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Systematic analysis of the quality of the scientific evidence and conflicts of interest in osteoarthritis of the hip and knee practice guidelines

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ABSTRACT

Objective: To determine the validity of the hip and knee osteoarthritis guidelines.
Methods: A systematic search of PubMed using a combination of Mesh and text terms with limitations to guidelines was performed to identify hip and knee osteoarthritis guidelines. The study was performed from April 17, 2014 to October 1, 2014. Guidelines were reviewed for graded levels of evidence, methods used to grade the evidence, and disclosures of conflicts of interest. Additionally, guidelines were also assessed for key quality measures using the AGREE II system for assessing the quality of guidelines.
Results: A total of 13 guidelines relevant to the diagnosis and/or treatment of hip/knee osteoarthritis was identified. The 180 recommendations reviewed were supported by 231 pieces of evidence. In total, 35% ($n = 80$; range: 0–26) were supported by level A evidence, 15% ($n = 35$; range: 0–10) were by level B, and 50% ($n = 116$; range: 0–62) were by level C. Median age of the guidelines was 4 years (± 4.8; range: 0–16) with no comments on planned updates. In total, 31% of the guidelines included patients in the development process. Only one guideline incorporated cost consideration, and only 15% of the guidelines addressed the surgical management of osteoarthritis. Additionally, 46% of guidelines did not comment on conflicts of interest (COI). When present, there was an average 29.8 COI. Notably, 82% of the COI were monetary support/consulting.
Conclusions: In total, 50% of the hip/knee osteoarthritis guideline recommendations are based on lower quality evidence. Nearly half the guidelines fail to disclose relevant COI and when disclosed, multiple potential COI are present. Future hip/knee osteoarthritis guideline development committees should strive to improve the transparency and quality of evidence used to formulate practice guidelines.

Introduction

Osteoarthritis (OA) is the most common form of arthritis in the United States and accounts for 185 billion dollars in United States' medical care expenditures [1]. OA is a progressive process damaging the functional and articular components of the joints. Multiple non-pharmacologic, pharmacologic, and surgical treatment modalities have been studied for the treatment of symptomatic OA [2]. However, none of these therapies reverse the underlying disease process. Given the frequency of this condition and high cost associated with it, multiple societies have developed clinical practice guidelines to help guide the management of OA [3–5].

Practice guidelines are defined by the Institute of Medicine (IOM) as "systematically developed statements to assist practitioner and patient decisions about appropriate health care for specific clinical circumstances [6]." Guidelines are used by insurance companies, managed care groups, and by governmental organizations to assess the quality and appropriateness of care. It is therefore imperative that the practice guidelines be based on the highest quality evidence available [7]. To date, practice

Abbreviations: AAOS, American Association of Orthopedic Surgeons; ACR, American College of Rheumatology; AGREE, Appraisal of Guidelines Research and Evaluation; AGSP, American Geriatrics Society Panel; APTA, American Physical Therapy Association; COA, Chinese Orthopedic Association; COI, conflicts of interest; DGSC, Dutch Guideline Steering Committee; EULAR, European League Against Rheumatism; FCPG, French Clinical Practice Guidelines; GRADE, Grading of Recommendations Assessment, Development and Evaluation; IOM, Institute of Medicine; NEGDG, North of England Guideline Development Group; NICE, National Institute for Health and Care Excellence; OA, osteoarthritis; OARSI, Osteoarthritis Research Society International; OP, Ottawa Panel.

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guidelines from multiple societies have been assessed noting that a significant proportion of the evidence is supported by only expert opinion [8–11].

While there are many different treatment modalities available for OA, no study has systematically evaluated the evidence supporting current recommendations underlying the treatment of knee or hip OA. Therefore, we sought to systematically assess the current evidence supporting the different societal recommendations regarding the management of hip and knee OA with a focus on the non-pharmacologic, pharmacologic, and surgical management recommendations.

Methods

Search criteria

We performed a PubMed search on April 17, 2014 for all the currently published osteoarthritis guidelines involving the treatment of hip and knee OA. PubMed was searched for the following MESH terms "Osteoarthritis, Knee"(Mesh) OR "Osteoarthritis, Hip" (Mesh) OR ("Osteoarthritis"[Mesh] AND ("Knee Joint"[Mesh] OR "Hip Joint"[Mesh] OR "hip"[mesh] OR "knee"[mesh])) OR (osteoarthritis[ti] OR degenerative arthritis[ti] OR (hip[ti] OR knee[ti])) with limitation of guidelines or practice guidelines. This resulted in 76 articles with a limit of English language only, a total of 66 articles were retrieved. References were also reviewed for any additional guidelines as well as any related citations in PubMed after selecting the abstract of relevant guidelines for this study. Any society that published guidelines included in the PubMed search criteria above, the societal website and national guideline clearinghouse (www.guideline.gov) were also reviewed for more guidelines relevant to hip or knee osteoarthritis and/or more updated versions of the guideline (Supplementary Figure S1). The study was performed from April 17, 2014 to October 1, 2014. Since 70% of the guidelines included in this study combined the recommendations for both hip and knee osteoarthritis, they were analyzed together.

Guidelines quality

Every guideline was reviewed for key quality measures. Measures were chosen based on the Appraisal of Guidelines Research and Evaluation (AGREE) II system for assessing the quality of clinical guidelines [12]. Each guideline was reviewed for presence of a grading system of evidence; clinical recommendations; level of evidence supporting recommendations; reporting of COI; use of systematic literature search to assess the evidence; year of publication; presence of all relevant parties: orthopedic surgeon, rheumatologist or physical medicine and rehabilitation specialist, primary care physician, physical or occupational therapist, and a patient representative or patient advocate; reported time for any update to the guideline; and if cost was a consideration in formulating recommendations.

Levels of evidence

To standardize the analysis, the graded evidence was merged, when possible, into the classic ABC grading system [11]:

Grade A: Randomized controlled trials/meta-analysis.

Grade B: Single randomized control/non-randomized.

Grade C: Expert opinion/case studies/standard of care.

Supplementary Table S1 describes the methods used to standardize the grading systems. The grading system of choice was the Grading of Recommendations Assessment, Development and Evaluation (GRADE) system which has more recently been accepted by most societies as the ideal means to use when developing recommendations [13]. However, given concern that using this method, strong observational trials can be graded as high-level evidence and poorly designed randomized control trials can be downgraded to moderate level of evidence that would not be feasible in this current analysis. Therefore, we opted for the historical standard ABC system [11].

The total number of recommendations was based on the numbers provided in the guidelines. However, many recommendations had varying degrees of level of evidence when the recommendation was referring to hip or knee osteoarthritis. If multiple levels of evidence were cited, then each level of evidence was counted separately. Similarly, if recommendations had sub-categories (e.g., 1a, 1b, and 1c) with levels of evidence cited after each sub-category, then each was counted as a separate level of evidence.

Conflicts of interest

Every guideline was reviewed if conflicts of interest (COI) were reported or not, or if there was a comment of COI. If COI were present, they were reviewed for total number of COI/author and if COI were present in the first author. Conflicts were subdivided into research awards/grants, government or non-profit-based awards, and other conflicts, including advisory board, speaker's bureau, consulting, and industry-sponsored continuing medical education activities.

Inclusion criteria

Only articles that were guidelines involving hip and/or knee osteoarthritis were included. Articles published in any medical journal that was indexed in PubMed as a guideline was included. Additionally, the societal websites and national guideline clearinghouse (www.guideline.gov) were also reviewed for more guidelines relevant to hip or knee osteoarthritis and/or more updated versions of the guideline. Such guidelines were included if they were also indexed on PubMed. There was no exclusion based on publication year.

Exclusion criteria

Articles that were not published and/or indexed in PubMed were excluded. Survey studies of experts without a clear guideline development process were excluded. Articles that did not specifically include hip/knee OA were also excluded. Additionally, older versions of previously updated guidelines were excluded as well. Finally, comments that recommendations could not be made were noted but were not included in further statistical analysis.

All the guidelines were reviewed by two authors (J.D.F. and S.L.) for presence of graded evidence and recommendations, methods by which the evidence was graded, and COI. The merging of grading systems into the ABC format was performed by two authors (J.D.F. and A.S.C.).

Statistical analysis

Chi-square test and Fisher's exact test were used for comparing proportions of graded evidence and COI reported between guidelines. Subsequently, pairwise comparisons of societal guidelines were evaluated. Bonferroni corrections were used whenever multiple pairwise comparisons were made, otherwise $p = 0.05$ was considered significant. Analysis was done using R version 3.0.2.

Results

Background

Of the 66 articles resulting from the search criteria, 11 were unique guidelines with recommendations for the diagnosis and/or treatment of hip or knee osteoarthritis [3–5,14–21]. One guideline, care and management of osteoarthritis in adults: summary of NICE guidance, had a more updated version from 2014 at www.nice.org.uk/guidance/cg177 [22]. An additional two guidelines, OARSI recommendations for the management of hip and knee osteoarthritis, Part II: OARSI evidence-based, expert consensus guidelines, and Ottawa panel evidence-based clinical practice guidelines for aerobic walking programs in the management of osteoarthritis were identified via the other search methods as outlined above [23,24]. Four of the guidelines were published by rheumatologic societies, three by physical therapy societies, and two by orthopedic societies. The median year of publication was 2010 (range: 1998–2014).

Methods of grading guidelines

In total, 85% ($n = 11$) of the guidelines utilized a grading system to assess the level of evidence supporting the recommendations. Seven different grading systems were used to evaluate the level of evidence (Supplementary Table S1). Both the National Institute for Health and Care Excellence (NICE) guideline and the American College of Rheumatology (ACR) guideline were excluded from the analysis involving the recommendations, since the means by which they presented their recommendations and supporting evidence could not be merged into the ABC system.

Level of evidence

In total, 180 recommendations were reported, of which 238 pieces of evidence were listed supporting these recommendations. There were seven pieces of evidences rated as inconclusive by the American Association of Orthopedic Surgeons (AAOS) commenting that they are unable to rate for or against the supporting evidence and therefore they were excluded. In total, 35% ($n = 80$; range: 0–26) were supporting by level A evidence, 15% ($n = 35$; range: 0–10) by level B evidence, and 50% ($n = 116$; range: 0–62) by level C evidence (Table 1) (Fig. 1). There was a strong negative correlation between the percentage of level C evidence and year of publication (Fig. 2).

The recommendations involving the treatment of osteoarthritis were further sub-categorized into non-medical recommendations (e.g., aerobic exercise), medical (e.g., ibuprofen), and surgical recommendations. There were 168 graded levels of evidence supporting the non-medical treatment options. In total, 35% ($n = 59$) were graded by level A evidence, 15% ($n = 25$) by level B evidence, and 50% by level C evidence. There were 42 pieces of evidence supporting the medical recommendations, of which 38% ($n = 16$) were level A evidence, 14% ($n = 6$) level B, and 48% ($n = 20$) level C. Lastly, there were nine pieces of evidence supporting the surgical recommendations. In total, 11% ($n = 1$) were level A evidence, 22% ($n = 2$) were level B evidence, and 67% ($n = 6$) were level C evidence (Table 2).

AGREE II elements

In total, 92% ($n = 12$) of the guidelines reported a systemic review of the literature in formulating the recommendations. However, only one guideline consistently incorporated cost consideration in the guideline development. In total, 23% ($n = 3$) of the guidelines included all relevant personal when formulating the guideline. Patient representatives were reported members in only 31% ($n = 4$) of the development committees. The median age of the guidelines was 4 years (range: 0–16). None of the guidelines indicated when an update would be provided. Lastly, only the NICE guideline provided strategies to implement the guidelines into clinical practice (Table 3).

Conflicts of interest

Overall, 46% ($n = 6$) of the guidelines did not comment on the presence or lack of any relevant COI there. In total, 15% ($n = 2$) of the guidelines commented that no COI were present and 38% ($n = 5$) reported that COI were present. COI were more frequently disclosed in guidelines published after 2008. Figure 3 shows correlation between COI disclosed and guidelines published after 2008. A total of 153 COI were reported, of which 82% ($n = 126$) were industry/privately funded grants, speaking bureau, advising, consulting, or expert testimony. When present, there were an average of 29.8 (± 33.5) COI. In total, 60% ($n = 3/5$) of guidelines with reported COI had relevant COI declared by the first author. Additionally, 40% ($n = 32/80$) of the authors in these articles reported COI. The average number of COI in the first author was 6.4 (± 11.1) (Table 4).

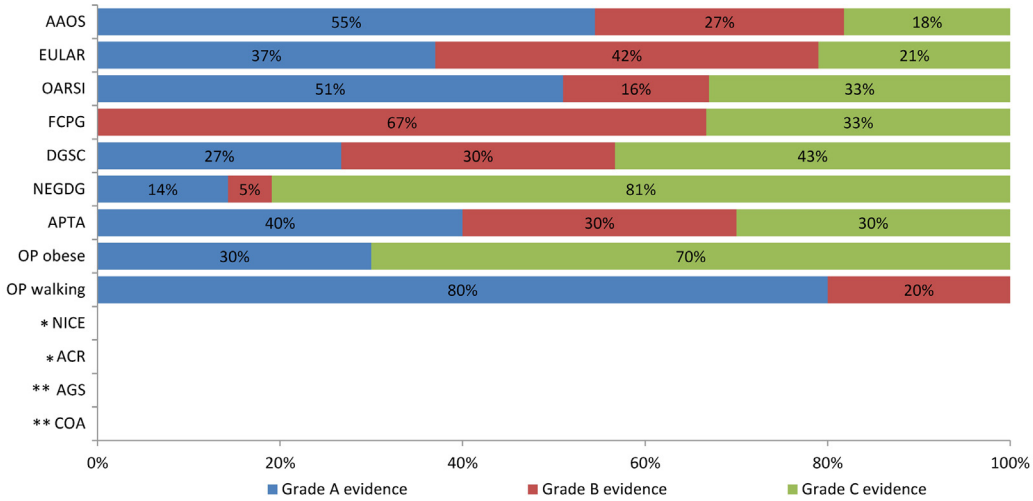
Discussion

While practice guidelines are meant to create a safer medical system, the strength of these guideline recommendations are rooted in the level of evidence used to support them [25]. In our systematic review of the current osteoarthritis guidelines related to hip or knee osteoarthritis, 50% of the evidence supporting the recommendations is based on expert opinion, case reports, or case series. While majority of the guidelines have been published within the last 4 years, there remains a paucity of strong evidence to support the current osteoarthritis recommendations. But furthermore, our study found that there are two guidelines that even mention surgery for osteoarthritis, the only definitive treatment option currently available. While many improvements in the guideline development process have become the norm, providing

Table 1
Total number of practice guidelines with graded evidence and quality of evidence for recommendations

	Combined (range)	AAOS	EULAR	ACR	DGSC	OP Obesity	OP aerobic	COA	APTA	FCPG	NICE	AGSP	NEGDG	OARSI
Guidelines with grades of evidence		Yes	Yes	Yes	Yes	Yes	Yes	No	Yes	Yes	Yes	No	Yes	Yes
Total number of graded evidence	231	11	24	NA	26	88	5	NA	4	2	NA	NA	21	38
Total number of recommendations	180	15	11	NA	11	79	5	NA	10	3	NA	NA	21	25
Recommendations with grade A evidence	80 (0–26)	6	9	0	8	26	4	0	0	0	0	0	3	20
Recommendations with grade B evidence	35 (0–10)	3	10	0	9	0	1	0	2	1	0	0	1	6
Recommendations with grade C evidence	116 (0–62)	2	5	0	9	62	0	0	2	1	0	0	17	12

Abbreviations: AAOS: American Association of Orthopedic Surgeons; ACR: American College of Rheumatology; AGSP: American Geriatrics Society Panel; APTA: American Physical Therapy Association; COA: Chinese Orthopedic Association; DGSC: Dutch Guideline Steering Committee; EULAR: European League Against Rheumatism; FCPG: French Clinical Practice Guidelines; NEGDG: North of England Guideline Development Group; NICE: National Institute for Health and Care Excellence; OARSI: Osteoarthritis Research Society International; OP: Ottawa Panel.



*Graded recommendations but unable to merge evidence into ABC format

**No graded recommendations

Abbreviations: AAOS American Association of Orthopedic Surgeons, ACR American College of Rheumatology, AGSP American Geriatrics Society Panel, APTA American Physical Therapy Association, COA Chinese Orthopedic Association, DGSC Dutch Guideline Steering Committee, EULAR European League Against Rheumatism, FCPG French Clinical Practice Guidelines, NEGDG North of England Guideline Development Group, NICE National Institute for Health and Care Excellence, OARSI Osteoarthritis Research Society International, OP Ottawa Panel

Fig. 1. Guidelines and grade of evidence.

a systematic review of the literature, grading the recommendations, and including other stakeholders in the development process, still the current state of the clinical practice guidelines does not meet the standards set forth by the IOM [26].

Clinical practice guidelines are considered one of the most important services that medical societies provide [27,28]. Guidelines serve a unique role to standardize care, define quality of care, and used in malpractice cases [26,28]. However, to satisfy these

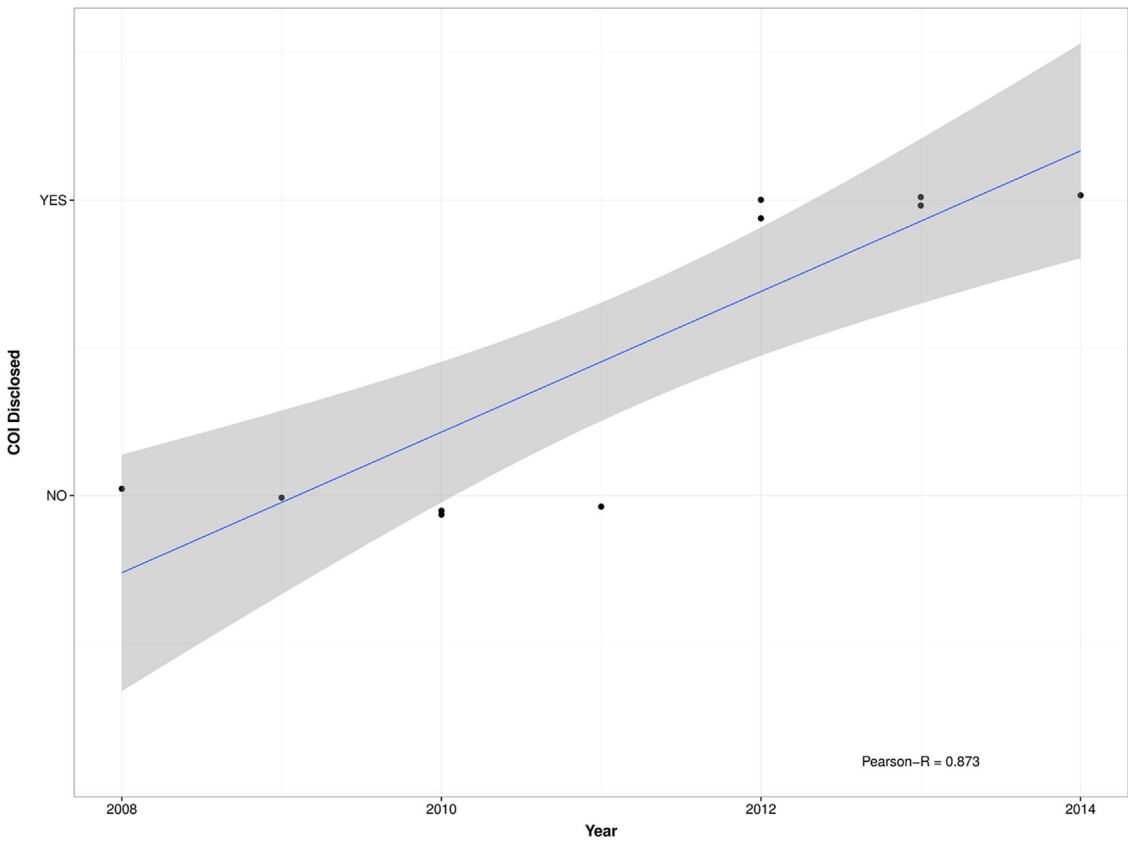


Fig. 2. Percentage of level C evidence and year of guideline publication.

Table 2
Subgroup analysis of recommendations based on non-medical, medical, and surgical treatment recommendations

	Combined	AAOS	EULAR	DGSC	OP obesity	OP aerobic	APTA	FCPG	NEGDG	OARSI
Non-medical	168	5	24	26	88	5	4	1	0	15
Recommendations with grade A evidence	59	3	9	8	26	4	0	0	0	9
Recommendations with grade B evidence	25	2	10	9	0	1	2	0	0	1
Recommendations with grade C evidence	84	0	5	9	62	0	2	1	0	5
Medical	42	3	0	0	0	0	0	1	21	17
Recommendations with grade A evidence	16	2	0	0	0	0	0	0	3	11
Recommendations with grade B evidence	6	1	0	0	0	0	0	1	1	3
Recommendations with grade C evidence	20	0	0	0	0	0	0	0	17	3
Surgical	9	3	0	0	0	0	0	0	0	6
Recommendations with grade A evidence	1	1	0	0	0	0	0	0	0	0
Recommendations with grade B evidence	2	0	0	0	0	0	0	0	0	2
Recommendations with grade C evidence	6	2	0	0	0	0	0	0	0	4

Abbreviations: AAOS: American Association of Orthopedic Surgeons; APTA: American Physical Therapy Association; COA: Chinese Orthopedic Association; DGSC: Dutch Guideline Steering Committee; EULAR: European League Against Rheumatism; FCPG: French Clinical Practice Guidelines; NEGDG: North of England Guideline Development Group; OARSI: Osteoarthritis Research Society International; OP: Ottawa Panel.

Table 3
AGREE II characteristics

	Combined	AAOS	EULAR	ACR	DGSC	OP obesity	OP aerobic	COA	APTA	FCPG	NICE	AGSP	NEGDG	OARSI
Age of guidelines (years) (mean)	4.9 ± 4.8	1	1	2	4	3	2	4	5	6	0	13	16	7
Presence of all applicable groups		No	Yes	No	Yes	No	No	No	No	No	Yes	No	No	No
Patient group included		No	Yes	No	Yes	No	Yes	No	No	No	Yes	No	No	No
Systematic review performed		Yes	Yes	Yes	Yes	Yes	Yes	No	Yes	Yes	Yes	Yes	Yes	Yes
Cost consdieraiton included		No	No	No	No	No	No	No	No	No	Yes	No	No	No
Implementation into practice strategies		No	No	No	No	No	No	No	No	No	Yes	No	No	No

Abbreviations: AAOS: American Association of Orthopedic Surgeons; ACR: American College of Rheumatology; AGSP: American Geriatrics Society Panel; AGREE: Appraisal of Guidelines Research and Evaluation; APTA: American Physical Therapy Association; COA: Chinese Orthopedic Association; DGSC: Dutch Guideline Steering Committee; EULAR: European League Against Rheumatism; FCPG: French Clinical Practice Guidelines; NEGDG: North of England Guideline Development Group; NICE: National Institute for Health and Care Excellence; OARSI: Osteoarthritis Research Society International; OP: Ottawa Panel.

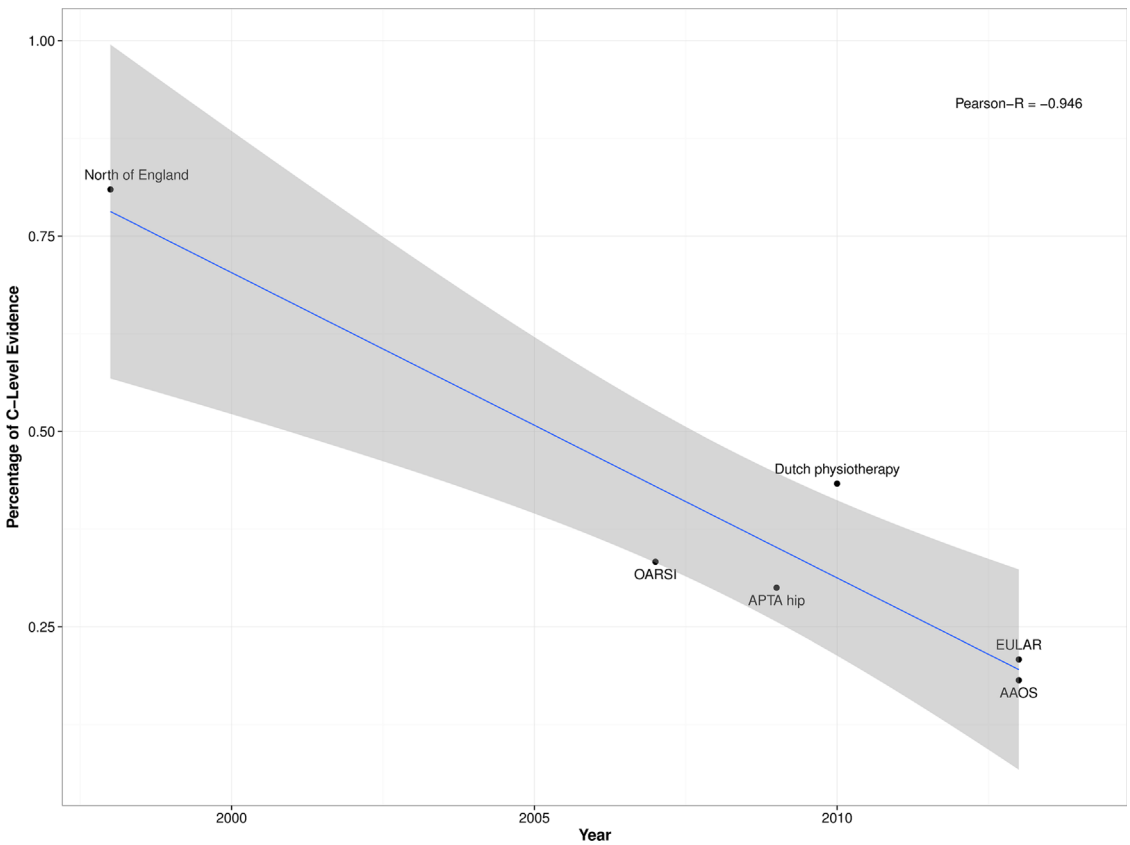


Fig. 3. Disclosure of COI based on year of guideline publication (2008 onwards).

Table 4
Conflicts of interest in practice guidelines

	Combined	AAOS	EULAR	ACR	DGSC	OP obesity	OP aerobic	COA	APTA	FCPG	NICE	AGSP	NEGDG	OARSI
Articles with no comment on COI					Yes	Yes		Yes	Yes	Yes		Yes		
Articles with no COI present							Yes						Yes	
Articles with COI present		Yes	Yes	Yes							Yes			Yes
Total number of conflicts	29.8 ± 33.5	35	3	84							25			2
Number of authors with COI present	6.4 ± 4.8	10	3	4							13			2
Number of COI present in first authors C	6.4 ± 11.1	3	0	26							3			0
Average number of conflicts/authors with conflicts (SD)	5.7 ± 8.6	3.5	1	21							1.9			1

Abbreviations: AAOS: American Association of Orthopedic Surgeons; ACR: American College of Rheumatology; AGSP: American Geriatrics Society Panel; APTA: American Physical Therapy Association; COA Chinese Orthopedic Association; DGSC: Dutch Guideline Steering Committee; EULAR: European League Against Rheumatism; FCPG: French Clinical Practice Guidelines; NEGDG: North of England Guideline Development Group; NICE: National Institute for Health and Care Excellence; OARSI: Osteoarthritis Research Society International; OP: Ottawa Panel.

roles, the guidelines must be based on the strongest possible evidence and updated frequently. In our review of the literature, none of the guidelines indicated when an update to the guideline would be published. While most of the guidelines were published within the last 4 years, the median publication year of the five guidelines published prior to 2010 was 2007. The age of practice guidelines is of significant concern. Shekelle et al. [29] indicated that 10% of guideline recommendations were no longer valid after 3.6 years and 50% were no longer valid after 5.8 years. In our study, approximately 30% of the recommendations would be at risk of being invalid.

In 2011, the IOM provided eight tenets for the development of trustworthy guidelines [26]. Included in this is the importance of involving a patient or patient advocate in the clinical practice guideline development committee [26]. Patients provide an important view point of what concerns them, way to formulate recommendations that are satisfactory to patients, and provide safeguards against potential COI that may result in bias influencing the guideline recommendations [26]. In total, 67% ($n = 4/6$) of the guidelines published after 2011 have correctly included a patient representative compared to zero guidelines published prior to 2011. Patient representatives provide unique insight to how they would want their disease treated, but also serve as a means to buffer any recommendations being influenced by potential COI. Nevertheless, the potential bias and COI present in patient representatives must also be evaluated and addressed in the guideline development process. While the inclusion of patients is an important improvement, 46% of the guidelines failed to disclose whether any relevant COI were present among the authors. When COI were disclosed, most guidelines had relevant COI of which over 80% were monetary support/consulting fees. Unfortunately, Kung et al. [30] confirmed similarly high rates of failure regarding compliance with the IOM standards. The lack of disclosure of COI raises significant issues regarding the transparency and validity of the guideline development process. Given that 50% of the recommendations are based on the committee's expert opinion, transparency regarding any untold influences is critical. Neuman et al. [31] noted a high prevalence of industry-related COI among guideline authors in the United States and Canada, raising concern of possible bias related to these relationships. Additionally, when COI are present, there is a concern for unconscious bias that is at greatest risk of occurring when COI are the accepted norm [32]. As a result, COI have the potential to cause a distrust and lack of acceptance of the guidelines [33].

Limitations

Our study has few limitations. While our goal was to utilize the GRADE system to assess the evidence, this was not feasible as discussed in the methods. We only included guidelines that were published and cited in PubMed, which may have completeness of our results. However, these are the guidelines that should be vetted the most via peer review and are expected to be of high quality. This study only assessed osteoarthritis related to the hip or knee, but it does not consider the recommendations related to any other type of arthritis. Also, our study did not include the ACR or NICE guidelines as we could not merge these guidelines. Nevertheless, these guidelines have similar weights regarding the level of evidence to the other guidelines without a preponderance of strong recommendations. Another limitation of our study was the need to combine the analysis of the recommendations for hip and knee osteoarthritis. These are not necessarily evaluated or treated the same way. However, majority of the guidelines reviewed combined the recommendations for both these conditions. Finally, we included all guidelines in this study even those greater than 10 years old given the limited number of guidelines included in this study. While this may have biased the study toward lesser quality evidence, we felt it was important to include all current guidelines that have not been updated in this article.

Conclusion

The current state of the hip and knee osteoarthritis guidelines is inadequate. In total, 50% of the recommendations are based on case series, case reports, or expert opinion, and most of the guidelines either fail to report COI or have relevant COI present among the authors. Further interventions are necessary to implement the IOM recommendations for the development of clinical practice guidelines.

Authors' Contributions

Author contributions: Dr. Feuerstein had full access to all of the data in the study and took responsibility for the integrity of the data and the accuracy of the data analysis.

Study concept and design: Feuerstein, Cheiftez, and Stone.

Acquisition of data: Feuerstein, Lloyd, and Pelsis.

Analysis and interpretation of data: Feuerstein, Cheifetz, Pelsis, Stone, and Lloyd.

Drafting of the article: Feuerstein and Pelsis.

Critical revision of the article for important intellectual content: Feuerstein, Pelsis, Cheifetz, and Stone.

Statistical analysis: Pelsis.

Study supervision: Feuerstein, Cheifetz, and Stone.

Each author has approved the final draft of this article.

Appendix A. Supplementary Information

Supplementary data associated with this article can be found in the online version at http://dx.doi.org/10.1016/j.semarthrit.2015.09.002.

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