction seems to be used except in Recommendation 5 where "screened" could be either. H. **Future Research –** this is outstanding. Here are a couple of thoughts Specifically, future research areas should attempt to: • Establish clear, widely accepted, reproducible criteria and definitions for: • Clinical terms that describe hip stability • Radiographic and ultrasound criteria for dysplasia and dislocation based upon age. • Historical and clinical risk factors to be assessed for all children that are related to DDH. • What constitutes "standard" brace treatment of DDH • Which brace has the most reliable outcomes • What are outcomes criteria that define successful or failed treatment for DDH • Establish universally accepted and reproducible ranges of normal values across ages for sonographic and/or radiographic hip measures or any future surrogates for normal hip development. • Establish clear relationships between these surrogates for hip development and demonstrate long-term functional limitations that are correlated to surrogate values that fall outside of the normal ranges. • Define the benefits and harms of late diagnosis of DDH • • Define the benefits and harms of early diagnosis and treatment of DDH

Workgroup Response

Dear Dr. Charles T. Price,

Thank you for your expert review of the Clinical Practice Guideline on the Detection and Nonoperative Management of Pediatric Developmental Dysplasia of the Hip in Infants up to Six Months of Age. We will address your comments by guideline section in the order that you listed them.

A. Recommendation 3 does support it if there is instability and you wish to follow the hip examination and acetabular development. Recommendation 2 does support this if there is a history of clinical instability.
B. Recommendation 4 – Original recommendation language changed from "Limited evidence supports the use of an AP pelvis radiograph instead of an ultrasound to assess DDH in infants between 4 and 6 months." To "Limited evidence supports the use of an AP pelvis radiograph instead of an ultrasound to assess DDH in infants beginning at 4 months of age."

C. Thank you for your comment.
D. The work group agrees with your comments and has added the following language to the rationale for Recommendation 6: "…supports observation without treatment for infants".
E. Recommendation 8: Type of Brace for the Unstable Hip – Original recommendation language changed from "Limited evidence supports the use of rigid brace over soft brace for initial treatment of an unstable hip" to "Limited evidence supports use of the von Rosen splint over Pavlik, Craig, or Frejka splints for initial treatment of an unstable hip".
F. Thank you for referring us to Azzoni R, 2011 study. This study was reviewed and excluded, as their primary outcome was number of days in the brace and they did not provide a clear description of how a decision was made to discontinue the brace.
G. We agree that a glossary of definitions would be useful but given the current state of the literature it is not feasible to create an evidence-based document to sufficiently define all terms.
H. Thank you for your comment; the work group has added specific harms of late diagnosis of DDH and benefits of early diagnosis and treatment of DDH to the future research section.

Respectfully,

2014 DDH CPG Workgroup

PUBLIC COMMENT RESPONSES

Public Comment Participant Key

Participant #	Name of Participant	Primary Specialty	Work Setting	What is the name of the society that you are representing?
1	David Jevsevar, MD,MBA	Adult Hip	Pre-paid Plan/ HMO	None Listed
2	Anonymous	Anonymous	Anonymous	None Listed
3	Molly Dempsey, MD	Other (Please Specify Below)	Clinical Hospital	None Listed
4	Richard Schwend, MD	Pediatric Orthopaedics	Academic Practice	None Listed
5	American Academy of Pediatrics Review Board	Multiple	Mulitple	American Academy of Pediatrics

Public Comment Participant's Disclosure Information

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

Disclosure Question Key

Disclosure Question	Disclosure Question Details
A	A) Do you or a member of your immediate family receive royalties for any pharmaceutical, biomaterial or orthopaedic product or device?
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?

Disclosure Information for Public Comment Participants

Participant Number	Name of Participant (Required)	A	B	C	D	E	F	G	H	I	J
1	David Jevsevar, MD,MBA	None	None	None	None	None	None	None	None	None	None
2	Anonymous	None	None	None	None	None	None	None	None	• Elsevier • Journal of Bone and Joint Surgery - American • Journal of Bone and Joint Surgery - American • Journal of the American Academy of Orthopaedic Surgeons • Spine	• Lumbar Spine Research Society • Medicare Coverage and Advisory Commission
3	Molly Dempsey, MD	None	None	None	None	None	None	None	None	None	Society for Pediatric Radiology Board of Directors, Society for Pediatric Radiology Research and Education Foundation Board of Directors
4	Richard Schwend, MD	No	Medtronic	No	No	No	No	No	No	No	Pediatric Orthopaedic Society of North America American Academy of Pediatrics Project Perf
5	American Academy of Pediatrics Review Board	None	None	None	None	None	None	None	None	None	None

Public Comment Participants' Responses to Structured Public Comment Questions

Questions 1-4

Reviewer #	Name of Reviewer (Required)	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	David Jevsevar, MD,MBA	Agree	Agree	Agree	Agree
2	Anonymous	Neutral	Strongly Agree	Neutral	Neutral
3	Molly Dempsey, MD	Strongly Agree	Strongly Agree	Agree	Agree
4	Richard Schwend, MD	Agree	Agree	Neutral	Strongly Agree
5	American Academy of Pediatrics Review Board	N/A	N/A	N/A	N/A

Questions 5-8

Reviewer #	Name of Reviewer (Required)	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	David Jevsevar, MD,MBA	Neutral	Strongly Agree	Strongly Agree	Strongly Agree
2	Anonymous	Neutral	Strongly Agree	Agree	Agree
3	Molly Dempsey, MD	Agree	Strongly Agree	Agree	Neutral
4	Richard Schwend, MD	Disagree	Agree	Strongly Agree	Agree
5	American Academy of Pediatrics Review Board	N/A	N/A	N/A	N/A

Questions 9-12

Reviewer #	Name of Reviewer (Required)	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	David Jevsevar, MD,MBA	Strongly Agree	Strongly Agree	Strongly Agree	Strongly Agree
2	Anonymous	Agree	Agree	Agree	Agree
3	Molly Dempsey, MD	Agree	Neutral	Agree	Neutral
4	Richard Schwend, MD	Agree	Agree	Agree	Agree
5	American Academy of Pediatrics Review Board	N/A	N/A	N/A	N/A

Questions 13-16

Reviewer #	Name of Reviewer (Required)	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	David Jevsevar, MD,MBA	Strongly Agree	Neutral	Agree	Strongly Agree
2	Anonymous	Agree	Agree	Agree	Disagree
3	Molly Dempsey, MD	Agree	Agree	Agree	Agree
4	Richard Schwend, MD	Neutral	Agree	Strongly Agree	Strongly Agree
5	American Academy of Pediatrics Review Board	N/A	N/A	N/A	N/A

Would you recommend these guidelines for use in clinical practice?

Participant Number	**Name of Participant (Required)**	**Would you recommend these guidelines for use in clinical practice?**
1	David Jevsevar, MD,MBA	Recommend With Revisions
2	Anonymous	Would Not Recommend
3	Molly Dempsey, MD	Recommend
4	Richard Schwend, MD	Recommend With Revisions
5	American Academy of Pediatrics Review Board	N/A

Public Comment Participants' Responses

Public Comment Participant #1, David Jevsevar, MD,MBA

Lines 469-476 in the Introduction. My concern is that this paragraph will be quoted as if it were evidence based. The authors appear to be circumnavigating the evidence, trying to create a correlation between the treatment of DDH and prevention of hip OA. While we all hope this is true, I don't believe current evidence supports this relationship. If taken out of context, this may be misconstrued as direct evidence. I would suggest further rewording this paragraph or eliminating it altogether. The workgroup should be congratulated on an excellent product, which hopefully is clinically implementable and should stimulate further research into the diagnosis and treatment for DDH.

Public Comment Participant #2, Anonymous

I commend the authors of the guidelines for the work they have done. I am at a loss as to what I should make of their conclusions / summary statements. The statements are likely all accurate in terms of "guidelines language" but do not help the surgeon / pediatrician / public at all. Almost all conclusions are moderate or limited. This can be interpreted in any way any one would like. Gettting an ultrasound or xray prior to 6 weeks may be acceptable or not! All this does is allow malpractice attorneys to use this information in the way they would like. The AAOS needs to seriously consider whether they should get out of the guidelines business. There has to be realization that interpretation of the literature in the way the guidelines process requires will not allow strong recommendations for most orthopaedic literature.

Public Comment Participant #3, Molly Dempsey, MD
No comments submitted.

Public Comment Participant #4, Richard Schwend, MD

1. It is not described how the AAOS guidelines specifically differ from the AAP 2000 CPG guidelines. Pediatricians and pediatric clinicians currently use the 2000 AAP CPG. It would be most helpful if the differences in findings and recommendations were specifically listed. 2. What is significance of the findings of this AAOS CPG in relation to the inconclusive recommendation by the 2006 USPSTF to not screen for DDH. Specifically, what new information did AAOS have available since 2006 at to decide on recommendation #2 (292)? 2. This document does not appear to be written for the primary care provider who is the first to see these patients. What are AAOS plans to communicate these guidelines to front line care providers? 3. Importance of newborn exam, training of those performing the exam, tracking of infants with abnormality, followup exam of equivocal findings, when to refer and who to refer to are important questions for the primary clinician, but not well described in the recommendations. Specifically, it is not clear from this CPG when and to whom a referral should go to. This is a key question that primary care clinician wants answered. 4. Effectiveness of newborn exam, ultrasound, and referral. Real life in the United States has great variability of competence and effectiveness of primary providers and imaging ability. There is a variation of distances that patients must travel that may restrict access. Insurance, transportation, time of year and financial hardship of the family may further restrict access to timely care. This further complicates the actual effectiveness of the already limited recommendations that were obtained from the best literature available. 5. Is the the evidence in this CPG strong enough to justify development of an AUC that would be useful to the primary care clinician?

Public Comment Participant #5, American Academy of Pediatrics Review Board

Section on Orthopaedics

Thank you for this opportunity to review the upcoming CPG. It is a well written document that thoroughly analyzed the best science available concerning nine (9) specific clinical and research questions regarding DDH in younger infants. It does an outstanding job exposing the gaps in the currently available literature, which is necessary for directing future research. Where there is evidence for some of the clinical questions studied, it provides practical recommendations. We think it will be a useful reference for researchers, some practicing orthopaedic surgeons who care for young infants and for the more interested pediatricians who must make decisions about universal ultrasound screening and the evaluation of children with risk factors. Pediatricians in leadership positions in health systems may find the CPG very useful for establishing practice guidelines and protocols. It also provides an agenda for some areas that could benefit by further clinical research. It may also be helpful for providing recommendations for imaging infants with unstable hips, for following infants with ultrasound abnormalities, for continued surveillance of infants through the first 6 months of life, and the conservative treatment and monitoring of treatment through radiographic imaging. The most useful and clear recommendation is the recommendation *against* universal ultrasound screening.

However, the Section on Orthopaedics has the following concerns about the CPG.

- The original 2000 AAP guidelines, which were retired after five years have been followed for 14 years by practicing pediatricians. Although the guidelines are not current, pediatricians still follow the clinical decision points. Pediatricians in practice are looking for these similar decision points to be addressed in a new CPG. The AAOS CPG does not follow this format and may make it less likely to be read and adopted by practicing pediatricians.
- Since AAP prepared the 2000 CPG for primary care clinicians, it is not apparent why AAOS decided to do this CPG rather than working with AAP as an equal partner in this CPG. By having this be an AAOS product, although with AAP member participation, it presents a real barrier to acceptance by the pediatric community. It may be perceived as "pediatricians being told by orthopaedic surgeons who to practice their primary care"
- In reading the AAOS CPG it is not clear in what ways it differs from the AAP 2000 CPG. Specifically, how does the AAOS CPG recommendations differ from the AAP 2000 Recommendations and the 2006 US Preventive Service Task Force conclusion (that there is insufficient evidence to recommend routine screening). Pediatricians who are well versed in the AAP 2000 CPG will want to understand the differences and rational. All three statements recommend against routine universal ultrasound screening. However, the AAP recommends that all newborns be screened by physical examination by a properly trained health care provider. If the Ortolani or Barlow exam is positive, then refer to orthopaedics. This has become ingrained in pediatric clinicians in the newborn nursery, despite the "Inconclusive" recommendation from USPSTF. AAOS gives imaging of the neonatal hip with instability a "limited", meaning insufficient evidence for or against, but does not recommend referral to orthopaedics. Rather AAOS CPG discusses limited evidence for or against brace treatment. All of this may be quite confusing to the pediatric clinician unless it is delivered in a manner that acknowledges current practice based on AAP guidelines and reason for recommendation for change of practice.
- By specifically listing the difference and similarities between the two CPGs would make it much easier for the practicing pediatric clinician to understand the new document.
- Risk factors. AAP 2000 recommendations indicate that there are thresholds for further evaluation of risk factors. These include one's values and risk avoidance, economic decision-making and other society factors. These do not seem to be addressed in the discussion of risk factors (p519). The 2006 USPSTF does not recommend imaging for patient with risk factors. What new evidence did AAOS evaluate that led to recommendation #2 to obtain imaging for listed risk factors (p292)? Another key difference is that the AAP

CPG did not recommend routine ultrasound screening for male breech. The AAOS CPG does. It is not clear if there is new scientific evidence for this change in recommendation, a change in methodology, or if it merely represents an arbitrary interpretation of cutoff values based on disease prevalence. Again, this is likely to be confusing to the pediatrician, especially when legal issues arise.

- This document does not appear to be written for the primary care provider who is the first to see these patients. The CPG lacks many of the very practical clinical questions and answers that most practicing pediatricians as well as other pediatric practitioners such as family practice, APNs and PAs commonly seek. Since there is such a paucity of quality studies to establish a CPG, seven (7) of the nine (9) recommendations are of such limited strength, that the primary care physicians are unlikely read the document. Due to the narrow focus, inconclusive recommendations of its questions, the CPG is likely to not change practice. Pediatricians are looking for more comprehensive guidelines to help direct their practice over the years that they see a child.
- The CPG does not explain how this information will be distributed to the front line primary care clinician. With the different conclusions from previous AAP CPG and USPSTF, what are specific plans for AAOS to communicate effectively with pediatric clinicians to educate them and to resolve these differences in recommendations with out confusing the pediatric clinician? The 2006 USPSTF recommendation seem to be essentially ignored by the pediatric community and our concern is that the same will happen with AAOS CPG. Does AAOS have plans to involve front line pediatricians and pediatric clinicians to determine how best to deliver this content?
- Although an appropriate use criteria may be the next step, there appears to be insufficient evidence in the CPG for development of an AUC that would be useful.
- ***In the AAPS CPG, the importance of a properly performed clinical newborn hip exam by a competent examiner with close follow-up and referral is not emphasized as much as might be expected by pediatric clinicians.*** What is proper training for practitioners for performing a hip examination? How should the training needs of primary care residency programs be addressed? Are there minimum standards for competence in the hip examination? When should the hip examination be done, by whom, how documented, how should abnormalities be followed? Is there even a role for the newborn nursery exam of the hips, if no treatment is indicated and the hips will be examined at the two-week visit? Should Barlow examination be discouraged, is Barlow even safe? AAP Bright Futures recommends both Ortolani and Barlow maneuvers be performed on the newborn. Is this an appropriate recommendation? What to do with infant who is screaming and cannot be adequately examined? What is best way to assure that the difficult to examine infant eventually receives proper examination? Effectiveness of newborn exam, ultrasound, and referral. Real life in the United States has great variability of competence and effectiveness of primary providers and imaging ability. There is a variation of distances that patients must travel that may restrict access. Insurance, transportation, time of year and financial hardship of the family may further restrict access to timely care. These are commonly heard clinical questions from pediatricians that are not addressed in the AAOS guidelines. This further complicates the actual effectiveness of the already limited recommendations that were obtained from the best literature available.
- Primary prevention is not discussed but pediatricians have many questions. How best to provide primary prevention of DDH, including safe swaddling, sleep position, carriers and proper carrying around the mother's body?
- Pediatricians continue to see patients past 6 months to 18 months and need guidance on evaluating and examining the infant and toddler for DDH. Pediatricians remain at risk for either diagnostic errors or late presenting DDH during the time period that is not covered by the AAOS CPG.
- Hip clicks. What to do with "hip clicks". Not all practitioners recognize the difference between a click and a positive Ortolani maneuver.
- Ultrasound imaging. Evidence suggests performing imaging study before 6 months with certain risk factors such as breech, family history, or history of clinical instability. In practice, pediatricians have many questions regarding the specifics and details. What to do with the infant who had been inappropriately swaddled? Is this a risk factor requiring an ultrasound exam? Should the primary care physician be ordering

the ultrasound examination? If so this can lead to over treatment and over referral when minor variations are detected. However, if practitioner is not capable to examine the hip, under-referral can be a problem. Is a history of breech earlier in pregnancy that resolves an indication for ultrasound? How strong does the family history need to be? Cousins? Second cousins? Is a positive Barlow that resolved spontaneously enough instability to justify an ultrasound examination?

- Local and regional variations in quality of imaging. Ultrasound imaging is very operator dependent. Many pediatricians live in remote areas where ultrasound screening is of questionable quality or of such low volume that adequate experience cannot be acquired. What does the pediatrician do if the imaging quality in their area is not reliable? Should all radiology programs follow ACR and AIUM guidelines to avoid under or over-treatment.? Should there be national criteria for imaging or more local based on local resources, training, experience and capabilities? We don't see that the Society for Pediatric Radiology was part of the initial peer review.
- Specifics of the referral to orthopaedics. When should the infant with hip dysplasia be referred? To whom? To pediatric orthopaedic surgeon only or to nearest orthopaedic surgeon? Rural patients may need to travel very far to see a pediatric orthopaedic surgeon. Is this always the best use of their time and resources? There are safety issues when travel occurs in severe weather.
- Infant with limited abduction. What to do with infants who presents with limited abduction? How much is abnormal? What to do with asymmetric proximal thigh creases?
- What to do with hip that has abnormal US screen? AAOS CPG recommends an imaging study for clinically stable hips if have risk factors or breech (Moderate evidence). However it also discusses the limited evidence for treatment if the imaging study shows morphologic abnormality. This recommendation is not clear in that a test is recommended, but no treatment is recommended if the test is abnormal.
- Brace treatment. Is it appropriate for pediatrician or other primary provider to initiate brace treatment? Is in hospital initiation of bracing necessary? Does it lead to over treatment, expense and stress to the family? How long should brace treatment be used? Will current practice of Pavlik harness really change based on a few studies that suggest von Rosen brace is more effective. When should alternative form of treatment be used if original does not work?

Committee on Practice and Ambulatory Medicine

This clinical guideline differs in a number of significant ways from the last AAP clinical guideline, so it would be helpful to summarize those differences.

- One significant difference is that the scope of the current AAP guideline extends from birth to 18 month of life in terms of evaluating for DDH, whereas this has a scope from birth to 6 months. One question for the AAP is whether this means we don't need to check or document specifically for DDH after 6 months, or if to continue to screen for clinical instability routinely for 18 months, does the AAP document need to be updated for the other AAOS recommendations?
- **Line 282-369:** The format of this summary seems really redundant. In the first page of the section, they present a table with the explanation of the visual grading system, which is good. Then, they repeat it under every single recommendation. This makes it redundant, way too long, and harder to read.
- **Table 23-24:** This is very confusing in that it appears to read that having a hip "click" is associated with a significant Relative Risk of developing hip instability and/or DDH. This contradicts current recommendations, and needs to be clearer. **Recommendation to do ultrasound for ALL breech infants - this is significantly different from current recommendations as the historical relative risk/incidence for males who were breech was cited as being near to non-breech females.**
- COPAM appreciates mention of the orthopedic idiosyncrasies practitioners must consider -- when to ultrasound, xray, examine, differences between clicks and clunks. The incidence and natural history of developmental abnormalities of the newborn hip is both troublesome and comforting; an acknowledgement of

how many I've missed and the self-cure rate. Most helpful would be a recommendation for best practice, remembering that all newborns will not have access to ultrasound evaluation.

Lastly, COPAM states that this report is entirely too large to get through in one sitting. While it is an all-encompassing gathering of opinions, literature search, and review of history and traditions and is interesting, practicing pediatricians need a MUCH shorter document, ideally even a one paragraph practicable recommendation. Perhaps it is in there but is impossible to find.

Committee on Medical Liability and Risk Management

Thank you for allowing the Committee on Medical Liability and Risk Management (COMLRM) to review the American Academy of Orthopedic Surgeons Clinical Practice Guideline on "Detection and Non-operative Management of Pediatric Developmental Dysplasia of the Hip in Infant up to Six Months of Age."

As you know, the COMLRM is charged with reviewing outside CPG under consideration for AAP endorsement to assess any medical liability implications for pediatricians and pediatric subspecialists.
The following significant concerns have been identified:

This CPG is limited to detection and non-operative management of DDH in infants six months of age or less. It does not address infants 6-8 months, or those 9-12 months when ambulation is likely to occur. This is concerning and greatly limits the usefulness of the CPG to pediatricians.

While this limitation is mentioned in lines 430-432, it should be noted that this CPG is not as comprehensive as the Academy's previous CPG published in 2000 with a target patient population that included the healthy newborn up to 18 months of age, excluding those with neuromuscular disorders, myelodysplasia, or arthrogryposis.

It would be helpful to know the incidence of DDH detection among infants > 6 months of age. The previous AAP CPG noted "When this process of care is followed, the number of dislocated hips diagnosed at 1 year of age should be minimized. However, the problem of late detection of dislocated hips will not be eliminated. The results of screening programs have indicated that 1 in 5000 children have a dislocated hip detected at 18 months of age or older."

A CPG targeting primary care pediatricians should clearly map out the clinical management decision points faced by the provider in a way that makes longitudinal sense following the disease's evolution. This CPG does not do this. In any case in which DDH is detected "late," there will be substantial liability risk as well as health risks for the child. Unfortunately, this document largely fails to provide critical guidance in this regard, which was provided in the previous AAP CPG on DDH and the draft clinical report authored by the AAP Section on Orthopedics, but set aside pending review of this AAOS CPG.

For example, the following guidance was provided in the 2000 AAP CPG on DDH:

- Screen all newborns' hips by physical examination.
- Examine all infants' hips according to the AAP periodicity schedule and follow-up until the child is an established walker.
- Record and document physical findings following each examination.
- Be aware of the changing physical examination for DDH.

- If physical findings raise suspicion of DDH, or if parental concerns suggest hip disease, confirmation is required by expert physical examination, referral to an orthopedist, or by an age-appropriate imaging study.

The above guidance does not appear in the AAOS CPG. This is a troubling deficiency given the severity of indemnity payments from DDH-related malpractice claims against pediatricians (average $202,000 for diagnostic error, $254,000 for failure/delay in referral/consultation*).

The previous AAP CPG also addressed early detection of DDH in preterm infants. The AAOS CPG does not. This inconsistency creates liability risks.

Line 478 discusses practice standards for musculoskeletal evaluation of all newborn children without defining such an exam. This is a problem that carries medical liability consequences. In addition the word "standard" should be eliminated.

Lines 1163-1166: The various parameters for screening family history are discussed but not defined in this section. As a result, there is some confusion about what constitutes "positive" family history (e.g., first generation, more distant relatives). Also this section identifies "clinical instability" as a risk factor with no supporting discussion or documentation. Again, this is unclear and confusing for practitioners who may not be clear on what constitutes "clinical instability." This lack of clarity results in additional medical liability risk.

Lines 1322-1344: The section on surveillance suggests limited evidence supporting re-exam of normal newborn hips. This is written in a confusing way and would be better phrased in a more positive manner for the provider such as, "ongoing surveillance is recommended," or "not recommended," and describing the strength of recommendation given.

Lines 470-476 and 546-551 appear to be contradictory. Lines 470-476: "It is widely believed that DDH is a condition that can lead to impaired function and quality of life for children and adults and that detection of this condition in early childhood may allow interventions that can alter this. It is also believed that earlier treatment creates less potential harm to the child than later treatment with the aggregate risk of those harms being less than the risk of impaired function and quality of life of the untreated condition." Lines 546-551: "Observational and case control studies suggest that the management of children who present with DDH at walking age or older has greater risk of being managed by open surgical hip reduction with its attendant risks of avascular necrosis, infection, hip stiffness, and early onset osteoarthritis as an adult. The harms of late diagnosis with no treatment are not established. If the latter has not been established, how can the former be deemed less?

Clarification is needed for 3 additional important definitions. Lack of clarity increases liability risks.

First, "clinical instability" is used in 5 of the recommendations, yet the way it is used varies. It is listed as a risk factor in recommendation 2, but then as a diagnostic physical finding in recommendations 3, 7, 8, and 9. The COMLRM does not believe that an unstable hip should not be considered a risk factor. This is different than observing potential abnormal physical findings like asymmetrical thigh folds or limited hip abduction that may be considered risk factors. This CPG needs to be very clear about this for the recommendations to be useful to pediatricians.

Second, recommendation 7 is titled "Treatment of Clinical Instability" and uses another undefined term "positive instability exam." This is unclear and needs to be corrected.

Third, the term "late presenting dysplasia" should be defined. Some reviewers believe a late presentation (when it is symptomatic) is when it presents at an age no longer conducive to simple bracing, and typically when the

infant begins to walk which is on average at 12 months. Since this systematic review only includes up to 6 months of age, it does not cover the ages that pose the highest liability risk for being accused of malpractice for missing hip dysplasia for pediatricians. The cutoff at 6 months of age seems arbitrary. Lines 1328-1332: state that the reviewed literature did not include up to walking age, but the authors don't provide an explanation for limiting the literature search to newborns to infants 6 months.

Line 1538 should include "benefits and harms" as is found in the section above it.

CONCLUSION

An endorsement of this AAOS as it currently is written would result in the following:

- A significant policy gap for the target population of healthy newborns and infants 6-12 months and preterm infants.
- Pediatricians relying on a CPG that does not clearly map out the clinical management decision points faced by the primary care provider in a way that makes longitudinal sense following the disease's evolution.
- Lack of risk management guidance on documenting DDH examination findings which may make it more difficult to defend allegations of missed diagnosis.
- Promotion of the belief that "late" detection of DDH results solely from diagnostic error, with the CPG insufficiently addressing the progressive nature of physiologic hip development in the child < 1 year (one of the reasons why it is no longer called "congenital" dysplasia of the hip).
- Problems with CPG users understanding and following the guidance due to the identified inadequate definitions and needed clarity.

*Source of closed malpractice claims data is the Physicians Insurers Association of America data sharing program accessed in June 2006 and reflecting DDH related claims against pediatricians from January 1985 through June 2006.

Section on Radiology

Like: Rigorous inclusion criteria

Concerns: The authors, trying to make this manageable only query the English literature

As the authors pointed out:
1506 - "We found significant gaps in the evidence that can be used to derive practice guidelines
1507 - for the early diagnosis and management of DDH. "

The above two lines summarizes my opinion about this guidelines.

All except one of the recommendations are based in 1-3 studies. And the recommendation with 16 studies, only 2 had moderate strength.

Only 5 of the recommendations had moderate strength studies, the other 5 have low strength studies

Having trouble understanding what are the recommendations – is the following what is going to be recommended:

- No universal screening

- Evaluation of Infants with Risk Factors for DDH before 6mo
- Imaging of unstable hip to decide treat or not, not necessary
- No recommendations about the use of X rays between 4- 6 mo
- No surveillance necessary after a normal infant hip exam
- Treat clinical instability
- No specific brace is preferred
- No need to monitor with ultrasound or Xray during brace treatment

Committee on Fetus and Newborn

We thought this was an excellent document, and had only one real suggestion: The summary section should be converted into a summary recommendation table that would be easy to interpret - see example below.

Item	Recommendation	Strength of the Evidence
Universal ultrasound screening of newborn infants.	**No**	 Moderate
An imaging study before 6 months of age in infants with one or more of the following risk factors: breech 294 presentation, family history, or history of clinical instability	**Yes**	 Moderate
Ultrasound in infants less than 6 weeks of age with a positive instability examination to guide the decision to initiate brace treatment.	**Yes**	Limited Two stars

Appendix A – Structured Peer Review/Public Comment Form

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

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

- Strongly Recommend
- Recommend
- Would Not Recommend
- Unsure

Additional Comments: