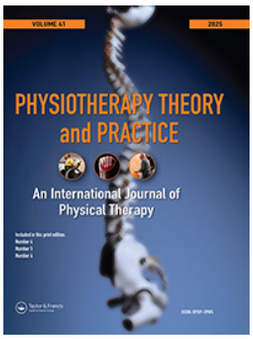

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SYSTEMATIC REVIEW

Quality of clinical practice guidelines for frozen shoulder: a systematic review

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ABSTRACT

Objective: Perform a systematic critical appraisal of current clinical practice guidelines (CPGs) for frozen shoulder.

Literature Survey: Systematic review of CPGs (PROSPERO number CRD42022368775). Inclusion criteria- CPGs written in English providing guidance on the evaluation and or treatment for frozen shoulder, traumatic injury and neurologic CPGs were excluded.Relevant studies were assessed for inclusion and selected studies were identified from PubMed, EMBASE, Scopus and CINAHL databases. The search strategy was developed by a biomedical librarian, performed on October 9, 2024.

Methodology: Data were extracted from the selected CPGs and underwent quality assessment using the Appraisal of Guidelines for Research and Evaluation (AGREE) II.

Synthesis: The search resulted in 38,428 studies and 2 CPGs were retained for appraisal. The mean overall AGREE II score was 75% (SD = 5.7). Lowest mean scores were found in the *applicability* (27% SD = 24.0) and *editorial independence* (48% SD = 14.1) domains. The highest domain scores were found in *scope and purpose* (92% SD = 7.8) and *clarity and presentation* (79% SD = 9.9). One CPG was rated as low quality based on *a priori* criteria and ultimately one higher quality CPG was recommended.

Conclusion: Given the advances in research that have developed over the last decade pertaining to the evaluation and treatment of frozen shoulder there is a critical need for an up to date, evidence informed, high quality CPG in order to identify gaps in our knowledge that the global research community should address.

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Shoulder; frozen shoulder; mobility; range of motion; adhesive capsulitis

Introduction

Frozen shoulder (FS) is a relatively common shoulder condition that may be present in up to 5.3% of the population (Kelley et al., 2013; van der Windt, Koes, de Jong, and Bouter, 1995). Current associations with the predilection to FS principally include individuals with diabetes, thyroid disease, obesity, being 50 years or older, being a biological females, and coronary heart disease (Cohen et al., 2020; Lamplot, Lillegraven, and Brophy, 2018; Sheridan and Hannafin, 2006; Walker-Bone et al., 2004; Zreik, Malik, and Charalambous, 2016). Research attests that people with diabetes have a less favorable prognosis (Dyer et al., 2023).

While the diagnosis of FS is made using the findings of a loss of glenohumeral passive and active motion in at least two directions (Kelley et al., 2013), additional classifications for FS exist. The classifications of FS have been provided as primary, also termed idiopathic, and secondary, which comprises of four subcategories. There is debate in the literature regarding the duration of symptoms, the stages of the condition, and the degree to which full pain-free range of motion and function is achieved. The duration of symptoms has been reported in the literature between one and four years with some individuals having symptoms that last longer. The initial understanding of the stages of FS involved a freezing, frozen and thawing stage with a recent addition proposed by some of a "pre-inflammatory" stage (Neviaser and Hannafin, 2010; Neviaser and Neviaser, 1987). Lewis (2015) suggested that once the clinical diagnosis

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of FS is established two clinical phases should be used, the first being the pain greater than stiffness phase, and the second being thestiffness greater than pain stage. Wong et al have reported that there is no evidence for complete resolution of this condition for everyone (Wong et al. 2017). What is not debated in the literature is the significant impact this condition has on individuals with increased pain and decreased range of motion in multiple planes that ultimately leads to decreased function and a poor quality of life (Lewis, 2015; Wong et al., 2017).

The treatment for individuals with FS has evolved over time with initial treatment includingnon-operative interventions including intra-articular corticosteroid injections and rehabilitation. Recalcitrant cases often undergo surgical interventions which include manipulation of the glenohumeral joint under anesthesia and capsular release of the glenohumeral joint (Lewis, 2015; Rangan et al., 2020). Given the changing and often times uncertain landscape of evidence surrounding the diagnosis, staging and treatment of FS, it is valuable for both researchers and clinicians to have current research appropriately synthesized in order to provide evidence based care for these individuals.

Clinical Practice Guidelines (CPGs) make recommendations based on the evidence to inform and guide treatment by translating evidence into clinical practice (Grimshaw and Russell, 1993). Clinicians, academics, and researchers have developed CPGs based on the available research to guide the assessment and management of FS. The use of high-quality CPGs in clinical settings has been shown to improve clinical practice when compared to intervention that does not follow a CPG. (Grimshaw and Russell, 1993). By using CPG the gap between evidence-based research and discordant practice can be reduced. For CPGs to be useful, they must be contemporary, valid, and of high quality. They should be created using systematic, rigorous, and transparent processes so that users can trust their recommendations (Eccles et al. 2012). Recent systematic reviews have examined the quality of CPGs as well as recommendations for diagnosis and treatment for various shoulder pathologies. These reviews included multiple shoulder pathologies, with one investigating the quality of the CPGs while the other examined both quality and recommendations (Barrett et al., 2021; Lowry et al., 2023). However, there have been no investigations looking specifically at the quality of CPGs related to FS specifically.

There are substantial gaps in our knowledge pertaining to the etiology, diagnosis, and management of primary and secondary frozen shoulder. There is no definitive diagnosis and as such clinicians should only hypothesize that the person seeking care has a frozen shoulder based on the careful exclusion of other causes of stiff and painful shoulders. It is acknowledged that we do not yet have unfaultable management for this condition, and there is considerable uncertainty if the management recommended for primary idiopathic frozen shoulder is appropriate for all the subcategories of secondary frozen shoulder. These unique and uncertain characteristics of FS set it apart from other non-traumatic shoulder conditions and provide cause for an investigation outside of other non-traumatic shoulder conditions.

While CPGs are intended to be used to reduce unnecessary variability in medical care and optimize the treatment process of a defined condition, inconsistencies in the management of these conditions persist (Lin et al., 2018). One explanation for this is that most current CPGs for musculoskeletal pain are based on poor quality (Eccles et al., 2012). Furthermore, they may not address the unique psychosocial variables of specific individuals. Limitations of CPGs include the sheer numbers available (i.e., for the same condition), voluminous documents that are not easy to assimilate or use, inconsistent opportunities for end-users to provide formal feedback, lack of detail regarding how evidence was interpreted, and weighted to formulate recommendations and having been developed by people with disclosed and potentially undisclosed professional or commercial conflicts of interest (Eccles et al., 2012). Due to the problems and inconsistencies with certain CPGs, confusion and ambiguity about what is considered "recommended care" may manifest and cause unwanted variations in clinical practice. (Eccles et al., 2012). In light of quality CPGs that have been found among other non-traumatic shoulder conditions and the unique characteristics of FS among non-traumatic shoulder conditions it is reasonable to question the quality of CPGs developed for FS. Therefore, in order to avoid perpetuating treatment or evaluation methods for the shoulder that may not be the most efficacious, the quality of current CPGs in this area needs to be evaluated. To this end, the purpose of this study was to evaluate the overall quality of CPGs developed for FS.

Methods

Guidelines

This systematic review was conducted utilizing the Preferred Reporting Items for Systematic Reviews and Meta-analyses (PRISMA) guidelines for the search and reporting phases of the process. The PRISMA statement includes a 27-item checklist designed to improve reporting of systematic reviews and meta-analyses (Page et al., 2021).

Search strategy

We searched Medline (PubMed), Embase (Elsevier), Scopus (Elsevier), and CINAHL Complete (EBSCOhost) using a combination of keywords and database-specific subject headings for the concepts of shoulder and pain. A search CADTH search filter to limit to guidelines was directly used in the PubMed and Embase searches, then translated to the other databases. No restrictions were placed by date or publication language. The original search was run on July 27, 2021 and updated on October9, 2024. Reproducible search strategies for all included databases are located in Appendix 1. The search strategy was developed and implemented by a biomedical librarian.

The searches yielded a total of 38,428 citations. All citations were imported into an Endnote (Clarivate, UK) library for storage before being sent to Covidence, a systematic review screening software Covidence detected 25,601 duplicates, from both the original and updated search, and automatically removed them to leave 12,827 unique citations for screening. This study was registered using the international prospective register of systematic reviews PROSPERO with the corresponding reference number CRD42022368775

Study selection

Title and abstract screening were performed by two independent reviewers (CW and MC). The two reviewers were trained research assistants, with guidance and oversight provided by the primary researcher who has over 15 years of research experience in this area. Once title and abstract screening was performed using the inclusion and exclusion criteria, full text articles were obtained for final review and consideration for inclusion. Discrepancies were handled by a third member of the team (MR), the primary researcher, when they arose. The inclusion criteria for studies included in this review consisted of the following: (1) articles specific to FS; (2) only clinical practice guidelines (3) related to evaluation and/or treatment. Studies were excluded if (1) not available in the English language (2) the clinical practice guidelines were related to other musculoskeletal shoulder conditions outside of FS, (i.e., rotator cuff related shoulder pain, traumatic shoulder injuries, humerus fracture, shoulder dystocia, etc.) as well as neurological conditions (i.e., stroke).

Data extraction and appraisal

Extracted variables included: the title/topic, developer, type of developer, first author (if applicable), accompanying documents, number of pages, and country of origin. Each CPG was independently appraised by two reviewers (DC and AS) and if necessary, the discrepancies were handled by a third author (PS) using the Appraisal of Guidelines for Research and Evaluation (AGREE) II instrument. The reviewers performing the appraisal were both senior research scientists with extensive experience developing and scoring orthopedic CPGs. The AGREE II was developed by the AGREE Collaboration as a generic instrument to evaluate the development and reporting of CPGs. Two overall assessment scores are assigned based on the score of 23 core items. AGREE II is comprised of 23 items which are organized into 6 quality domains which include scope and purpose, stakeholder involvement, the rigor of development, clarity of presentation, applicability, and editorial independence (Brouwers et al., 2010). Each item is ranked on a 7-point scale Likert scale (1-strongly disagree to 7- strongly agree). AGREE II is the most widely used guideline appraisal instrument (Siering et al., 2013)and is a reliable and valid tool for use with any CPG in any area (Brouwers et al., 2010).

Analysis

In accordance with AGREE II, each of the domain scores were calculated as a percentage by first adding all the scores within a particular domain and scaling the overall sum as a percentage of the total points possible within that domain. In addition to domain scoring, reviewers were also asked to provide the overall quality of the ranking for the CPG, which was calculated as a percentage of the total possible score. The mean and standard deviation of these percentages were calculated using SPSS (IBM SPSS Statistics V.27.0).

The AGREE II tool does provide instructions for author teams in the "Interpreting Domain Scores" section to identifydomains that are of importance. Three senior research scientists on the team identified three domains *a priori* as being of high priority when considering overall quality of the CPG's; domain 2 (stakeholder involvement), domain 3 (rigor of development) and domain 6 (editorial independence). These three domains appear to be the areas that may be the most influenced and the most impactful with regard to the quality of CPGs. When considering a cut point for high or low quality we utilized examples from the AGREE II tool and previous research to establish a cut point of all three of the *a priori* identified domains (2, 3, and 6) needing to have a rating great than 50% for all three to be considered high quality (Armstrong, Goldfarb, Instrum, and MacDermid, 2017; Bouwmeester, van Enst, and van Tulder, 2009; Cosgrove et al., 2013; Haran, van Driel, Mitchell, and Brodribb, 2014; Lin et al., 2018; Pak

et al., 2014). Accord was reached by the research team that this was a reasonable threshold to set for the three domains we identified as high priority, in order for the findings to be of clinical importance and therefore scoring < 50% for all three of these domains would indicate low quality. Lastly, as part of the overall guideline assessment reviewers were asked if they would recommend the guideline for use.

Results

The searches yielded a total of 38,428 citations 25,601 duplicates, from both the original and updated search, were detected and removed them to leave 12,827 unique citations for screening of which three (Hanchard et al., 2012; Kelley et al., 2013; Pandey and Madi, 2021) were ultimately retained for appraisal with one (Pandey and Madi, 2021) being removed during the appraisal process (Figure 1).

The mean overall AGREE II score was 75% (SD = 5.7). The lowest mean scores were found in the *applicability* (27% SD = 24.0) and *editorial independence* (48% SD = 14.1) domains. The highest domain scores were found in *scope and purpose* (92% SD = 7.8) and *clarity and presentation* (79% SD = 9.9). The domain scores are calculated as a percentage by first adding all the scores within a particular domain and scaling the overall sum as a percentage of the total points possible within that domain.The overall mean percentage score for each domain and the overall mean score for each item of the AGREE II tool can be seen in Table 1. One CPG was rated as low quality based on *a priori* criteria and ultimately one was recommended for use based on

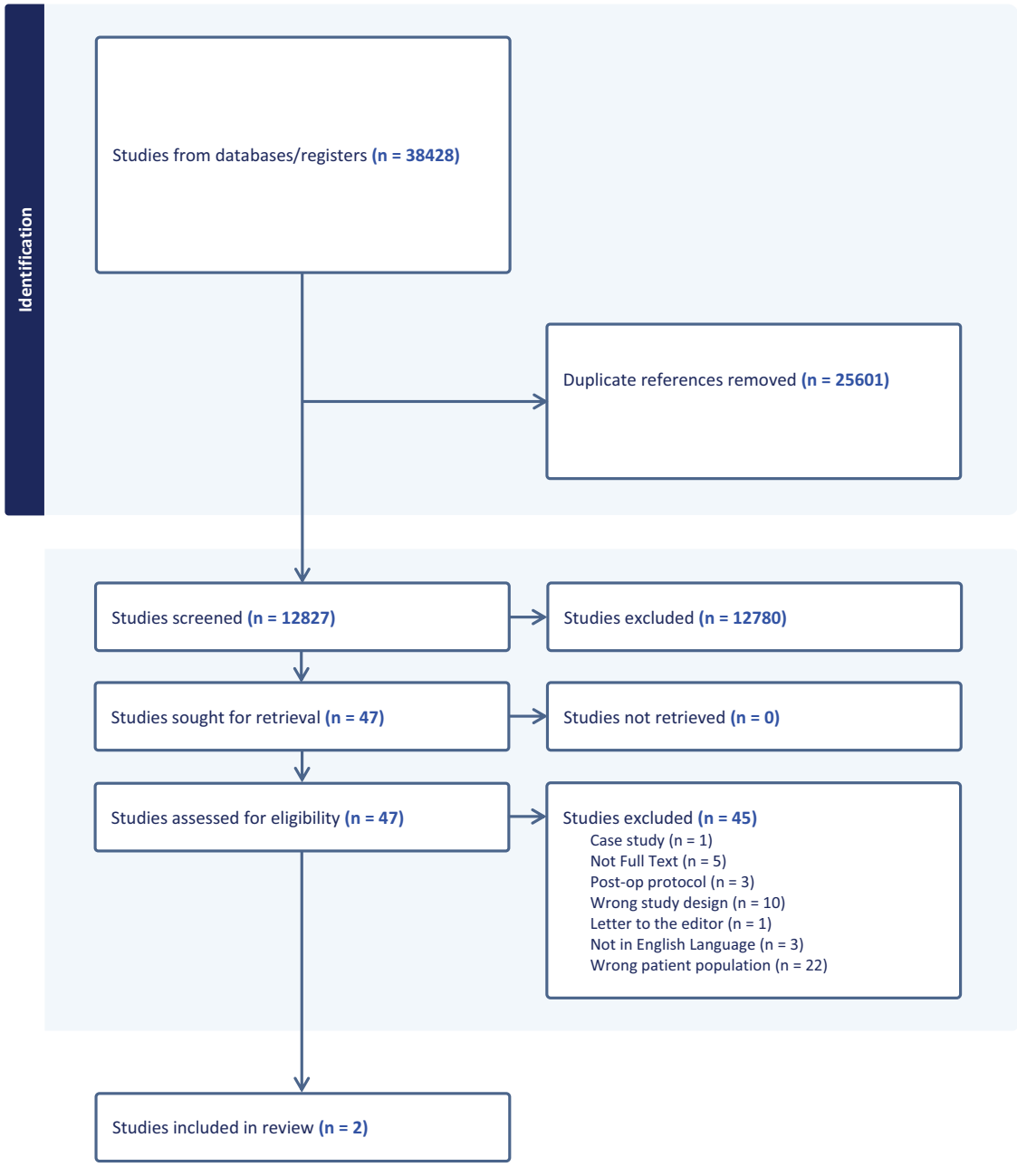

Figure 1. PRISMA flow diagram.

overall guideline assessment. Domain scores for each CPG along with specific questions related to each domain for context can be found in Table 2.

Discussion

Over the past few decades, significant advances have been made in developing CPGs, leading to their overall improved quality. The most evident reason for this improvement is likely the development and implementation of the AGREE tool and, subsequently, the AGREE II tool. The development of the AGREE tool allows both developers and consumers of CPGs to objectively evaluate their quality. A significant increase in domain scores has been seen over time, with a significantly greater proportion of CPGs being recommended based on AGREE II scores after 2010 (Armstrong, Goldfarb, Instrum, and MacDermid, 2017). Despite these advances, we continue to see CPGs across a variety of health-related areas being rated as poor quality.

This review identified two CPGs for FS, both specific to physiotherapy. The overall quality of the two FSCPGs differed substantially, one rated as high quality (Hanchard et al., 2012) and the other as low. (Kelley et al., 2013). The lowest mean scores on the AGREE II Tool for the two articles were applicability and editorial independence. Reasons for poor applicability scores include a lack of attention to the facilitators and barriers to applying the recommendations, and the absence of tools for CPG implementation into practice. Guideline implementation tools have a positive influence on clinician behaviors and patient outcomes (Flodgren et al., 2016). When implementation tools are included in CPGs, this provides the clinician with summaries of the CPG recommendations, making it more useful to implement into their everyday care (Liang et al., 2017). Making CPGs in this area more accessible and providing meaningful recommendations and or resources that are easily digested by clinicians, perhaps in the form of an infographic, may help to overcome these limitations.

Table 1. Overall mean (SD) percentage score for each domain and overall mean (SD) for each item of the AGREE II tool.

	Mean (SD)
Domain 1: Scope and Purpose (%)	**91.5 (7.8)**
Q1: Overall objectives described	6.5 (1.0)
Q2: Health questions described	6.3 (1.0)
Q3: Population described	6.5 (0.6)
Domain 2: Stakeholder Involvement (%)	**69.5 (3.5)**
Q4: Guideline group includes individuals from all relevant professional groups	4.3 (1.3)
Q5: Views and preferences of target pop have been sought	4.8 (1.0)
Q6: Target users of guidelines are defined	6.5 (0.6)
Domain 3: Rigour of Development (%)	**61.0 (21.2)**
Q7: Systematic methods were used to search for evidence	5.5 (1.7)
Q8: Criteria for selecting evidence clearly defined	4.5 (1.3)
Q9: Strengths and limitations of body of evidence clearly defined	3.3 (2.2)
Q10: Methods for formulating recommendations clearly described	4.8 (2.9)
Q11: Health benefits, side effects, and risks have been considered in formulating recommendations	3.0 (2.2)
Q12: Explicit link between recommendations and supporting evidence	6.5 (0.6)
Q13: Guideline has been reviewed externally by experts	6.0 (1.4)
Q14: Procedure for updating guideline is provided	3.8 (1.0)
Domain 4: Clarity of Presentation (%)	**79.0 (9.9)**
Q15: Recommendations are specific and unambiguous	6.3 (1.0)
Q16: Different options for management of condition or health issue are clearly presented	5.0 (0.8)
Q17: Key recommendations are easily identifiable	6.0 (1.4)
Domain 5: Applicability (%)	**27.0 (24.0)**
Q18: Guideline describes facilitators and barriers to application	3.8 (3.2)
Q19: Guideline provides advice on how the recommendations can be put into practice	3.8 (2.5)
Q20: Potential resource implications of applying the recommendations have been considered	2.0 (1.2)
Q21: Guideline presents monitoring and/or auditing criteria	1.0 (0.0)
Domain 6: Editorial Independence (%)	48.0 (14.1)
Q22: Views of funding body have not influenced the content of the guideline	3.3 (2.6)
Q23: Competing interests of guideline development group members have been recorded and addressed	4.5 (1.3)

* The range for each question is 1–7, answered on a Likert scale (1, strongly disagree – 7, strongly agree)

Table 2. CPG AGREE II domain scores and quality assessment (%).

Author	1. Scope and purpose	2. Stakeholder involvement	3. Rigour of development	4. Clarity of presentation	5. Applicability	6. Editorial Independence	Overall Assessment	Quality High/ Low
Hanchard et al., (2012)	97	72	76	72	44	58	79	High
Kelley et al., (2013)	86	67	46	86	10	38	71	Low

As for editorial independence, developers often fail to provide explicit information about the influence of funding bodies and competing interests, which is arguably one of the easiest criteria for developers to satisfy. If the CPGs do not provide this information, then quality may be affected as shown in one of the two CPGs retained in this study. Not only disclosing funding sources and competing interests but also adjusting the evidence synthesis and overall recommendations with this information considered would allow for increased quality reporting in this domain. Guideline users must be confident that the development process for the guideline is independent from any other individual and/or body with any conflict of interest.

Our findings of the lowest scores assigned to applicability and editorial independence are not unique to the CPGs for FS. A systematic review of overall quality from 415 health-related CPGs noted that although the quality of CPGs they investigated over the past two decades has improved, the authors outlined that much work was still needed in the areas of editorial independence and applicability (Armstrong, Goldfarb, Instrum, and MacDermid, 2017). Additionally, two systematic reviews investigating the quality of CPGs related to overall shoulder conditions had similar findings, with one study (Lowry et al., 2023) having the domain of applicability scoring the lowest and the other study (Barrett et al., 2021), having both applicability and editorial independence receiving the two lowest scores of all domains evaluated. Although the AGREE II was developed prior to the publication of both CPGs related to FS, the areas of editorial independence and applicability still scored low. This is of particular concern given that editorial independence is one of the two domains, in addition to rigor of development, considered to have the most direct impact on CPGs overall content quality (Alonso-Coello et al., 2010). Of note, neither of the existing CPGs on FS has been updated in the last decade. Recent evidence suggests that CPGs should be developed to allow fluidity for updates to be made as new evidence emerges. It is suggested that CPGs be reassessed for validity every three years and updated every 5 years (Shekelle et al., 2001).

The highest scores on the AGREE II Tool for the two articles were scope, and the purpose and clarity of presentation. Having a clear presentation of scope and purpose indicates that the developers were able to identify appropriately and state objectives specific to both the condition of FS and the individuals suffering from FS. Developing a strong scope and purpose helps build the foundation for the CPGs to stand on in order to ensure the appropriate evidence unique to the population at hand is evaluated and considered. Clarity of presentation is a vital domain as it allows the clinician to easily identify key recommendations and management options of the condition concisely. The domains clear presentation of scope, and purpose and clarity of presentation were the highest scoring domains in 450 CPGs across three systematic reviews, 415 general health related and 35 shoulder specific (Armstrong, Goldfarb, Instrum, and MacDermid, 2017; Barrett et al., 2021; Lowry et al., 2023). These cumulative findings would suggest that most developers of CPGs, including those related to FS, are able to set clear objectives related to the identification and management of specific conditions related to the CPGs and even present the findings in a clear and easy to interpret manner. However, a key missing element is taking this information and making it easily applicable to guide clinical practice.

As a way to continue improving approaches to developing CPGs, a recent scoping review and document analysis on CPGs in healthcare was performed. The authors of this scoping review outlined six core principles to be utilized during CPG development and eight core processes consistently reported as essential when developing CPGs (De Leo, Bloxsome, and Bayes, 2023). It is beyond the scope of this review to discuss these new principles in detail. However, employing these principles along with increased efforts to overcome barriers to applicability while increasing transparency around editorial independence bias will help to improve the overall quality of CPGs related to FS.

Clinical implications

We aimed to assess the quality of CPGs for the identification and management of FS. Given that FSisassociated with substantial morbidity and is relatively common, there is a clear need for high-quality CPGs to help guide practice for physical therapists, orthopedic surgeons, general practitioners, and others who manage this population. To date there are only two CPGs published related to the diagnosis and management of individuals with FS, one being rated as having low quality and both specific to physiotherapy. There being only one high quality CPG published over a decade ago for this specific diagnosis may contribute to the inconsistencies in how FS is diagnosed and managed. Greater attention to the development process, particularly in the areas of applicability and editorial independence is needed to allow for precision-based medicine to be available within this population.

Limitations

The low number of CPGs related to FS is the most notable limitation. While this is a limitation from

a systematic review standpoint, the finding reveals a gap in the development and dissemination of high-quality CPGs for a condition that has been studied for over 150 years (Duplay, 1872). For perspective, the number of CPGs related to other non-traumatic musculoskeletal conditions such as low back pain (11CPGs), neck pain (5 CPGs) and rotator cuff related shoulder pain (5 CPGs) are significantly greater (Barrett et al., 2021; Childs et al., 2008; Lin et al., 2018). Lastly, like with any scoring tool, there are biases and areas of subjectivity that may be present in scoring. By having two senior researchers with experience developing and scoring orthopedic CPGs we belief this was mitigated to best extend possible.

Conclusion

We identified two CPGs related to FS, one rated as high and the other as low quality. Given the plethora of recent research and reviews it is a concern that only one high quality CPG exists and that it was published over a decade ago. There is a critical need for both more primary mixed methods research and an up to date, evidence informed, high quality CPG for FS, in order to identify gaps in our knowledge that the global research community should address.

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